# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# AMENDMENT NO. 1 TO FORM S-1

## REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

# **INOZYME PHARMA, INC.**

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization) 2834

(Primary Standard Industrial Classification Code Number)

38-4024528 (I.R.S. Employer Identification Number)

321 Summer Street Suite 400

Boston, Massachusetts 02210 (857) 330-4340

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Axel Bolte President and Chief Executive Officer 321 Summer Street Suite 400 Boston, Massachusetts 02210 (857) 330-4340

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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#### Approximate date of commencement of proposed sale to public:

As soon as practicable after this Registration Statement is declared effective.

box. 🗆	If any of the secu	urities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Se	curities Act of 1933, check the followin	g
statement num		ed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following laterities registration statement for the same offering. $\Box$	oox and list the Securities Act registration	on
of the earlier e		post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities for the same offering. $\Box$	curities Act registration statement numb	er
of the earlier e		post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities for the same offering. $\Box$	curities Act registration statement numb	er
See the definit		k mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting con Perated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Ex		7.
Large accelera	ted filer		Accelerated filer	
Non-accelerate	ed filer		Smaller reporting company	$\times$
			Emerging growth company	X
accounting sta	0 00	rowth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying Section 7(a)(2)(B) of the Securities Act. $\Box$	ng with any new or revised financial	

# CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to Be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Share(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee(3)(4)
Common stock, par value \$0.0001 per share	5,750,000	\$16.00	\$92,000,000	\$11,942

- Includes 750,000 shares of common stock the underwriters have an option to purchase
- Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(a) under the Securities Act of 1933, as amended.

  Calculated pursuant to Rule 457(a) under the Securities Act of 1933, as amended, based on an estimate of the proposed maximum aggregate offering price.

  A registration fee of \$11,195.25 was previously paid in connection with the Registration Statement, and the additional amount of \$746.75 is being paid herewith.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

> Subject to Completion Preliminary Prospectus dated July 20, 2020

## **PROSPECTUS**

# 5,000,000 Shares



# **Common Stock**

This is Inozyme Pharma, Inc.'s initial public offering. We are selling 5,000,000 shares of our common stock.

We expect the public offering price to be between \$14.00 and \$16.00 per share. Currently, no public market exists for the shares. After pricing of the offering, we expect that the shares will trade on the Nasdaq Global Market under the symbol "INZY."

We are an emerging growth company under the federal securities laws and are subject to reduced public company disclosure standards. See "Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company."

Investing in the common stock involves risks that are described in the "Risk Factors" section beginning on page 12 of this prospectus.

	Per Share	Total
Public offering price	\$	\$
Underwriting discount(1)	\$	\$
Proceeds, before expenses, to us	\$	\$

We refer you to "Underwriting" beginning on page 209 of this prospectus for additional information regarding underwriting compensation.

The underwriters may also exercise their option to purchase up to an additional 750,000 shares from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The shares will be ready for delivery on or about , 2020.

**BofA Securities** 

Cowen

**Piper Sandler** 

Wedbush PacGrow

, 2020.

The date of this prospectus is July

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Neither we nor the underwriters have authorized anyone to provide you with any information other than that contained in this prospectus, any amendment or supplement to this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: we have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of our common stock and the distribution of this prospectus outside the United States.

We own or have rights to, or have applied for, trademarks, service marks and trade names that we use in connection with the operation of our business, including our corporate name, logos and website names. Other trademarks, service marks and trade names appearing in this prospectus are the property of their respective owners. Solely for convenience, some of the trademarks, service marks and trade names referred to in this prospectus are listed without the <sup>®</sup> and <sup>™</sup> symbols.

#### PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, especially the sections titled "Risk Factors," "Cautionary Note Regarding Forward-Looking Statements and Industry Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes appearing at the end of this prospectus, before making an investment decision.

# **Company Overview**

We are a rare disease biopharmaceutical company developing novel therapeutics for the treatment of diseases of abnormal mineralization impacting the vasculature, soft tissue and skeleton. Through our in-depth understanding of the biological pathways involved in mineralization, we are pursuing the development of therapeutics to address the underlying causes of these debilitating diseases. It is well established that two genes, ENPP1 and ABCC6, play key roles in a critical mineralization pathway and that defects in these genes lead to abnormal mineralization. We are initially focused on developing a novel therapy to treat the rare genetic diseases of ENPP1 and ABCC6 deficiencies.

Our lead product candidate, INZ-701, is a soluble, recombinant, or genetically engineered, fusion protein that is designed to correct a defect in the mineralization pathway caused by ENPP1 and ABCC6 deficiencies. This pathway is central to the regulation of calcium deposition throughout the body and is further associated with neointimal proliferation, or the overgrowth of smooth muscle cells inside blood vessels. We have generated robust preclinical proof of concept data demonstrating that in animal models INZ-701 prevented pathological calcification, led to improvements in overall health and survival and prevented neointimal proliferation. In addition, an earlier murine research version of INZ-701 achieved survival benefit in a mouse model. We plan to file an Investigational New Drug Application, or IND, with the U.S. Food and Drug Administration, or FDA, and Clinical Trial Authorizations, or CTAs, with regulatory authorities in Europe for INZ-701 in the second half of 2020. We plan to advance INZ-701 into two separate Phase 1/2 clinical trials, one in patients with ENPP1 deficiency in the United States and in Europe and another in patients with ABCC6 deficiency in Europe. The FDA and the European Medicines Agency, or EMA, have granted orphan drug designation to INZ-701 for the treatment of ENPP1 deficiency. Subject to successfully completing clinical development of INZ-701 in these indications, we plan to seek marketing approvals for INZ-701 on a worldwide basis. Beyond our development focus on INZ-701, we believe that our therapeutic approach has the potential to benefit patients suffering from additional diseases of abnormal mineralization, including those without a clear genetic basis.

# **Pathological Diseases of Abnormal Mineralization**

Mineralization is a biological process during which an organism deposits calcium salt crystals, typically calcium polyphosphates, onto an organic extracellular matrix that gives rise to essential structures, such as bone and teeth in humans. A metabolic pathway that has been conserved throughout evolution in higher organisms is the key to regulating mineralization in the human body. Multiple enzymes and other proteins perform sequential reactions in this pathway as part of a normal mineralization process.

In a properly functioning mineralization pathway, the protein encoded by the ABCC6 gene (ATP-Binding Cassette in the C6 family) located on the cellular membrane is responsible for transporting adenosine triphosphate, or ATP, from inside a cell to outside the cell. The enzyme encoded by the ENPP1 gene (ectonucleotide pyrophosphatase/phosphodiesterase 1) then cleaves ATP into pyrophosphate, or PPi, and adenosine monophosphate, or AMP. PPi is a potent regulator of mineralization and, in particular, controls the rate of calcium crystal deposition in bone. AMP is further metabolized into adenosine, a potent regulator of cellular proliferation that, in particular, modulates a blood vessel's response to injury and is responsible for preventing neointimal proliferation.

If the proper function of the key mineralization pathway is altered or disturbed, then both genetic and non-genetic diseases and conditions involving abnormal mineralization can result. Genetic mutations affecting ENPP1, a critical enzyme in the mineralization pathway, result in low levels of PPi and AMP, a precursor of adenosine. Genetic mutations affecting ABCC6, a critical protein in the mineralization pathway, decrease the availability of extracellular ATP required for proper ENPP1 function and give rise indirectly to low levels of PPi and AMP, a precursor of adenosine.

Low levels of PPi lead to abnormal mineralization and pathological calcification in areas of the body where it should not occur, referred to as ectopic calcification. This ectopic calcification occurs in the vasculature and soft tissue, including multiple organ systems, and results in disease. The heart, kidney and skin are especially vulnerable to the effects of abnormal mineralization and pathological, ectopic calcification. Pathological, ectopic calcification in blood vessels inside bones can also interfere with normal skeletal mineralization. Low levels of adenosine lead to the narrowing and obstruction of blood vessels caused by neointimal proliferation and potential development of cardiovascular disease.

ENPP1 and ABCC6 deficiencies are systemic, progressive and continuous diseases occurring over the course of a patient's lifetime, starting as early as fetal development and spanning into adulthood. These diseases represent a significant unmet medical need, with high mortality rates for infants with ENPP1 deficiency and high levels of morbidity occurring for patients with these diseases throughout their life. ENPP1 deficiency is estimated to occur in approximately one in 200,000 births, and we believe there are between 11,000 and 12,000 patients worldwide with ENPP1 deficiency. In the United States, Europe and other major markets, including Australia, Brazil, Canada, Japan and Russia, we believe there are approximately 3,500 patients with ENPP1 deficiency. ABCC6 deficiency is estimated to afflict approximately one per 50,000 individuals, and we believe there are more than 67,000 patients worldwide with ABCC6 deficiency. In the United States, Europe and other major markets, including Australia, Brazil, Canada, Japan and Russia, we believe there are approximately 20,000 patients with ABCC6 deficiency. There are currently no approved therapies for either ENPP1 or ABCC6 deficiency. Currently available treatments are only palliative, seeking to minimize the symptoms of these diseases.

We conducted what we believe is the largest retrospective, cross-sectional natural history study of 127 patients with a presumed diagnosis of ENPP1 deficiency. Preliminary results from this study suggest that the spectrum of manifestations for ENPP1 deficiency includes an infantile phase, a pediatric phase and an adult phase. Infants with ENPP1 deficiency have pathological vascular calcification, which has been referred to in the medical literature as generalized arterial calcification of infancy, or GACI, in which abnormal mineralization and neointimal proliferation result in narrowed blood vessels that can cause heart and kidney failure. Approximately 45% to 50% of infants with ENPP1 deficiency die within 12 months of birth. Children with ENPP1 deficiency who survive beyond infancy develop rickets, which has been referred to in the medical literature as autosomal-recessive hypophosphatemic rickets type 2, or ARHR2. Rickets leads to severe skeletal deformities, short stature, severe bone pain and increased bone fractures. These children also experience continuing vascular and organ calcification. In adults, in addition to further vascular and organ calcification, ENPP1 deficiency manifests as a condition referred to as osteomalacia. Osteomalacia leads to severe bone pain, fatigue, muscle weakness and risk of recurring bone fractures. We plan to conduct a prospective, longitudinal natural history study of patients with ENPP1 deficiency designed to test and validate our findings from the retrospective natural history study.

ABCC6 deficiency is associated with pathological mineralization in blood vessels and soft tissues throughout the body resulting in significant morbidity, including blindness, potentially life-threatening cardiovascular complications and skin calcification. Some infants with ABCC6 deficiency are diagnosed with a vascular calcification condition resembling the acute infantile form of ENPP1 deficiency. In older patients, ABCC6 deficiency presents as pseudoxanthoma elasticum, or PXE, a rare disorder in which individuals develop calcification of soft connective tissues, including in the eyes, cardiovascular system and skin.

# **Our Solution: INZ-701**

INZ-701 is a soluble, recombinant protein containing the extracellular domain of native human ENPP1 fused to the Fc domain, or crystallizable fragment, of the immunoglobulin IgG1. In its native form, ENPP1 is a transmembrane enzyme with a modular structure consisting of a short intracellular domain, a single transmembrane domain and an extracellular domain that contains a conserved catalytic site responsible for enzymatic activity. ENPP1 is expressed predominantly in the liver and, to a lesser extent, in the kidney and bone. INZ-701 contains the extracellular soluble domain of ENPP1 fused to the Fc domain of IgG1 to minimize immunogenicity, stabilize the construct, increase the plasma half-life and allow ease of purification.

INZ-701 is designed to replace the lost enzymatic function of genetically deficient ENPP1 by restoring the normal balance in PPi and adenosine for ENPP1 deficiency and providing therapeutic effect to treat other diseases, like ABCC6 deficiency, involving low PPi levels. In contrast to native ENPP1, INZ-701 is a soluble protein that is designed to circulate throughout the body and access extracellular ATP and other nucleotide proteins. Like native ENPP1, INZ-701 cleaves ATP into PPi and AMP, a precursor of adenosine. Pharmacologically, INZ-701 is designed to have prolonged distribution and elimination phases, leading to steady-state concentrations in the blood over time and making dosing possible at infrequent intervals, potentially as long as weekly. INZ-701 is formulated for subcutaneous delivery.

In our preclinical studies conducted in ENPP1-deficient mouse models, dosing with INZ-701 resulted in increased plasma PPi levels, reduction in ectopic calcium deposits in a variety of tissues, prevention of calcification in the heart and aorta, and improvements in overall health. In ABCC6-deficient mouse models, dosing with INZ-701 also increased plasma PPi levels. Further, overexpressing ENPP1 in an ABCC6-deficient mouse model reduced calcification in key tissues. In addition to normalizing levels of PPi, in preclinical studies, INZ-701 prevented neointimal proliferation in both wild-type and ENPP1-deficient mice, which we believe is attributable to increased levels of adenosine. The nonclinical INZ-701 toxicology studies that we conducted in two animal species showed no systemic adverse effects at doses that significantly exceeded potential human doses.

We plan to file an IND with the FDA and a CTA with regulatory authorities in Europe for INZ-701 in the second half of 2020 to allow us to initiate clinical development for the treatment of ENPP1 deficiency. Subject to our IND and CTA becoming effective, we plan to conduct a Phase 1/2 clinical trial of INZ-701 designed as an open-label, dose-escalation trial in adult patients with ENPP1 deficiency in the United States and in Europe. We plan to file a CTA with the regulatory authorities in Europe for INZ-701 in the second half of 2020 to allow us to initiate clinical development for the treatment of ABCC6 deficiency. Subject to our CTA becoming effective, we plan to conduct a Phase 1/2 clinical trial of INZ-701 designed as an open-label, dose-escalation trial in adult patients with ABCC6 deficiency in Europe. Our Phase 1/2 clinical trials will primarily investigate the safety and tolerability of INZ-701 and characterize its pharmacokinetic and pharmacodynamic profile, including plasma PPi levels, to establish a recommended dosing regimen for the applicable indication.

If a safe dose is identified for further development, we plan to conduct Phase 2/3 clinical trials of INZ-701 in adult, infant and pediatric patient populations with ENPP1 deficiency and a Phase 2/3 clinical trial of INZ-701 in adults with ABCC6 deficiency. Prior to initiating Phase 2/3 clinical trials for either ENPP1 deficiency or ABCC6 deficiency, we plan to engage with the regulatory authorities in the United States, Europe and other jurisdictions to determine appropriate primary efficacy endpoints and other requirements for potential marketing approval. In particular if we propose new or novel endpoints or methodologies for our clinical trials, regulatory authorities will ultimately need to conclude that the endpoints of our clinical trials have provided clinically meaningful results before we are able to obtain potential marketing approval. We intend to design any such Phase 2/3 clinical trials as pivotal trials for registrational purposes.

Beyond ENPP1 and ABCC6 deficiencies, we believe that INZ-701 has the potential to provide therapeutic benefit to patients suffering from additional diseases of abnormal mineralization related to low PPi levels and diseases of neointimal proliferation related to low levels of adenosine, including diseases without a clear genetic basis. For example, calciphylaxis, a manifestation of chronic kidney disease, or CKD, may represent a particularly attractive area for drug development for abnormal mineralization. Calciphylaxis is characterized by pathological calcification of the vasculature in the skin and fat leading to blood clots and skin ulcers, likely as a result of low PPi levels. There are currently no approved therapies for calciphylaxis, and the condition has a reported one-year survival rate of approximately 50%. We are currently in the early stages of development of INZ-701 for the treatment of calciphylaxis and are aware of competition at a more advanced stage of clinical development for this disease. As a science-driven company, we also plan to continue to apply our expertise to identify and develop new therapeutics for diseases of abnormal mineralization. For example, we are currently exploring the potential for development of a gene therapy for ENPP1 deficiency.

### Pipeline

We hold development and commercialization rights to our pipeline and programs, including INZ-701, on a worldwide basis. Our current development programs are protected through exclusive intellectual property rights, including with filed and issued patents covering composition of matter for ENPP1-Fc fusion proteins, including INZ-701, and methods of treatment. We obtained an exclusive, worldwide license to our foundational intellectual property rights from Yale University in January 2017.

	ASSET	Sī	NEXT				
PROGRAM		Research	IND Enabling	Phase 1/2	Phase 2/3	ANTICIPATED MILESTONE	
GENETIC DISEASES							
ENPP1 Deficiency	INZ-701 (ENPP1-Fc)					File IND and CTA 2H 2020	
ABCC6 Deficiency	INZ-701 (ENPP1-Fc)					File CTA 2H 2020	
ADDITIONAL DISEASES							
Calciphylaxis	INZ-701 (ENPP1-Fc)					Generate pre-clinical proof of concept	
Diseases of Neointimal Proliferation	INZ-701 (ENPP1-Fc)					Generate pre-clinical proof of concept	

## Strategy

Our goal is to develop and commercialize safe and effective therapies for the treatment of patients suffering from a broad range of genetic and non-genetic diseases of abnormal mineralization. The critical components of our strategy to achieve this goal include:

- Efficiently advance clinical development for our lead product candidate, INZ-701, with an initial focus on ENPP1 and ABCC6 deficiencies.
- Expand our research and development efforts for INZ-701 in additional diseases of abnormal mineralization and for other therapies beyond INZ-701.
- Establish commercialization infrastructure for the marketing and sale of INZ-701 for rare indications.

- Build a patient-focused company to treat diseases of abnormal mineralization.
- Continue to expand our scientific understanding of abnormal mineralization, our related intellectual property portfolio and our rights to complementary technologies.

#### **Our Team**

We have assembled a leadership team with a strong track record and experience in building and managing biopharmaceutical companies and in rare disease research, development and commercialization. Our executives have experience, in particular, in developing new markets, obtaining marketing approval for and commercializing therapies for rare diseases that had not previously been the focus for drug development. Axel Bolte, our President and Chief Executive Officer and a co-founder of our company, previously had a successful career in healthcare venture capital, investing in and serving on the boards of directors of multiple private and public biopharmaceutical companies. Members of our science and medical leadership team previously led various discovery, development and manufacturing programs at Genzyme Corp., Shire Human Genetic Therapies, BioMarin Pharmaceutical, Inc., Alexion Pharmaceuticals, Inc., Pfizer Inc. and Ultragenyx Pharmaceutical Inc., among other companies. To date, we have funded our operations primarily with proceeds from sales of convertible preferred stock to investors that include Longitude Venture Partners, New Enterprise Associates, Novo Holdings A/S, Pivotal bioVenture Partners, RA Capital Healthcare Fund and Sofinnova Venture Partners.

#### **Risks Associated with Our Business**

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the "Risk Factors" section of this prospectus. These risks include the following:

- We have incurred significant losses since our inception. To date, we have not generated any revenue from product sales. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future and may never achieve or maintain profitability. Our net losses were \$7.7 million for the three months ended March 31, 2020, \$19.7 million for the year ended December 31, 2019 and \$7.0 million for the year ended December 31, 2018.
- We will need substantial additional funding. If we are unable to raise capital when needed or on attractive terms, we may be required to delay, limit, reduce or terminate our research and development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.
- We have a limited operating history and are very early in our development efforts. All of our product candidates are still in preclinical development. We are heavily dependent on the success of our lead product candidate, INZ-701.
- The COVID-19 pandemic, which has spread worldwide, may affect our ability to initiate and complete preclinical studies, delay the
  initiation of our planned clinical trials or future clinical trials, disrupt regulatory activities, disrupt our manufacturing and supply
  chain or have other adverse effects on our business and operations. We cannot be certain what the overall impact of the COVID-19
  pandemic will be on our business, and it has the potential to materially and adversely affect our business, financial condition, results
  of operations and prospects.
- We cannot be certain of the timely completion or outcome of our preclinical testing and clinical trials. The results of preclinical studies may not be predictive of the results of clinical trials, the

results of any early-stage clinical trials we conduct may not be predictive of the results of later-stage clinical trials and our product candidates could be associated with serious adverse events or undesirable side effects.

- If we are unable to obtain required marketing approvals for, commercialize, manufacture, obtain, maintain and enforce patent
  protection for, gain market acceptance of or obtain and maintain coverage, adequate pricing and adequate reimbursement from thirdparty payors for our product candidates, or experience significant delays in doing so, our business will be materially harmed and our
  ability to generate revenue from product sales will be materially impaired.
- The design and conduct of our clinical trials for the treatment of ENPP1 or ABCC6 deficiencies may take longer, be more costly or be less effective as a result of the novelty of development in these diseases. We may use new or novel endpoints or methodologies and regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results.
- We currently plan to conduct some clinical trials for our product candidates at sites outside the United States. If the FDA determines that any such trial did not comply with all applicable U.S. laws and regulations, the FDA may not accept the data from that trial, in which case we would likely need to conduct one or more additional clinical trials.
- We focus our research and product development on treatments for rare diseases. Given the small number of patients who have the diseases that we are targeting, it is critical to our ability to grow and become profitable that we continue to successfully identify patients with these rare diseases and capture a significant market share.
- We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates receive marketing approval. This reliance on third parties may increase the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.
- If we are unable to obtain, maintain, enforce and protect patent protection for our technology and products or if the scope of the
  patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products
  similar or identical to ours, and our ability to successfully commercialize our technology and products may be adversely affected.
- We are highly dependent on the research and development, clinical, financial, operational and other business expertise of our executive officers, as well as the other principal members of our management, scientific and clinical teams. Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

# **Our Corporate Information**

We were formed under the laws of the State of Delaware in September 2015 as a limited liability company under the name Inozyme Pharma, LLC. On January 12, 2017, Inozyme Pharma, LLC converted into a Delaware corporation and changed its name to Inozyme Pharma, Inc. Our principal executive offices are located at 321 Summer Street, Suite 400, Boston, Massachusetts 02210, and our telephone number is (857) 330-4340. Our website address is http://www.inozyme.com. The information contained on, or that can be accessed through, our website is not a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

In this prospectus, unless otherwise indicated or the context otherwise requires, references to "Inozyme," "we," "us," "our" and similar references refer to Inozyme Pharma, Inc. and its consolidated subsidiaries.

#### Implications of Being an Emerging Growth Company and a Smaller Reporting Company

As a company with less than \$1.07 billion in revenue during our last fiscal year, we qualify as an "emerging growth company," or EGC, as defined in the Jumpstart Our Business Startups Act of 2012. We may remain an EGC until the last day of the fiscal year in which the fifth anniversary of the closing of this offering occurs, although if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of any June 30 before that time or if we have annual gross revenues of \$1.07 billion or more in any fiscal year, we would cease to be an EGC as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than \$1 billion of non-convertible debt over a three-year period. For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an EGC. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock. We have elected to use the extended transition period for complying with new or revised accounting standards and will do so until such time that we either (1) irrevocably elect to "opt out" of such extended transition period or (2) no longer qualify as an EGC. As a result of this election, our consolidated financial statements may not be companies that comply with public company Financial Accounting Standards Board standards' effective dates.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates is less than \$700 million and our annual revenue was less than \$100 million during our most recently completed fiscal year. We may continue to be a smaller reporting company if either (1) the market value of our stock held by non-affiliates is less than \$250 million or (2) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. For so long as we remain a smaller reporting company, we are permitted and intend to rely on exemptions from certain disclosure and other requirements that are applicable to other public companies that are not smaller reporting companies.

#### THE OFFERING

Common stock offered 5,000,000 shares

Common stock to be outstanding immediately following 20,314,851 shares this offering

Option to purchase additional shares

We have granted the underwriters an option for a period of 30 days to purchase up to 750,000 additional shares of our common stock.

Use of proceeds

Risk Factors

We estimate that the net proceeds from this offering will be approximately \$66.5 million (or approximately \$76.9 million if the underwriters exercise their option to purchase additional shares in full), based on an assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, for the completion of our IND and CTA submissions and conduct of our Phase 1/2 clinical trial of INZ-701 for ENPP1 deficiency, for the completion of our CTA submission and conduct of our Phase 1/2 clinical trial of INZ-701 for ABCC6 deficiency, for preclinical studies for research stage programs and for working capital and other general corporate purposes. See the "Use of Proceeds" section of this prospectus for a more complete description of the intended use of proceeds from this offering.

You should read the "Risk Factors" section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.

Proposed Nasdaq Global Market symbol

"INZY"

The number of shares of our common stock to be outstanding after this offering is based on 1,361,001 shares of our common stock outstanding as of July 17, 2020 and 13,953,850 additional shares of our common stock issuable upon the automatic conversion of all outstanding shares of our preferred stock upon the closing of this offering.

The number of shares of our common stock to be outstanding after this offering does not include:

- 2,078,405 shares of our common stock issuable upon exercise of stock options outstanding as of July 17, 2020, at a weighted average
  exercise price of \$1.99 per share;
- 426,065 additional shares of our common stock reserved for future issuance under our existing Amended and Restated 2017 Equity Incentive Plan, as amended, as of July 17, 2020;

- 1,588,315 additional shares of our common stock that will be available for future issuance under our new 2020 Stock Incentive Plan that we are implementing in connection with this offering, of which we have granted options to purchase 768,380 shares of our common stock to our employees and non-employee directors effective upon the effectiveness of the registration statement of which this prospectus is a part; and
- 198,539 additional shares of our common stock that will be available for future issuance under our new 2020 Employee Stock Purchase Plan that we are implementing in connection with this offering.

Unless otherwise indicated or the context otherwise requires, all information in this prospectus:

- assumes no exercise by the underwriters of their option to purchase 750,000 additional shares of our common stock from us;
- gives effect to the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 13,953,850 shares of our common stock upon the closing of this offering;
- · assumes no exercise of the outstanding options described above; and
- gives effect to the restatement of our certificate of incorporation and the amendment and restatement of our bylaws upon the closing
  of this offering.

In addition, unless otherwise indicated, all information in this prospectus gives effect to a one-for-7.4730 reverse stock split of our common stock, and a proportionate adjustment in the ratio at which our preferred stock is convertible into our common stock, that became effective on July 17, 2020.

## SUMMARY CONSOLIDATED FINANCIAL DATA

You should read the following summary consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus. We have derived the consolidated statements of operations data for the years ended December 31, 2018 and 2019 from our audited consolidated financial statements appearing at the end of this prospectus. The consolidated interim statements of operations data for the three months ended March 31, 2019 and 2020 and the consolidated balance sheet data as of March 31, 2020 have been derived from our unaudited consolidated financial statements appearing at the end of this prospectus and have been prepared on the same basis as the audited consolidated financial statements. Our historical results are not necessarily indicative of the results that may be expected in the future, and our results for any interim period are not necessarily indicative of results that should be expected for any full year.

		Year Ende		2019		Three Months 2019		<u>1arch 31,</u> <u>2020</u>
Consolidated Statements of Operations Data:			(in the	ousands, except	share an	ıd per share dat	a)	
Operating expenses:								
Research and development	\$	8,099	\$	16,220	\$	4,134	\$	6,406
General and administrative		3,494		4,586		1,030		1,500
Total operating expenses		11,593		20,806		5,164		7,906
Loss from operations		(11,593)		(20,806)		(5,164)		(7,906)
Other income (expense):								
Interest income		284		1,106		210		171
Other expense, net		(29)		(24)		(17)		(3)
Change in fair value of preferred stock tranche liability		4,374			_			
Other income (expense), net		4,629		1,082		193		168
Net loss	\$	(6,964)	\$	(19,724)	\$	(4,971)	\$	(7,738)
Net loss per share attributable to common stockholders—basic and diluted(1)	\$	(6.63)	\$	(16.67)	\$	(4.27)	\$	(6.42)
Weighted-average common shares outstanding—basic and diluted(1)	1	,050,706		1,183,144		1,164,173		1,205,346
Pro forma net loss per share attributable to common stockholders— basic and diluted (unaudited)(1)			\$	(1.30)			\$	(0.51)
Pro forma weighted-average common shares outstanding—basic and diluted (unaudited)(1)			_1	5,136,994				15,159,196

(1) See Note 10 to our consolidated financial statements appearing at the end of this prospectus for a description of the method used to calculate basic and diluted net loss per share and unaudited pro forma basic and diluted net loss per share as well as the weighted-average number of common shares used in the calculation of the per share amounts.

		D E 4		
	<u>Actual</u>	Pro Forma(1) (in thousands)	Pro Forma As <u>Adjusted(2)</u>	
Consolidated Balance Sheet Data:				
Cash, cash equivalents and short-term investments	\$ 40,840	\$ 74,540	\$ 140,990	
Working capital(3)	36,354	70,054	136,504	
Total assets	42,036	75,736	142,186	
Convertible preferred stock	77,927	_	_	
Accumulated deficit	(42,390)	(59,039)	(59,039)	
Total stockholders' (deficit) equity	(40,800)	70,827	137,277	

- (1) The pro forma balance sheet data give effect to (i) our issuance and sale in June 2020 of an aggregate of 23,566,431 shares of our Series A-2 Convertible Preferred Stock for net proceeds of \$33.7 million and our issuance in July 2020 of an aggregate of 8,294,360 shares of our Series A-2 Convertible Preferred Stock to Alexion Pharmaceuticals, Inc., or Alexion, in consideration for the sale and assignment to us of specified patent rights and assets and (ii) the automatic conversion of all outstanding shares of our preferred stock, including our shares of Series A-2 Convertible Preferred Stock issued in June 2020 and July 2020, into an aggregate of 13,953,850 shares of our common stock upon the closing of this offering. For purposes of the pro forma balance sheet data, we have assumed an as converted value per common share of \$15.00, which is the midpoint of the price range set forth on the cover page of this prospectus, for the shares of our Series A-2 Convertible Preferred Stock issued to Alexion that will automatically convert into 1,109,910 shares of our common stock upon the closing of this offering. The actual per share amount will be determined in connection with the issuance of our consolidated financial statements for the three months ended September 30, 2020. We will expense the assets acquired from Alexion as of the acquisition date because we will use them in our research and development activities and believe they have no alternative future uses. For a further description of our intellectual property asset acquisition from Alexion, see "Business—Alexion Intellectual Property Asset Acquisition."
- (2) The proforma as adjusted balance sheet data give further effect to our issuance and sale of 5,000,000 shares of our common stock in this offering at an assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.
- (3) We define working capital as current assets less current liabilities. See our consolidated financial statements for further details regarding our current assets and current liabilities.

The pro forma as adjusted information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. A \$1.00 increase (decrease) in the assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents and short-term investments, working capital, total assets and total stockholders' equity by \$4.7 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents and short-term investments, working capital, total assets and total stockholders' equity by \$14.0 million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

#### RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this prospectus, including our consolidated financial statements and the related notes appearing at the end of this prospectus, before deciding to invest in our common stock. If any of the following risks actually occur, our business, prospects, operating results and financial condition could suffer materially. In such event, the trading price of our common stock could decline and you might lose all or part of your investment.

## Risks Related to our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception. We expect to continue to incur significant expenses and operating losses for the foreseeable future and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. Our net losses were \$7.7 million for the three months ended March 31, 2020, \$19.7 million for the year ended December 31, 2019 and \$7.0 million for the year ended December 31, 2018. As of March 31, 2020, we had an accumulated deficit of \$42.4 million. To date, we have not yet commercialized any products or generated any revenue from product sales and have financed our operations primarily with proceeds from sales of convertible preferred stock. We have devoted substantially all of our financial resources and efforts to pursuing research and development of our product candidates. We are still in the early stages of development of our lead product candidate, INZ-701, and plan to file applications with regulatory authorities in the United States and Europe in the second half of 2020 to allow us to initiate clinical development.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- prepare for, initiate and conduct a planned Phase 1/2 clinical trial of INZ-701 for ENPP1 deficiency;
- prepare for, initiate and conduct a planned Phase 1/2 clinical trial of INZ-701 for ABCC6 deficiency;
- prepare for, initiate and conduct later stage clinical trials of INZ-701 for patients with ENPP1 and ABCC6 deficiencies;
- conduct research and preclinical testing of INZ-701 for additional indications;
- conduct research and preclinical testing of other product candidates;
- advance INZ-701 for additional indications or any other product candidate into clinical development;
- seek marketing approval for INZ-701 or any other product candidate if it successfully completes clinical trials;
- scale up our manufacturing processes and capabilities to support clinical trials of INZ-701 or any other product candidates we develop and for commercialization of any product candidate for which we may obtain marketing approval;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;

- in-license or acquire additional technologies or product candidates;
- · make any payments to Yale University, or Yale, under our license agreement or sponsored research agreement with Yale;
- maintain, expand, enforce and protect our intellectual property portfolio;
- · hire additional clinical, regulatory, quality control and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our research, product development and planned future commercialization efforts and our operations as a public company.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses could increase beyond our expectations if, among other things:

- we are required by regulatory authorities in the United States, Europe or other jurisdictions to perform trials or studies in addition to, or different than, those that we currently expect;
- there are any delays in establishing appropriate manufacturing arrangements for or completing the development of any of our product candidates; or
- there are any third-party challenges to our intellectual property or we need to defend against any intellectual property-related claim.

Even if we obtain marketing approval for and are successful in commercializing one or more of our product candidates, we expect to incur substantial additional research and development and other expenditures to develop and market additional product candidates or to expand the approved indications of any marketed product. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

#### We have never generated revenue from product sales and may never achieve or maintain profitability.

We have not initiated clinical development of any product candidate and expect that it will be a number of years, if ever, before we have a product candidate ready for commercialization. To become and remain profitable, we must succeed in completing development of, obtaining marketing approval for and eventually commercializing, one or more products that generates significant revenue. The ability to achieve this success will require us to be effective in a range of challenging activities, including completing preclinical testing and clinical development of INZ-701 for ENPP1 and ABCC6 deficiencies, completing research, preclinical testing and clinical development of INZ-701 for additional indications or of other product candidates, scaling up our manufacturing processes and capabilities to support clinical trials of INZ-701 or of other product candidates we develop, obtaining marketing approval for INZ-701 or any other product candidates and manufacturing, marketing and selling any products for which we may obtain marketing approval. We are currently only in the preclinical testing stage for INZ-701. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We are heavily dependent on the success of our lead product candidate, INZ-701, which will require significant clinical testing before we can seek marketing approval and potentially launch commercial sales. If INZ-701 does not receive marketing approval or is not successfully commercialized, or if there is significant delay in doing so, our business will be harmed.

We currently have not yet advanced any product candidates into clinical development, have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures for the foreseeable future will be devoted to INZ-701. Our business currently depends heavily on the successful development, marketing approval and commercialization of INZ-701. We cannot be certain that INZ-701 will achieve success in future clinical trials, receive marketing approval or be successfully commercialized.

If we were required to discontinue development of INZ-701, or if INZ-701 does not receive marketing approval for one or more of the indications we pursue, fails to achieve significant market acceptance, or fails to receive adequate reimbursement, we would be delayed by many years in our ability to achieve profitability, if ever, and may not be able to generate sufficient revenue to continue our business.

We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect to devote substantial financial resources to our ongoing and planned activities, particularly as we prepare for, initiate and conduct our planned Phase 1/2 clinical trials of INZ-701 for ENPP1 and ABCC6 deficiencies, and continue research and development and initiate additional clinical trials of, and seek marketing approval for, INZ-701 and any other product candidates we develop. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance our preclinical activities and clinical trials. In addition, if we obtain marketing approval for INZ-701 or any other product candidate we develop, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital or obtain adequate funds when needed or on acceptable terms, we may be required to delay, limit, reduce or terminate our research and development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and distract from our research and development efforts.

Our future capital requirements will depend on many factors, including:

- the progress, costs and results of our planned Phase 1/2 clinical trials of INZ-701 for ENPP1 and ABCC6 deficiencies and any future clinical development of INZ-701 for these indications;
- the scope, progress, costs and results of research, preclinical testing and clinical trials of INZ-701 for additional indications;
- the number of and development requirements for additional indications for INZ-701 or for any other product candidates we develop;
- our ability to scale up our manufacturing processes and capabilities to support clinical trials of INZ-701 and any other product candidates we develop;
- the costs, timing and outcome of regulatory review of INZ-701 and any other product candidates we develop;

- potential changes in the regulatory environment and enforcement rules;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the payment of license fees and other costs of our technology license arrangements;
- the costs and timing of future commercialization activities, including product manufacturing, sales, marketing and distribution, for INZ-701 and any other product candidates we develop for which we may receive marketing approval;
- the amount and timing of revenue, if any, received from commercial sales of INZ-701 and any other product candidates we develop for which we receive marketing approval;
- potential changes in pharmaceutical pricing and reimbursement infrastructure;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property-related claims; and
- · the extent to which we in-license or acquire additional technologies or product candidates.

Our independent registered public accounting firm's report on our consolidated financial statements as of and for the year ended December 31, 2019 included a going concern uncertainty paragraph.

As of March 31, 2020, we had cash, cash equivalents and short-term investments of approximately \$40.8 million. We also received net proceeds of \$33.7 million from the sale of additional shares of our Series A-2 Convertible Preferred Stock in June 2020. We believe that the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments as of March 31, 2020 and the net proceeds from the sale of additional shares of Series A-2 Convertible Preferred Stock in June 2020, will enable us to fund our operating expenses and capital expenditure requirements at least into the second half of 2022. However, we have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. In addition, changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. As a result, we could deplete our capital resources sooner than we currently expect. In addition, because the successful development of INZ-701 and any other product candidates that we pursue is highly uncertain, at this time we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the development of any product candidate.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. We will not generate commercial revenues unless and until we can achieve sales of products, which we do not anticipate for a number of years, if at all. Accordingly, we will need to obtain substantial additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all, and may be impacted by the economic climate and market conditions. For example, market volatility resulting from the COVID-19 pandemic or any other future infectious diseases, epidemics or pandemics could also adversely impact our ability to access capital as and when needed. Alternatively, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

Raising additional capital may cause dilution to our stockholders, including purchasers of our common stock in this offering, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial revenues from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our operations and ability to take specific actions, such as incurring additional debt, making acquisitions, engaging in acquisition, merger or collaboration transactions, selling or licensing our assets, making capital expenditures, redeeming our stock, making certain investments or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We commenced activities in 2017 and are an early-stage company. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, securing intellectual property rights, conducting research and development activities, establishing arrangements for the manufacture of INZ-701 and longer term planning for potential commercialization. All of our product candidates are still in preclinical development. Our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in their early stages of operations. We have not yet demonstrated our ability to successfully initiate or complete any clinical trials, obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing, obtaining marketing approval for and commercializing products.

In addition, as our business grows, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown obstacles. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

As we continue to build our business, we expect our financial condition and operating results to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

The COVID-19 pandemic, which began in late 2019 and has spread worldwide, may affect our ability to initiate and complete preclinical studies, delay the initiation of our planned clinical trials or future clinical trials, disrupt regulatory activities, disrupt our manufacturing and supply chain or have other adverse effects on our business and operations. In addition, this pandemic has caused substantial disruption in the financial markets and may adversely impact economies worldwide, both of which could result in adverse effects on our business and operations.

The COVID-19 pandemic, which began in December 2019 and has spread worldwide, has caused many governments to implement measures to slow the spread of the outbreak through quarantines, travel restrictions,

heightened border scrutiny and other measures. The outbreak and government measures taken in response have also had a significant impact, both directly and indirectly, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The future progression of the outbreak and its effects on our business and operations are uncertain.

We and the third-party manufacturers and clinical research organizations that we engage may face disruptions that could affect our ability to initiate and complete preclinical studies or clinical trials, including disruptions in procuring items that are essential for our research and development activities, such as, for example, raw materials used in the manufacturing of our product candidates, laboratory supplies for our preclinical studies and planned clinical trials, or animals that are used for preclinical testing, in each case, for which there may be shortages because of ongoing efforts to address the outbreak.

As a result of the COVID-19 pandemic, we may experience further disruptions that could severely impact our business, including:

- disruptions related to our planned clinical trials or future clinical trials arising from delays in completing preclinical studies required to begin clinical development;
- manufacturing disruptions;
- · the inability to obtain necessary site approvals or other delays at clinical trial sites;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by foreign, federal or state governments, employers and others;
- interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the U.S. Food and Drug Administration, or FDA, or other regulatory authorities, which may impact review and approval timelines;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- difficulties recruiting or retaining patients for our planned clinical trials if patients are affected by the virus or are fearful of visiting or traveling to clinical trial sites because of the outbreak; and
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events and refusal of the FDA to accept data from clinical trials in these affected geographies.

The response to the COVID-19 pandemic may redirect resources with respect to regulatory and intellectual property matters in a way that would adversely impact our ability to pursue marketing approvals and protect our intellectual property. In addition, we may face impediments to regulatory meetings and potential approvals due to measures intended to limit in-person interactions.

Furthermore, third parties, including manufacturers, medical institutions, clinical investigators, contract research organizations and consultants with whom we conduct business, are similarly adjusting their operations and assessing their capacity in light of the COVID-19 pandemic. If these third parties continue to experience shutdowns or business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

The COVID-19 pandemic continues to evolve and has already caused significant disruptions in the financial markets, and may continue to cause such disruptions, which could impact our ability to raise additional funds through public offerings and may also impact the volatility of our stock price and trading in our stock. Moreover, it is possible the pandemic will further significantly impact economies worldwide, which could result in adverse effects on our business and operations. We cannot be certain what the overall impact of the COVID-19 pandemic will be on our business, and it has the potential to materially and adversely affect our business, financial condition, results of operations and prospects. To the extent the COVID-19 pandemic adversely affects our business, financial condition and results of operations, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section

#### Changes in tax laws or in their implementation may adversely affect our business and financial condition.

Changes in tax law may adversely affect our business or financial condition. On December 22, 2017, the U.S. government enacted legislation commonly referred to as the Tax Cuts and Jobs Act, or the TCJA, which significantly reformed the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, contained significant changes to corporate taxation, including a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, the limitation of the tax deduction for net interest expense to 30% of adjusted earnings (except for certain small businesses), the limitation of the deduction for net operating losses, or NOLs, arising in taxable years beginning after December 31, 2017 to 80% of current year taxable income and elimination of NOL carrybacks for losses arising in taxable years ending after December 31, 2017 (though any such NOLs may be carried forward indefinitely), the imposition of a one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, the elimination of U.S. tax on foreign earnings (subject to certain important exceptions), the allowance of immediate deductions for certain new investments instead of deductions for depreciation expense over time, and the modification or repeal of many business deductions and credits.

As part of Congress's response to the COVID-19 pandemic, the Families First Coronavirus Response Act, or FFCR Act, was enacted on March 18, 2020, and the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, was enacted on March 27, 2020. Both contain numerous tax provisions. In particular, the CARES Act retroactively and temporarily (for taxable years beginning before January 1, 2021) suspends application of the 80%-of-income limitation on the use of NOLs, which was enacted as part of the TCJA. It also provides that NOLs arising in any taxable year beginning after December 31, 2017 and before January 1, 2021 are generally eligible to be carried back up to five years. The CARES Act also temporarily (for taxable years beginning in 2019 or 2020) relaxes the limitation of the tax deductibility for net interest expense by increasing the limitation from 30% to 50% of adjusted taxable income.

Regulatory guidance under the TCJA, the FFCR Act and the CARES Act is and continues to be forthcoming, and such guidance could ultimately increase or lessen impact of these laws on our business and financial condition. It is also likely that Congress will enact additional legislation in connection with the COVID-19 pandemic, some of which could have an impact on our company. In addition, it is uncertain if and to what extent various states will conform to the TCJA, the FFCR Act or the CARES Act.

Our ability to use our NOLs and research and development tax credit carryforwards to offset future taxable income may be subject to certain limitations.

We have a history of cumulative losses and anticipate that we will continue to incur significant losses in the foreseeable future. As a result, we do not know whether or when we will generate taxable income necessary

to utilize our NOLs or research and development tax credit carryforwards. As of December 31, 2019, we had federal and state NOL carryforwards of \$34.6 million and \$21.6 million, respectively, and federal and state research and development tax credit carryforwards totaling \$0.4 million.

In general, under Section 382 of the Code and corresponding provisions of state law, a corporation that undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three year period, is subject to limitations on its ability to utilize its pre-change NOLs and research and development tax credit carryforwards to offset future taxable income. We have not conducted a study to assess whether any such ownership changes have occurred. We may have experienced such ownership changes in the past and may experience such ownership changes in the future as a result of this offering or subsequent changes in our stock ownership (which may be outside our control). As a result, if and to the extent we earn net taxable income, our ability to use our pre-change NOLs and research and development tax credit carryforwards to offset such taxable income may be subject to limitations.

### Risks Related to Research and Development of our Product Candidates

We are very early in our development efforts. Our lead product candidate, INZ-701, is in preclinical development. If we are unable to commercialize INZ-701 or experience significant delays in doing so, our business will be materially harmed.

We are very early in our development efforts, and all of our product candidates are still in preclinical development. We plan to file applications with regulatory authorities in the United States and Europe in the second half of 2020 to allow us to initiate clinical development of INZ-701. Our ability to generate revenues from product sales, which we do not expect will occur for a number of years, if ever, will depend heavily on the successful development, marketing approval and eventual commercialization of INZ-701 or other product candidates we develop, which may never occur. The success of INZ-701 and any other product candidate we develop will depend on several factors, including the following:

- successfully completing preclinical studies and initiating clinical trials, including acceptance of our Investigational New Drug Application, or IND, for INZ-701 by the FDA and similar applications by regulatory authorities in Europe to allow us to initiate clinical development of INZ-701;
- successfully enrolling patients in and completing clinical trials;
- scaling up manufacturing processes and capabilities to support clinical trials of INZ-701 and any other product candidates we develop;
- · applying for and receiving marketing approvals from applicable regulatory authorities;
- obtaining and maintaining intellectual property protection and regulatory exclusivity for INZ-701 and any other product candidates we develop;
- making arrangements for commercial manufacturing capabilities;
- establishing sales, marketing and distribution capabilities and launching commercial sales of INZ-701 and any other product candidates we develop, if and when approved, whether alone or in collaboration with others;
- acceptance of INZ-701 and any other product candidates we develop, if and when approved, by patients, the medical community and third-party payors;
- · effectively competing with other therapies;

- · obtaining and maintaining coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;
- maintaining, enforcing, defending and protecting our rights in our intellectual property portfolio;
- · not infringing, misappropriating or otherwise violating others' intellectual property or proprietary rights; and
- · maintaining a continued acceptable safety profile of our products following receipt of any marketing approvals.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize INZ-701 or any other product candidate we develop, which would materially harm our business. As a company, we do not have any experience in clinical development and have not advanced INZ-701 or any other product candidates into clinical development. Any predictions about the future success or viability of INZ-701 or any product candidates we develop may not be as accurate as they could be if we had a history of conducting clinical trials.

Drug development involves a lengthy and expensive process, with an uncertain outcome. The results of preclinical studies and early clinical trials may not be predictive of future results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of INZ-701 or any other product candidate. If our clinical trials do not meet safety or efficacy endpoints, or if we experience significant delays in trials, our ability to commercialize INZ-701 or any other product candidates we develop and our financial position will be impaired.

Our lead product candidate, INZ-701, is in preclinical development and its risk of failure is high. It is impossible to predict when or if INZ-701 or any other product candidate that we develop will prove effective or safe in humans or will receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of INZ-701 or any other product candidate we develop, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. We have not yet begun a clinical trial of INZ-701 or any other product candidate. Clinical trials may fail to demonstrate that INZ-701 or any other product candidates we develop is safe for humans and effective for indicated uses. Even if the clinical trials are successful, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application.

In order to obtain regulatory approval to market a new biological product, we must demonstrate proof of safety, purity and potency or efficacy in humans. To satisfy these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our applications to regulatory authorities in the United States and Europe to allow us to initiate clinical development. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the outcome of our preclinical testing and studies will ultimately support the further development of our current or future product candidates or whether regulatory authorities will accept our proposed clinical programs. As a result, we may not be able to submit applications to initiate clinical development of INZ-701 or any other product candidate we develop on the timelines we expect, if at all, and the submission of these applications may not result in regulatory authorities allowing clinical trials to begin. Furthermore, product candidates are subject to continued preclinical safety studies, which may be conducted concurrently with our clinical testing. The outcomes of these safety studies may delay the launch of or enrollment in future clinical trials and could impact our ability to continue to conduct our clinical trials.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to the outcome. We cannot guarantee that any of our clinical trials will be conducted as planned or completed on schedule, or at all. A failure of one or more clinical trials can occur at any stage of testing, which may result from a multitude of factors, including, among other things, flaws in study design, dose selection issues, placebo effects, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and preliminary or interim results of a clinical trial do not necessarily predict final results. For example, our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. As a result, we cannot assure you that any clinical trials that we may conduct will demonstrate consistent or adequate efficacy and safety to support marketing approval.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Furthermore, the failure of any of our product candidates to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of our other product candidates or cause regulatory authorities to require additional testing before approving any of our product candidates.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any product candidates that we develop, including:

- regulators or institutional review boards, or IRBs, may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or at all;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- regulators may determine that the planned design of our clinical trials is flawed or inadequate;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- we may be unable to establish clinical endpoints that applicable regulatory authorities consider clinically meaningful, or, if we seek
  accelerated approval, biomarker efficacy endpoints that applicable regulatory authorities consider likely to predict clinical benefit;
- preclinical testing may produce results based on which we may decide, or regulators may require us, to conduct additional preclinical studies before we proceed with certain clinical trials, limit the scope of our clinical trials, halt ongoing clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all:

- we may decide, or regulators or IRBs may require us, to suspend or terminate clinical trials of our product candidates for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- regulators or IRBs may require us to perform additional or unanticipated clinical trials to obtain approval or we may be subject to additional post-marketing testing requirements to maintain marketing approval;
- · regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our clinical investigators, regulators or IRBs to suspend or terminate the trials;
- regulators may withdraw their approval of a product or impose restrictions on its distribution; and
- business interruptions resulting from the COVID-19 pandemic.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive, if there are safety concerns or if we determine that the observed safety or efficacy profile would not be competitive in the marketplace, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates;
- · not obtain marketing approval at all;
- · obtain marketing approval in some countries and not in others;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in preclinical studies or clinical trials or in obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. We may also determine to change the design or protocol of one or more of our clinical trials, including to add additional patients or arms, which could result in increased costs and expenses or delays. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to

commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Because we are developing INZ-701 for the treatment of diseases in which there is little clinical experience and, in some cases, using new endpoints or methodologies, the FDA or other regulatory authorities may not consider the endpoints of our clinical trials to predict or provide clinically meaningful results.

There are currently no therapies approved to treat ENPP1 or ABCC6 deficiencies, and there may be no therapies approved to treat the underlying causes of diseases that we attempt to address or may address in the future. As a result, the design and conduct of clinical trials of product candidates for the treatment of these diseases may take longer, be more costly or be less effective as a result of the novelty of development in these diseases. In some cases, we may use new or novel endpoints or methodologies, such as change in plasma PPi, which we plan to evaluate in our Phase 1/2 clinical trials of INZ-701, and regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results. Any such regulatory authority may require evaluation of additional or different clinical endpoints in our clinical trials or ultimately determine that these clinical endpoints do not support marketing approval. In addition, if we are required to use additional or different clinical endpoints by regulatory authorities, INZ-701 may not achieve or meet such clinical endpoints in our clinical trials.

Even if a regulatory authority finds our clinical trial success criteria to be sufficiently validated and clinically meaningful, we may not achieve the pre-specified endpoint to a degree of statistical significance in any pivotal or other clinical trials we may conduct for our product candidates. Further, even if we do achieve the pre-specified criteria, our trials may produce results that are unpredictable or inconsistent with the results of other efficacy endpoints in the trial. Regulatory authorities also could give overriding weight to other efficacy endpoints over a primary endpoint even if we achieve statistically significant results on that primary endpoint, if we do not do so on our secondary efficacy endpoints. Regulatory authorities also weigh the benefits of a product against its risks and may view the efficacy results in the context of safety as not being supportive of approval.

If we experience delays or difficulties in the enrollment of patients in our clinical trials for INZ-701 or any other product candidate we develop, our receipt of necessary marketing approvals could be delayed or prevented.

Identifying and qualifying patients to participate in clinical trials for INZ-701 and any other product candidate we develop is critical to our success. Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients who remain in the trial until its conclusion. Because of our primary focus on rare diseases, we may have difficulty enrolling a sufficient number of eligible patients. ENPP1 deficiency is estimated to occur in approximately one in 200,000 births, and we believe there are between 11,000 and 12,000 patients worldwide with ENPP1 deficiency. In the United States, Europe and other major markets, including Australia, Brazil, Canada, Japan and Russia, we believe there are approximately 3,500 patients worldwide with ABCC6 deficiency is estimated to afflict approximately one per 50,000 individuals, and we believe there are more than 67,000 patients worldwide with ABCC6 deficiency. In the United States, Europe and other major markets, including Australia, Brazil, Canada, Japan and Russia, we believe there are approximately 20,000 patients with ABCC6 deficiency. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside of the United States. We cannot predict how successful we will be at enrolling subjects in future clinical trials. Patient enrollment is affected by a variety of other factors, including:

- the prevalence and severity of the disease under investigation;
- the eligibility criteria for the trial in question;
- the perceived risks and benefits of the product candidate under trial;

- the requirements of the trial protocols;
- the availability of existing treatments for the indications for which we are conducting clinical trials;
- · the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the efforts to facilitate timely enrollment in clinical trials;
- the ability to identify specific patient populations based on specific genetic mutations or other factors;
- · the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain patient consents;
- the proximity and availability of clinical trial sites for prospective patients;
- the conduct of clinical trials by competitors for product candidates that treat the same indications or address the same patient populations as our product candidates;
- the cost to, or lack of adequate compensation for, prospective patients; and
- the impact of the ongoing COVID-19 pandemic.

Our inability to locate and enroll a sufficient number of patients for our clinical trials would result in significant delays, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary regulatory approvals. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

If serious adverse events, undesirable side effects or unexpected characteristics are identified during the development of INZ-701 or any other product candidate we may develop, we may need to abandon or limit our further clinical development of those product candidates.

We have not yet evaluated INZ-701 or any other product candidate in clinical trials. If INZ-701 or any other product candidate we develop is associated with serious adverse events or undesirable side effects in clinical trials or have characteristics that are unexpected in clinical trials or preclinical testing, we may need to abandon development of such product candidate or limit development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or unexpected characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In pharmaceutical development, many compounds that initially show promise in early-stage or clinical testing are later found to cause side effects that delay or prevent further development of the compound.

Additionally, if results of our clinical trials reveal undesirable side effects, we, regulatory authorities or the IRBs at the institutions in which our studies are conducted could suspend or terminate our clinical trials, regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications or we could be forced to materially modify the design of our clinical trials. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials or result in potential liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff.

If we elect or are forced to suspend or terminate any clinical trial of our product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate revenues from sales of such product candidate will be delayed or eliminated. Any of these occurrences could materially harm our business.

Interim top-line and preliminary results from our clinical trials that we announce or publish from time to time may change as more participant data become available and are subject to audit and verification procedures, which could result in material changes in the final data.

From time to time, we may publish interim top-line or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participant enrollment continues and more participant data become available. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data. Preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could be material and could significantly harm our reputation and business prospects and may cause the trading price of our common stock to fluctuate significantly.

If any of our product candidates receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the drug could be compromised.

We have not yet evaluated any product candidates in clinical trials. Clinical trials will be conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of our product candidates receives marketing approval, and we, or others, later discover that they are less effective than previously believed, or cause undesirable side effects, a number of potentially significant negative consequences could result, including:

- withdrawal or limitation by regulatory authorities of approvals of such product;
- seizure of the product by regulatory authorities;
- recall of the product;
- restrictions on the marketing of the product or the manufacturing process for any component thereof;
- requirement by regulatory authorities of additional warnings on the label;
- requirement that we implement a risk evaluation and mitigation strategy or create a medication guide outlining the risks of such side
  effects for distribution to patients;
- commitment to expensive post-marketing studies as a prerequisite of approval by regulatory authorities of such product;
- the product may become less competitive;
- initiation of regulatory investigations and government enforcement actions;

- initiation of legal action against us to hold us liable for harm caused to patients; and
- harm to our reputation and resulting harm to physician or patient acceptance of our products.

Any of these events could prevent us from achieving or maintaining market acceptance of a particular product candidate, if approved, and could significantly harm our business, financial condition, and results of operations.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Failure to allocate resources or capitalize on strategies in a successful manner will have an adverse impact on our business.

We currently plan to conduct some clinical trials for our product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

We plan to conduct clinical trials of INZ-701 outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and be performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will depend on its determination that the trials also complied with all applicable U.S. laws and regulations. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and could delay or permanently halt our development of the applicable product candidates.

In addition, there are risks inherent in conducting clinical trials in multiple jurisdictions, inside and outside of the United States, such as:

- regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our ability to conduct our clinical trials;
- · foreign exchange rate fluctuations;
- manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- the risk that the patient populations in such trials are not considered representative as compared to the patient population in the target markets where approval is being sought.

Because gene therapy is novel and the regulatory landscape that governs any product candidates we may develop is uncertain and may change, we cannot predict the time and cost of obtaining regulatory approval, if we receive it at all, for any product candidates we may develop.

The regulatory requirements that will govern any novel gene therapy product candidates we develop are not entirely clear and may change. Within the broader genetic medicine field, we are aware of a limited number of gene therapy products that have received marketing authorization from the FDA and the European Medicines Authority, or EMA. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing. Regulatory requirements governing gene therapy products and cell therapy products have changed frequently and will likely continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing gene therapy products and cell therapy products. For example, in the United States, the FDA has established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. Gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at the institution participating in the clinical trial. Gene therapy clinical trials conducted at institutions that receive funding for recombinant DNA research from the National Institutes of Health, or NIH, are also subject to review by the NIH Office of Biotechnology Activities' Recombinant DNA Advisory Committee. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation. The same applies in the European Union. The EMA's Committee for Advanced Therapies, or CAT, is responsible for assessing the quality, safety, and efficacy of advanced-therapy medicinal products. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for a gene therapy medicinal candidate that is submitted to the EMA. In the European Union, the development and evaluation of a gene therapy medicinal product must be considered in the context of the relevant European Union guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that we comply with these new guidelines. As a result, the procedures and standards applied to gene therapy products and cell therapy products may be applied to any gene therapy product candidates we may develop, but that remains uncertain at this point.

Adverse public perception of genetic medicine, and gene therapy in particular, may negatively impact regulatory approval of, or demand for, our potential products.

The clinical and commercial success of our potential products will depend in part on public acceptance of the use of gene therapy for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene therapy is unsafe, unethical, or immoral, and, consequently, our products may not gain the acceptance of the public or the medical community. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.

#### Risks Related to the Commercialization of our Product Candidates

Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, and the market opportunity for any of our product candidates, if approved, may be smaller than we estimate.

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Efforts to

educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenues from product sales and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages of our product candidates compared to the advantages and relative risks of alternative treatments;
- the effectiveness of sales and marketing efforts;
- our ability to offer our products, if approved, for sale at competitive prices;
- the clinical indications for which the product is approved;
- the cost of treatment in relation to alternative treatments;
- the convenience and ease of administration compared to alternative treatments;
- · the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- the availability of third-party coverage and adequate reimbursement, and patients' willingness to pay out of pocket for required co-payments or in the absence of third-party coverage or adequate reimbursement;
- product labeling or product insert requirements of the FDA, the EMA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- the prevalence and severity of any side effects;
- support from patient advocacy groups; and
- any restrictions on the use of our products, if approved, together with other medications.

Our assessment of the potential market opportunity for our product candidates is based on industry and market data that we obtained from industry publications, research, surveys and studies conducted by third parties and our analysis of these data, research, surveys and studies. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. Our estimates of the potential market opportunities for our product candidates include a number of key assumptions based on our industry knowledge, industry publications and third-party research, surveys and studies, which may be based on a small sample size and fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions. If any of our assumptions or estimates, or these publications, research, surveys or studies prove to be inaccurate, then the actual market for any of our product candidates may be smaller than we expect, and as a result our revenues from product sales may be limited and it may be more difficult for us to achieve or maintain profitability.

If we are unable to establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience as a company in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product for which we have obtained marketing approval, we will need to establish a sales, marketing and distribution organization, either ourselves or through collaborations or other arrangements with third parties.

We believe that we will be able to commercialize INZ-701, if approved, for ENPP1 or ABCC6 deficiency with a small, targeted, internal sales and commercial organization in the United States and other major markets. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. These efforts may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. In general, the cost of establishing and maintaining a sales and marketing organization may exceed the cost-effectiveness of doing so.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales, marketing, coverage or reimbursement, customer service, medical affairs and other support personnel;
- our inability to equip sales personnel with effective materials, including medical and sales literature to help them educate physicians and other healthcare providers regarding rare diseases and our future products;
- our inability to effectively manage a geographically dispersed sales and marketing team;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement and other acceptance by payors;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales, marketing and distribution capabilities and we enter into arrangements with third parties to perform these services, our revenues from product sales and our profitability, if any, are likely to be lower than if we were to market, sell and distribute any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and

distribute our product candidates or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do, thus rendering our products non-competitive, obsolete or reducing the size of our market.

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face and will continue to face competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, government agencies and public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

We are aware of a number of companies generally pursuing the development of different enzyme replacement therapies or treatments for vascular calcification disorders and many other companies are focused on rare disease markets. For example, SNF472, a calcification inhibitor, is currently in Phase 3 clinical development for calciphylaxis by Sanifit, and Inositec has product candidates in preclinical development for calcification inhibitors.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our development programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. Because of our primary focus on rare disease, if our product candidates achieve marketing approval, we expect to seek premium pricing.

Technology in the pharmaceutical and biotechnology industries has undergone rapid and significant change, and we expect that it will continue to do so. Any compounds, products or processes that we develop may become obsolete or uneconomical before we recover any expenses incurred in connection with their development.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We may pursue the in-license or acquisition of rights to complementary technologies and product candidates on an opportunistic basis. However, we may be unable to in-license or acquire any additional

technologies or product candidates from third parties. The acquisition and licensing of technologies and product candidates is a competitive area, and a number of more established companies also have similar strategies to in-license or acquire technologies and product candidates that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to in-license or acquire the relevant technology or product candidate on terms that would allow us to make an appropriate return on our investment.

If the market opportunities for our product candidates are smaller than we currently believe, our revenue may be adversely affected, and our business may suffer. Because the target patient populations of our product candidates are small, we must be able to successfully identify patients and capture a significant market share to achieve profitability and growth.

We focus our research and product development on treatments for rare diseases. Given the small number of patients who have the diseases that we are targeting, it is critical to our ability to grow and become profitable that we continue to successfully identify patients with these rare diseases. Our projections of the number of people who have these diseases are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific and medical literature, industry publications, third-party research, surveys and studies, patient foundations or market research that we conducted, and may prove to be incorrect or contain errors. New studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. The effort to identify patients with diseases we seek to treat is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. Additionally, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business.

Further, even if we obtain significant market share for our product candidates, because the potential target populations are very small, we may never achieve profitability despite obtaining such significant market share. For example, the estimated incidence of ENPP1 deficiency is approximately one in 200,000 births worldwide. In the United States, Europe and other major markets, including Australia, Brazil, Canada, Japan and Russia, we believe there are approximately 3,500 patients with ENPP1 deficiency. ABCC6 deficiency is estimated to afflict approximately one per 50,000 individuals, and we believe there are more than 67,000 patients worldwide with ABCC6 deficiency. In the United States, Europe and other major markets, including Australia, Brazil, Canada, Japan and Russia, we believe there are approximately 20,000 patients with ABCC6 deficiency. In addition, while we are pursuing marketing approval for ENPP1 deficiency and ABCC6 deficiency indications, the FDA may only grant approval for more narrow, specific disease indications that would result in a smaller market than we initially sought.

Because there are currently no products approved for the treatment of our target indications, such as ENPP1 and ABCC6 deficiencies, the pricing and reimbursement of our product candidates, if approved, is uncertain, but must be adequate to support commercial infrastructure. In addition, while we are pursuing additional non-genetic indications for INZ-701 such as for calciphylaxis and neointimal proliferation, we may not receive approval for such indications or such indications may not expand the target population for INZ-701 in an amount sufficient to achieve profitability. Furthermore, if we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell our product candidates will be adversely affected.

Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the

approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidate to other available therapies. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. The availability of coverage and adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford medical services and pharmaceutical products, including our product candidates. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

There can be no assurance that our product candidates, even if they are approved for sale in the United States, in the European Union or in other countries, will be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payors, or that coverage and an adequate level of reimbursement will be available or that third-party payors' reimbursement policies will not adversely affect our ability to sell our product candidates profitably.

Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties that, if they materialize, could harm our business.

Our future profitability will depend, in part, on our ability to commercialize our product candidates in markets outside of the United States and the European Union. We are not permitted to market or promote INZ-701 or any other product candidates we develop before we receive approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for any of our product candidates. To obtain separate marketing approvals in other countries we may be required to comply with numerous and varying regulatory requirements of such countries regarding the safety and efficacy of our product candidates and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates. If we commercialize our product candidates in these foreign markets, we will be subject to additional risks and uncertainties, including:

- economic weakness, including inflation, or political instability in particular economies and markets;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements, many of which vary between countries:
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- tariffs and trade barriers, as well as other governmental controls and trade restrictions;
- · other trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or foreign governments;
- · longer accounts receivable collection times;
- longer lead times for shipping;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- · workforce uncertainty in countries where labor unrest is common;
- language barriers for technical training;
- · reduced protection of intellectual property rights in some foreign countries, and related prevalence of generic alternatives to therapeutics;
- · foreign currency exchange rate fluctuations and currency controls;
- · differing foreign reimbursement landscapes;

- uncertain and potentially inadequate reimbursement of our products; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

If risks related to any of these uncertainties materializes, it could have a material adverse effect on our business.

Clinical trial and product liability lawsuits against us could divert our resources and could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of clinical trial and product liability exposure related to the testing of our product candidates in human clinical trials, and we will face an even greater risk if we commercially sell any products that we may develop. While we currently have no products that have been approved for commercial sale, the planned and future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies or others selling such products. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trials;
- · withdrawal of marketing approval, recall, restriction on the approval or a "black box" warning or contraindication for an approved drug;
- · withdrawal of clinical trial participants;
- significant costs to defend any related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- injury to our reputation and significant negative media attention;
- · reduced resources of our management to pursue our business strategy;
- · distraction of management's attention from our primary business; and
- the inability to commercialize any products that we may develop.

We currently hold \$10 million in product liability insurance coverage in the aggregate, with a per incident limit of \$10 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful clinical trial or product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

# **Risks Related to our Dependence on Third Parties**

We plan to rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, which may prevent or delay our ability to seek or obtain marketing approval for or commercialize our product candidates or otherwise harm our business. If we are not able to maintain these third party relationships or if these arrangements are terminated, we may have to alter our development and commercialization plans and our business could be adversely affected.

We plan to rely on third-party clinical research organizations, in addition to other third parties such as research collaboratives, clinical data management organizations, medical institutions and clinical investigators, to conduct our planned Phase 1/2 clinical trials of INZ-701 and any other clinical trials we conduct. We do not plan to independently conduct clinical trials of INZ-701 or any other product candidate that we may develop. These contract research organizations and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. These third-party arrangements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, our product development activities might be delayed.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities in Europe and other jurisdictions have similar requirements. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our contract research organizations or trial sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully develop and commercialize our product candidates. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned, and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit to the FDA. Any such delay or rejection could prevent us from commercializing our product candidates.

If any of our relationships with these third-parties terminate, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding additional contract research organizations, investigators and other third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new contract research organization commences work. As a result, delays can occur, which could materially impact our ability to meet our desired clinical development timelines. The COVID-19 pandemic and government measures taken in

response have also had a significant impact on many contract research organizations. Although we plan to carefully manage our relationships with our contract research organizations, investigators and other third parties, we may nonetheless encounter challenges or delays in the future, which could have a material and adverse impact on our business, financial condition and prospects.

Manufacturing biologic products is complex and subject to product loss for a variety of reasons. We contract with third parties for the manufacture of our product candidates for preclinical and clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of both drug substance and finished drug product for INZ-701 and any future product candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates receive marketing approval. We also rely on these third parties for packaging, labeling, sterilization, storage, distribution and other production logistics. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the potential failure to manufacture our product candidate or product according to our specifications;
- the potential failure to manufacture our product candidate or product according to our schedule or at all;
- · the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

We have only limited supply agreements in place with respect to our product candidates, and these arrangements do not extend to commercial supply. We obtain supplies of drug substance and finished drug product for INZ-701 on a purchase order basis. We do not have long term committed arrangements with respect to any of our product candidates or other materials. We are continuing the process of scaling up our manufacturing processes and capabilities with our third-party manufacturers to support future clinical trials. In addition, if we receive marketing approval for any of our product candidates, we will need to establish an agreement for commercial manufacture with a third party.

We or our third-party manufacturers may encounter shortages in the raw materials or active pharmaceutical ingredients necessary to produce our product candidates in the quantities needed for our clinical trials or, if our product candidates are approved, in sufficient quantities for commercialization or to meet an increase in demand, as a result of capacity constraints or delays or disruptions in the market for the raw materials or active pharmaceutical ingredients, including shortages caused by the purchase of such raw materials or active pharmaceutical ingredients by our competitors or others. The failure of us or our third-party manufacturers to obtain the raw materials or active pharmaceutical ingredients necessary to manufacture sufficient quantities of our product candidates, may have a material adverse effect on our business.

Our third-party manufacturers are subject to inspection and approval by regulatory authorities before we can commence the manufacture and sale of any of our product candidates, and thereafter subject to ongoing inspection from time to time. Third-party manufacturers may not be able to comply with current good manufacturing practices, or cGMP, regulations or similar regulatory requirements outside of the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in regulatory actions, such as the issuance of FDA Form 483 notices of observations, warning letters or sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Manufacturing biologic products, such as INZ-701, is complex, especially in large quantities. Biologic products must be made consistently and in compliance with a clearly defined manufacturing process. Accordingly, it is essential to be able to validate and control the manufacturing process to assure that it is reproducible. The manufacture of biologics is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the product process. We have not yet scaled up the manufacturing process for any of our product candidates for potential commercialization. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could harm our results of operations and cause potential reputational damage. Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If any of our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement or be unable to reach agreement with an alternative manufacturer. In addition, the COVID-19 pandemic may impact our ability to procure sufficient supplies for the development of our product candidates. The extent of this impact will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We may enter into collaborations with third parties for the development or commercialization of our product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates and our business could be adversely affected.

While we hold development and commercialization rights to our pipeline and programs, including INZ-701, on a worldwide basis, we could in the future enter into development, distribution, marketing or funding arrangements with third parties with respect to our existing or future product candidates. Our likely collaborators for any sales, marketing, co-promotion, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We are not currently party to any such arrangement. However, if we do enter into any such arrangements with any third parties in the future, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements.

Collaborations that we enter into may not be successful, and any success will depend heavily on the efforts and activities of such collaborators. Collaborations pose a number of risks, including the following:

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations:
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development of our product candidates or may elect not to continue or renew development programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition or business combination, that divert resources or create competing priorities;
- collaborators may not pursue commercialization of any product candidates that achieve marketing approval or may elect not to continue or renew commercialization programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition or business combination, that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- we may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product candidates on a discretionary basis;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product
  candidates and products if the collaborators believe that the competitive products are more likely to be successfully developed or can be
  commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product
  candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates; a
  collaborator may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or
  marketing of a product candidate or product;
- a collaborator may seek to renegotiate or terminate their relationship with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve marketing approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over intellectual property or proprietary rights, contract interpretation or the
  preferred course of development, might cause delays or terminations of the research, development or commercialization of product
  candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration,
  any of which would be time-consuming and expensive;

- collaborators may not properly obtain, maintain, enforce, defend or protect our intellectual property or proprietary rights or may use our proprietary information in such a way as to potentially lead to disputes or legal proceedings that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property or proprietary rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If any collaborations that we enter into do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this prospectus also apply to the activities of our collaborators.

Additionally, subject to its contractual obligations to us, if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

If we are not able to establish or maintain collaborations, we may have to alter our development and commercialization plans and our business could be adversely affected.

We may decide to collaborate with pharmaceutical or biotechnology companies for the development and potential commercialization of one or more of our product candidates. We face significant competition in seeking appropriate collaborators, and a number of more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been

combinations among large pharmaceutical and biotechnology companies that have resulted in a reduced number of potential future collaborators.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market.

We have agreements with Yale to supplement our internal research and development program. If Yale decides to discontinue or devote less resources to such research, our research efforts could be diminished.

Our set of arrangements with Yale provide us with access to certain of Yale's intellectual property and to Professor Demetrios Braddock's laboratory in a manner that we believe closely aligns our scientific interests with those of Yale. We are a party to both a license agreement and a sponsored research agreement with Yale. While Yale has contractual obligations to us, it is an independent entity and is not under our control or the control of our officers or directors. The license agreement is structured to provide Yale with license maintenance fees, development and regulatory milestone payments, royalties on net sales of products, and a portion of sublicense income that we receive. Upon the scheduled expiration of the Yale sponsored research agreement in December 2021, we may not be able to renew the research agreement or any renewal could be on terms less favorable to us than those contained in the existing agreement. Furthermore, either we or Yale may terminate the sponsored research agreement for convenience following a specified notice period. If Yale decides to not renew or to terminate the Yale research agreement or decides to devote fewer resources to such activities, our research efforts would be diminished, while our royalty obligations to Yale would continue unmodified.

Our license agreement with Yale also provides that so long as Professor Braddock remains meaningfully involved in our company by serving as a member of our scientific advisory board or has a similar advisory arrangement or has an active consulting arrangement with us, and so long as he is an employee or faculty member (including emeritus faculty member) at Yale, any future invention by Professor Braddock's laboratory in the license agreement's field is included in the licensed intellectual property. If Professor Braddock were to leave Yale or no longer be meaningfully involved with us, we would no longer have access to future inventions in the license agreement's field from Yale.

Additionally, the license granted under the license agreement terminates after a specified period following a qualifying change of control, unless we elect or our successor or assignee elects to continue the agreement. If the license is terminated after such a change of control, royalty payments would continue to be paid on certain licensed products.

Any acquisitions or in-license transactions that we complete could disrupt our business, cause dilution to our stockholders or reduce our financial resources.

We may enter into transactions to in-license or acquire other businesses, intellectual property, technologies, product candidates or products. If we determine to pursue a particular transaction, we may not be able to complete the transaction on favorable terms, or at all. Any in-licenses or acquisitions we complete may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an in-license or acquisition or issue our common stock or other equity securities to the stockholders of the target company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities that are not

covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and nondisruptive manner. In-license and acquisition transactions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. For example, we completed an acquisition of specified patent rights and other specified assets related to ENPP1 from Alexion Pharmaceuticals, Inc. in July 2020. We cannot predict the number, timing or size of additional future in-licenses or acquisitions or the effect that any such transactions might have on our operating results.

#### **Risks Related to our Intellectual Property**

If we are unable to obtain, maintain and enforce patent protection for our technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.

Our success depends in large part on our ability to obtain, maintain and enforce protection of the intellectual property we may own solely and jointly with others or may license from others, particularly patents, in the United States and other countries with respect to any proprietary technology and product candidates we develop. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our technologies and product candidates that are important to our business and by in-licensing intellectual property related to such technologies and product candidates. If we are unable to obtain, maintain or enforce patent protection with respect to any proprietary technology or product candidate, our business, financial condition, results of operations and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, defend or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain, enforce and defend the patents, covering technology that we license from third parties. Therefore, these in-licensed patents and applications may not be prepared, filed, prosecuted, maintained, defended and enforced in a manner consistent with the best interests of our business.

The patent position of pharmaceutical and biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the scope of patent protection outside of the United States is uncertain and laws of foreign countries may not protect our rights to the same extent as the laws of the United States or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. With respect to both owned and in-licensed patent rights, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not published at all. Therefore, neither we nor our licensors can know with certainty whether either we or our licensors were the first to make the inventions claimed in the patents and patent applications we own or in-license now or in the future, or that either we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Moreover, our owned or in-licensed pending and future patent applications may not result in patents being issued which protect our technology and product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the

Moreover, we or our licensors may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, revocation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Our owned or licensed patent estate includes patent applications, many of which are at an early stage of prosecution. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our owned or in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from our management and employees, even if the eventual outcome is favorable to us. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Furthermore, our competitors may be able to circumvent our owned or in-licensed patents by developing similar or alternative technologies or products in a non-infringing manner. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing technology and products similar or identical to any of our technology and product candidates.

# Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales or an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and product candidates, which could harm our business, financial condition, results of operations and prospects significantly.

Additionally, if we fail to comply with our obligations under any license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology or impede, or delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements.

# Our product candidates may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full biologics license application, or BLA, for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any product candidate of ours that may be approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

#### If we do not obtain patent term extension for any product candidates we may develop, our business may be materially harmed.

In the United States, the term of a patent that covers an FDA-approved drug may, in certain cases, be eligible for a patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, as compensation for the loss of a patent term during the FDA regulatory review

process. The Hatch-Waxman Act permits a patent term extension of up to five years, but patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and certain other non-United States jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those product candidates, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially harmed.

Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy-Smith America Invents Act, or the Leahy-Smith Act, could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the maintenance, enforcement or defense of our owned or in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future.

The federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights". March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the

patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. We collaborate with a number of universities with respect to certain of our research and development. While it is our policy to avoid engaging our university collaborators in projects in which there is a risk that federal funds may be commingled, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or in-license technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

Although we or our licensors are not currently involved in any litigation, we may become involved in lawsuits to protect or enforce our patent or other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors and other third parties may infringe, misappropriate or otherwise violate our or our licensor's issued patents or other intellectual property. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's product. To counter infringement or misappropriation, we or our licensors may need to file infringement, misappropriation or other intellectual property related claims, which can be expensive and time-consuming and can distract our management and scientific personnel. There can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Any claims we assert against perceived infringers could provoke such parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property.

In addition, in a patent infringement proceeding, such parties could counterclaim that the patents we or our licensors have asserted are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions, such as opposition proceedings. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Similarly, if we or our licensors assert trademark infringement claims, a court may determine that the marks we or our licensors have asserted are invalid or unenforceable, or that the party against whom we or our licensors have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks, which could materially harm our business and negatively affect our position in the marketplace.

An adverse result in any such proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly, could put any of our owned or in-licensed patent applications at risk of not yielding an issued patent, and could limit our or our licensor's ability to assert those patents against those parties or other competitors and curtail or preclude our ability to exclude third parties from developing and commercializing similar or competitive products. A court may also refuse to stop the third party from using the technology at issue in a proceeding on the grounds that our owned or in-licensed patents do not cover such technology. Even if we establish infringement, a court may not order the third party to stop using the technology at issue and instead award only monetary damages to us, which may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information or trade secrets could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it

could have a material adverse effect on the price of our common stock. Any of the foregoing could allow such third parties to develop and commercialize competing technologies and products and have a material adverse impact on our business, financial condition, results of operations and prospects.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. There is considerable patent and other intellectual property litigation in the pharmaceutical and biotechnology industries. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and product candidates, including interference proceedings, post grant review, *inter partes* review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions, such as opposition proceedings before the European Patent Office. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the pharmaceutical and biotechnology industries expand and more patents are issued, the risk increases that our technologies or product candidates that we may identify may be subject to claims of infringement of the patent rights of third parties.

The legal threshold for initiating litigation or contested proceedings is low, so even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if and as our product candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of merit. Even if we diligently search third-party patents for potential infringement by our products or product candidates, we may not successfully find patents our products or product candidates may infringe. We may not be aware of all such intellectual property rights potentially relating to our technology and product candidates and their uses, or we may incorrectly conclude that third party intellectual property is invalid or that our activities and product candidates do not infringe such intellectual property. Thus, we do not know

with certainty that our technology and product candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate any third party's intellectual property.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations or methods, such as methods of manufacture or methods for treatment, related to the discovery, use or manufacture of the product candidates that we may identify or related to our technologies. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that the product candidates that we may identify may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, as noted above, there may be existing patents that we are not aware of or that we have incorrectly concluded are invalid or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover, for example, the manufacturing process of the product candidates that we may identify, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize the product candidates that we may identify. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may choose to take a license or, if we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, we could also be required to obtain a license from such third party to continue developing, manufacturing and marketing our technology and product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right and could be forced to indemnify our customers or collaborators. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. In addition, we may be forced to redesign our product candidates, seek new regulatory approvals and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations and prospects.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

While we seek to protect the trademarks and trade names we use in the United States and in other countries, we may be unsuccessful in obtaining registrations or otherwise protecting these trademarks and trade names, which we need to build name recognition in our markets of interest and among potential partners or customers. We rely on both registration and common law protection for our trademarks. Our registered or unregistered trademarks or trade names may be challenged, infringed, diluted or declared generic, or determined to be infringing on other marks. At times, competitors may adopt trademarks and trade names similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there

could be potential trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks. If we are unable to protect our rights to trademarks and trade names, we may be prevented from using such marks and names unless we enter into appropriate royalty, license or coexistence agreements, which may not be available or may not be available on commercially reasonable terms.

During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Effective trademark protection may not be available or may not be sought in every country in which our products are made available. Any name we propose to use for our products in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed product names, we may be required to expend significant additional resources in an effort to identify a usable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Intellectual property litigation or other legal proceedings relating to intellectual property could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could compromise our ability to compete in the marketplace.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance, renewal and annuity fees and various other government fees on any issued patent and pending patent application must be paid to the USPTO and foreign patent agencies in several stages or annually over the lifetime of our patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency. With respect to our patents, we rely on an annuity service, outside firms and outside counsel to remind us of the due dates and to make payment after we instruct them to do so. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in

abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical products or technology. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, it would have a material adverse effect on our business, financial condition, results of operations and prospects.

If we fail to comply with our obligations in our current and future intellectual property licenses and funding arrangements with third parties, or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.

We are party to a license agreement with Yale that provides us with the foundational intellectual property rights for our lead product candidate, INZ-701. This license agreement imposes diligence, development and commercialization timelines, and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with such obligations, including achieving specified milestone events, Yale may have the right to terminate the license agreement or require us to grant them certain rights, in which event we might not be able to develop, manufacture or market any product that is covered by the intellectual property we in-license from them and may face other penalties. For example, Yale would have the right to terminate the license agreement if we do not file an IND for INZ-701 with the FDA on or before December 31, 2020. Any such occurrence could materially adversely affect the value of any product candidate being developed under any such agreement.

For a variety of purposes, we will likely enter into additional licensing and funding arrangement with third parties that may impose similar obligations on us. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, which would have a material adverse effect on our business, financial condition, results of operations and prospects. While we still face all of the risks described herein with respect to those agreements, we cannot prevent third parties from also accessing those technologies. In addition, our licenses may place restrictions on our future business opportunities.

In addition to the above risks, intellectual property rights that we license in the future may include sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize our product candidates may be materially harmed.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- · our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected technology and product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Further, licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on our licensors to control the prosecution, maintenance and enforcement of all of our licensed and sublicensed intellectual property, and even when we do have such rights, we may require the cooperation of our licensors and upstream licensors, which may not be forthcoming. For example, under the license agreement with Yale, any patent applications and issued patents under the agreement remain the property of Yale, and Yale has the right to choose patent counsel. Licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. Our business could be adversely affected if we or our licensors are unable to prosecute, maintain and enforce our licensed and sublicensed intellectual property effectively.

Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents and patent applications we in-license. If other third parties have ownership rights to patents or patent applications we in-license, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products and technologies identical to ours. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

# We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, and even where such protection is nominally available, judicial and governmental enforcement of such intellectual property rights may be lacking. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing

countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, certain jurisdictions do not protect to the same extent or at all inventions that constitute new methods of treatment.

Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

# We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims by third parties asserting that our employees, consultants or contractors have wrongfully used or disclosed confidential information of third parties, or we have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, consultants and contractors were previously employed at universities or other pharmaceutical or biotechnology companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our intellectual property assignment agreements with them may not be self-

executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial conditions, results of operations and prospects.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could have a material adverse effect on our competitive business position and prospects. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products, which license may not be available on commercially reasonable terms, or at all, or such license may be non-exclusive. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and employees.

# If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants, but we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside of the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

# Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own;
- we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent applications that we license or may own in the future;
- we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or in-licensed intellectual property rights;

- it is possible that our owned or in-licensed pending patent applications or those we may own or in-license in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we cannot ensure that any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates;
- we cannot ensure that any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates or will provide us with any competitive advantages;
- the U.S. Supreme Court, other federal courts, Congress, the USPTO or similar foreign authorities may change the standards of patentability and any such changes could narrow or invalidate, or change the scope of, our or our licensors' patents;
- patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time;
- we cannot ensure that our commercial activities or product candidates will not infringe upon the patents of others;
- we cannot ensure that we will be able to successfully commercialize our product candidates on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

# Risks Related to Regulatory Approval and Other Legal Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process of the FDA, the EMA and comparable foreign authorities is expensive, time-consuming, and uncertain and may prevent us from obtaining approvals for the commercialization of any product candidates we develop. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, product candidates we develop, and our ability to generate revenue will be materially impaired.

Any product candidates we develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling,

storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States, the EMA and other regulatory authorities in the European Union and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the biologic product candidate's safety, purity, and potency. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities, or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA, the EMA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical, or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired.

Failure to obtain marketing approval in foreign jurisdictions would prevent any product candidates we develop from being marketed in such jurisdictions, which, in turn, would materially impair our ability to generate revenue.

In order to market and sell any product candidates we develop in the European Union and many other foreign jurisdictions, we or our collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. The failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any jurisdiction, which would materially impair our ability to generate revenue.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. Following protracted negotiations, the United Kingdom left the

European Union on January 31, 2020. Under the withdrawal agreement, there is a transitional period until December 31, 2020 (extendable up to two years). Discussions between the United Kingdom and the European Union have so far mainly focused on finalizing withdrawal issues and transition agreements but have been extremely difficult to date. To date, only an outline of a trade agreement has been reached. Much remains open but the Prime Minister has indicated that the United Kingdom will not seek to extend the transitional period beyond the end of 2020. If no trade agreement has been reached before the end of the transitional period, there may be significant market and economic disruption. The Prime Minister has also indicated that the UK will not accept high regulatory alignment with the European Union.

Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime that applies to products and the approval of product candidates in the United Kingdom. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business.

Fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process, and does not assure FDA approval of our product candidates.

If a product candidate is intended for the treatment of a serious or life threatening condition and the product candidate demonstrates the potential to address unmet medical need for this condition, the sponsor may apply for FDA fast track designation. However, a fast track designation does not ensure that the product candidate will receive marketing approval or that approval will be granted within any particular timeframe. As a result, while we may seek and receive fast track designation for our product candidates, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

A breakthrough therapy designation by the FDA for our product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive breakthrough therapy designation, the receipt of such designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Priority review designation by the FDA may not lead to a faster regulatory review or approval process and, in any event, does not assure FDA approval of our product candidates.

If the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for certain of our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily mean a faster regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or thereafter.

Accelerated approval by the FDA, even if granted for our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a biomarker efficacy endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. The FDA or other applicable regulatory agency makes the determination regarding whether a biomarker efficacy endpoint is reasonably likely to predict long-term clinical benefit.

We may seek approval of our product candidates using the FDA's accelerated approval pathway. Prior to seeking such accelerated approval, we will seek feedback from the FDA and otherwise evaluate our ability to seek and receive such accelerated approval. As a condition of approval, the FDA may require that a sponsor of a drug or biologic product candidate receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence and we may be required to evaluate different or additional endpoints in these post-marketing confirmatory trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

There can be no assurance that the FDA will agree with any biomarker efficacy endpoints that we propose, or that we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that, after feedback from FDA, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation, there can be no assurance that such submission or application will be accepted or that any expedited review or approval will be granted on a timely basis, or at all.

Moreover, as noted above, for drugs granted accelerated approval, the FDA typically requires post-marketing confirmatory trials to evaluate the anticipated effect on IMM or other clinical benefit. These confirmatory trials must be completed with due diligence. We may be required to evaluate additional or different clinical endpoints in these post-marketing confirmatory trials. These confirmatory trials may require enrollment of more patients than we currently anticipate and will result in additional costs, which may be greater than the estimated costs we currently anticipate. The FDA may withdraw approval of a product candidate approved under the accelerated approval pathway if, for example, the trial required to verify the predicted clinical benefit of our product candidate fails to verify such benefit or does not demonstrate sufficient clinical benefit to justify the risks associated with the drug. The FDA may also withdraw approval if other evidence demonstrates that our product

candidate is not shown to be safe or effective under the conditions of use, we fail to conduct any required post approval trial of our product candidate with due diligence or we disseminate false or misleading promotional materials relating to our product candidate. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidates, or withdrawal of a product candidate, would result in a longer time period for commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate FDA approval.

We may not be able to obtain or maintain orphan drug exclusivity for INZ-701 or any other product candidates we develop for one or more indications, and even if we do, that exclusivity may not prevent the FDA or the EMA from approving other competing products.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. A similar regulatory scheme governs approval of orphan products by the EMA in the European Union. Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same product for the same therapeutic indication for that time period. The applicable period is seven years in the United States and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for orphan drug designation, in particular if the product is sufficiently profitable so that market exclusivity is no longer justified.

The FDA and the EMA have granted orphan drug designation to INZ-701 for the treatment of ENPP1 deficiency. We have applied for orphan drug designation from the FDA for INZ-701 for ABCC6 deficiency, but our initial application was not granted. Although we have received an extension of time to submit an amendment to our application, there is no guarantee that any amendment we submit will result in the FDA granting orphan drug designation for INZ-701 for ABCC6 deficiency.

In order for the FDA to grant orphan drug exclusivity to one of our products, the agency must find that the product is indicated for the treatment of a condition or disease with a patient population of fewer than 200,000 individuals annually in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the biologic for the disease or condition will be recovered from sales of the product in the United States. In order for the EMA to grant orphan drug designation, we must establish that the product is intended for the diagnosis, prevention or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union when the application is made, or (2) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment. For either of these conditions, we must demonstrate that there exists no satisfactory method of diagnosis, prevention, or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the drug will be of significant benefit to those affected by that condition

The FDA or the EMA may conclude that the condition or disease for which we seek orphan drug exclusivity does not meet the applicable standard. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may

also be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition.

On August 3, 2017, the Congress passed the FDA Reauthorization Act of 2017, or the FDARA. FDARA, among other things, codified the FDA's pre-existing regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The new legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

We may seek a Rare Pediatric Disease Designation, or RPDD, for one or more of our product candidates. However, a BLA for one or more of our product candidates may not meet the eligibility criteria for a priority review voucher upon approval.

With enactment of the Food and Drug Administration Safety and Innovation Act in 2012, Congress authorized the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications that meet the criteria specified in the law. This provision is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application.

For the purposes of this program, a "rare pediatric disease" is a (a) serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and (b) rare disease or conditions within the meaning of the Orphan Drug Act. The FDA may determine that a BLA for one or more of our product candidates does not meet the eligibility criteria for a priority review voucher upon approval. Moreover, even if one or more of our product candidates does satisfy those criteria, the product will need to be designated as a drug for a rare pediatric disease before September 30, 2020, and licensed before September 30, 2022, in order to be granted a rare disease priority review voucher.

Even if we, or any collaborators we may have, obtain marketing approvals for any product candidates we develop, the terms of approvals and ongoing regulation of our products could require the substantial expenditure of resources and may limit how we, or they, manufacture and market our products, which could materially impair our ability to generate revenue.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising, and promotional activities for such product, will be subject to continual requirements of and review by the FDA, the EMA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or

contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

Accordingly, assuming we, or any collaborators we may have, receive marketing approval for one or more product candidates we develop, we, and such collaborators, and our and their contract manufacturers will continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance, and quality control. If we and such collaborators are not able to comply with post-approval regulatory requirements, we and such collaborators could have the marketing approvals for our products withdrawn by regulatory authorities and our, or such collaborators', ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our business, operating results, financial condition, and prospects.

Any product candidate for which we obtain marketing approval could be subject to restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

The FDA and other regulatory agencies closely regulate the post-approval marketing and promotion of products to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other regulatory agencies impose stringent restrictions on manufacturers' communications regarding off-label use, and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing by the FDA and other federal and state enforcement agencies, including the Department of Justice. Violation of the Federal Food, Product, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws.

In addition, later discovery of previously unknown problems with our products, manufacturers, or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on the distribution or use of a product;
- requirements to conduct post-marketing clinical trials;
- · receipt of warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution, or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- · suspension of any ongoing clinical trials;

- refusal to permit the import or export of our products;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any product candidates we develop and adversely affect our business, financial condition, results of operations, and prospects.

Regulatory reform may limit the FDA's ability to engage in oversight and implementation activities in the normal course, and that could negatively impact our business.

The current presidential administration has taken several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. On January 30, 2017, the president issued an executive order, applicable to all executive agencies, including the FDA, that requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This executive order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the executive order requires agencies to identify regulations to offset any incremental cost of a new regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within the Office of Management and on February 2, 2017, the current presidential administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Our relationships with healthcare providers, physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings.

Healthcare providers, physicians, and third-party payors play a primary role in the recommendation and prescription of any product candidates that we develop for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented,

to the federal government, claims for payment or approval from Medicare, Medicaid, or other government payors that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at \$11,181 to \$22,363 per false claim;

- the federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a
  Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of
  a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception
  applies;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as further amended by the Health Information Technology for Economic and Clinical Health Act, which imposes certain requirements, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses, and health care providers;
- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services;
- the Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the federal transparency requirements under the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics, and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous state laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing
  arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private
  insurers, and certain state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance
  guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to
  report information related to payments to physicians and other health care providers or marketing expenditures; and
- similar healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain protected information, such as the General Data Protection Regulation, or the GDPR, which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the European Union (including health data).

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of

such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations, and prospects.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of European Union Member States, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization, and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs. Liabilities they incur pursuant to these laws could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Current and future legislation may increase the difficulty and cost for us and any collaborators to obtain marketing approval and commercialize our product candidates and affect the prices we, or they, may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our drug candidates, restrict or regulate post-approval activities, impact pricing and reimbursement and affect our ability, or the ability of any collaborators, to profitably sell or commercialize any product candidate for which we, or they, obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

Among the provisions of the ACA of potential importance to our business, including, without limitation, our ability to commercialize our products and the prices we may obtain for any of our product candidates that are approved for sale, are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription products and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new
  government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient products to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting "transfers of value" made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members;
- · a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in April 2013 and, due to subsequent legislative amendments, will stay in effect through 2029 unless additional Congressional action is taken. The CARES Act, which was signed into law on March 27, 2020, and designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020, through December 31, 2020, and extended the sequester by one year, through 2030, in order to offset the added expense of the 2020 cancellation. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Further, there have been several recent U.S. congressional inquiries and proposed state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of products under Medicare and reform government program reimbursement methodologies for products.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the current presidential administration to repeal or replace certain aspects of the ACA. Since January 2017, the president has signed two executive orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The TCJA includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare plans, commonly referred to as the "donut hole." In July 2018, the Centers for Medicare and Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment.

The current presidential administration has also taken executive actions to undermine or delay implementation of the ACA. Since January 2017, the president has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than \$12 billion in ACA risk corridor payments to third-party payors who argued such payments were owed to them, which the U.S. Supreme Court is reviewing during its current term. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

In addition, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. The current presidential administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the same judge issued an order staying the judgment pending appeal. The current presidential administration recently represented to the Court of Appeals considering this judgment that it does not

oppose the lower court's ruling. On July 10, 2019, the Court of Appeals for the Fifth Circuit heard oral argument in this case. On December 18, 2019, that court affirmed the lower court's ruling that the individual mandate portion of the ACA is unconstitutional and it remanded the case to the district court for reconsideration of the severability question and additional analysis of the provisions of the ACA. On January 21, 2020, the U.S. Supreme Court declined to review this decision on an expedited basis. On March 3, 2020, the U.S. Supreme Court agreed to hear this case. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

We will continue to evaluate the effect that the ACA and its possible repeal and replacement could have on our business. It is possible that repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. While the timing and scope of any potential future legislation to repeal and replace ACA provisions is uncertain in many respects, it is also possible that some of the ACA provisions that generally are not favorable for the research-based pharmaceutical industry could also be repealed along with ACA coverage expansion provisions. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates.

Further, there have been several recent U.S. congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of products under Medicare and reform government program reimbursement methodologies for products. At the federal level, the current presidential administration's budget proposal contains further price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain products under Medicare Part B, to allow some states to negotiate product prices under Medicaid, and to eliminate cost sharing for generic products for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the current presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control product costs.

Specifically, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of products under Medicare and reform government program reimbursement methodologies for products. At the federal level, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control product costs. For example, on May 11, 2018, the current administration issued a plan to lower product prices. Under this blueprint for action, the current administration indicated that the Department of Health and Human Services will take steps to end the gaming of regulatory and patent processes by product makers to unfairly protect monopolies, advance biosimilars and generics to boost price competition, evaluate the inclusion of prices in makers' ads to enhance price competition, speed access to and lower the cost of new products by clarifying policies for sharing information between insurers and makers, avoid excessive pricing by relying more on value-based pricing by expanding outcome-based payments in Medicare and Medicaid, work to give Medicare Part D plan sponsors more negotiation power with makers, examine which Medicare Part B prices could be negotiated by Medicare Part D plans, improve the design of the Medicare Part B Competitive Acquisition Program, update Medicare's drug-pricing dashboard to increase transparency, prohibit Medicare Part D contracts that include "gag rules" that prevent pharmacists from informing patients when they could pay less out-of-pocket by not using insurance, and require that Medicare Part D plan members be provided with an annual statement of plan payments, out-of-pocket spending, and price increases.

In addition, on December 23, 2019, the current presidential administration published a proposed rulemaking that, if finalized, would allow states or certain other non-federal government entities to submit

importation program proposals to the FDA for review and approval. Applicants would be required to demonstrate that their importation plans pose no additional risk to public health and safety and will result in significant cost savings for consumers. At the same time, the FDA issued draft guidance that would allow manufacturers to import their own FDA-approved products that are authorized for sale in other countries (multi-market approved products).

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription product and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved.

In markets outside of the United States and the European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the European Union or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the

GDPR, which took effect across all member states of the European Economic Area, or EEA, in May 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR increases our obligations with respect to clinical trials conducted in the EEA by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators. In addition, the GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States and, as a result, increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information and/or impose substantial fines for violations of the GDPR, which can be up to 4% of global revenues or 20 million Euros, whichever is greater, and it also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

Similar actions are either in place or under way in the United States. There are a broad variety of data protection laws that are applicable to our activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered at both the state and federal levels. For example, the California Consumer Privacy Act, which went into effect on January 1, 2020, is creating similar risks and obligations as those created by the GDPR, though the Act does exempt certain information collected as part of a clinical trial subject to the Federal Policy for the Protection of Human Subjects (the Common Rule). Many other states are considering similar legislation. A broad range of legislative measures also have been introduced at the federal level. Accordingly, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding privacy and security of personal information could expose us to fines and penalties under such laws. There also is the threat of consumer class actions related to these laws and the overall protection of personal data. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business.

Given the breadth and depth of changes in data protection obligations, preparing for and complying with these requirements is rigorous and time intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data collected in the European Union. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations.

We cannot assure you that our third-party service providers with access to our or our customers', suppliers', trial patients' and employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn

adversely affect our business, results of operations and financial condition. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, storage and transmission of such information.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain product candidates outside of the United States and require us to develop and implement costly compliance programs.

We are subject to numerous laws and regulations in each jurisdiction outside the United States in which we operate. The creation, implementation and maintenance of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The Foreign Corrupt Practices Act, or the FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expansion outside of the United States has required, and will continue to require, us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs. The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Governments outside of the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that

compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

If we or any third-party manufacturer we engage now or in the future fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs or liabilities that could have a material adverse effect on our business.

We and third-party manufacturers we engage now are, and any third-party manufacturer we may engage in the future will be, subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain general liability insurance as well as workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Further, with respect to the operations of our current and any future third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products. In addition, our supply chain may be adversely impacted if any of our third-party contract manufacturers become subject to injunctions or other sanctions as a result of their non-compliance with environmental, health and safety laws and regulations.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new products to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory

agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

## Risks Related to Employee Matters and Managing Growth

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development, clinical, financial, operational and other business expertise of our executive officers, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. Recruiting and retaining qualified scientific, clinical, manufacturing, accounting, legal and sales and marketing personnel will also be critical to our success.

The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain marketing approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Our success as a public company also depends on implementing and maintaining internal controls and the accuracy and timeliness of our financial reporting. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, clinical, regulatory affairs, manufacturing and quality control and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and regulatory review process for INZ-701 and any other
  product candidate we develop, while complying with our contractual obligations to contractors and other third parties; and
- · improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to advance development of and, if approved, commercialize INZ-701 and any other product candidate we develop will depend, in part, on our ability to effectively manage any future growth. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. If we do not effectively manage the expansion of our operations, we could experience weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The expansion of our operations also could lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Many of the pharmaceutical and biotechnology companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can develop product candidates and operate our business will be limited.

Our internal computer systems, or those of our collaborators, vendors, suppliers, contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Our internal computer systems and those of any collaborators, vendors, suppliers, contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such systems are also vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third-party vendors and/or business partners, or from cyber-attacks by malicious third parties. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, unauthorized access to or deletion of files, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Cyber-attacks also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient.

If we experience any material system failure, accident, cyber-attack or security that causes interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

Our employees, independent contractors, including principal investigators, consultants and vendors and any third parties we may engage in connection with research, development, regulatory, manufacturing, quality assurance and other pharmaceutical functions and commercialization may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, including principal investigators, consultants and vendors and any other third parties we engage. Misconduct by these partners could include intentional, reckless or negligent conduct or unauthorized activities that include failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities,

provide complete and accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards, comply with federal and state data privacy, security, fraud and other healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report complete financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. This could include violations of HIPAA, other U.S. federal and state law, and requirements of non-U.S. jurisdictions, including the European Union Data Protection Directive. We are also exposed to risks in connection with any insider trading violations by employees or others affiliated with us. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards, regulations, guidance or codes of conduct. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and

#### **Risks Related to our Common Stock**

After this offering, our executive officers, directors and principal stockholders, if they choose to act together, will continue to have the ability to control or significantly influence all matters submitted to stockholders for approval.

Upon the closing of this offering, our executive officers and directors and our stockholders who owned more than 5% of our outstanding common stock before this offering will, in the aggregate, beneficially own shares representing approximately 65% of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

This concentration of ownership control may:

- delay, defer or prevent a change in control;
- · entrench our management and board of directors; or
- · delay or prevent a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

The foregoing discussion does not reflect any potential purchases by our existing principal stockholders or their affiliated entities of shares of our common stock in this offering.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current directors and members of management.

Provisions in our certificate of incorporation and our bylaws that will become effective upon the closing of this offering may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these

provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that
  would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved
  by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws that will become effective upon the closing of this offering.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

## If you purchase shares of common stock in this offering, you will suffer immediate dilution of your investment.

The initial public offering price of our common stock will be substantially higher than the pro forma as adjusted net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our pro forma as adjusted net tangible book value per share after this offering. To the extent outstanding options are exercised, you will incur further dilution. Based on an assumed initial public offering price of \$15.00 per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, you will experience immediate dilution of \$8.19 per share, representing the difference between our pro forma as adjusted net tangible book value per share, after giving effect to this offering, and the assumed initial public offering price.

## An active trading market for our common stock may not develop.

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock will be determined through negotiations with the underwriters. Although we have

applied to have our common stock approved for listing on the Nasdaq Global Market, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop, it may be difficult for you to sell shares you purchase in this offering without depressing the market price for the shares or at all.

If securities analysts do not publish or cease publishing research or reports or publish misleading, inaccurate or unfavorable research about our business or if they publish negative evaluations of our stock, the price and trading volume of our stock could decline.

The trading market for our common stock will rely, in part, on the research and reports that industry or financial analysts publish about us or our business. We do not currently have, and may never obtain, research coverage by industry or financial analysts. If no, or few, analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock or publish inaccurate or unfavorable research about our business, or provides more favorable relative recommendations about our competitors, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price and trading volume to decline.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

Our stock price is likely to be volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the initial public offering price. The market price for our common stock may be influenced by many factors, including:

- results of or developments in preclinical studies and clinical trials of our product candidates or those of our competitors or potential collaborators;
- our success in commercializing our product candidates, if and when approved;
- the success of competitive products or technologies;
- regulatory actions with respect to our product candidates;
- regulatory or legal developments in the United States and other countries;
- changes in physician, hospital or healthcare provider practices;
- developments or disputes concerning patent applications, issued patents or other intellectual property or proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license products, product candidates or technologies, the costs of commercializing any such products and the costs of development of any such product candidates or technologies;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;

- variations in our financial results or the financial results of companies that are perceived to be similar to us;
- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- sales of common stock by us, our executive officers, directors or principal stockholders, or others;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our offerings or business practices. Such litigation may also cause us to incur other substantial costs to defend such claims and divert management's attention and resources. Furthermore, negative public announcements of the results of hearings, motions or other interim proceedings or developments could have a negative effect on the market price of our common stock.

## We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that losses value.

## Participation in this offering by our existing principal stockholders or their affiliated entities may reduce the public float for our common stock.

To the extent our existing principal stockholders or their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our shares, meaning the number of shares of our common stock that are not held by officers, directors and principal stockholders. A reduction in the public float could reduce the number of shares that are available to be traded at any given time, thereby adversely impacting the liquidity of our common stock and depressing the price at which you may be able to sell shares of common stock purchased in this offering.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have 20,314,851 shares of common stock outstanding based on the number of shares outstanding as of July 17, 2020. This includes the shares that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates or

existing principal stockholders or their affiliated entities. The remaining shares are currently restricted as a result of securities laws or lock-up agreements (which may be waived, with or without notice, by BofA Securities, Inc., Cowen and Company, LLC and Piper Sandler & Co.) but will become eligible to be sold at various times beginning 180 days after this offering, unless held by one of our affiliates, in which case the resale of those securities will be subject to volume limitations under Rule 144 of the Securities Act of 1933, as amended, or Rule 144. Moreover, beginning 180 days after the completion of this offering, holders of an aggregate of 13,953,850 shares of our common stock will have rights under our investor rights agreement, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. In addition, holders of an aggregate of 1,925,429 shares of our common stock, including shares of our common stock issued upon conversion of our convertible preferred stock and shares of our common stock issued or issuable upon exercise of options, will have rights under our registration rights agreement, subject to specified conditions, to require us to file registration statements covering their shares and to include their shares in registration statements that we may file for ourselves or for other stockholders. We also intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Underwriting" section of this prospectus.

We are an "emerging growth company" and a "smaller reporting company," and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company," or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We may remain an EGC until the last day of the fiscal year in which the fifth anniversary of the closing of this offering occurs, although if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of any June 30 before that time or if we have annual gross revenues of \$1.07 billion or more in any fiscal year, we would cease to be an EGC as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than \$1 billion of non-convertible debt over a three-year period. For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. These exemptions include:

- being permitted to provide only two years of audited financial statements in this prospectus, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding
  mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial
  statements;
- · reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any
  golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting obligations in this prospectus. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an EGC.

Further, even after we no longer qualify as an EGC, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements allowed for an EGC, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. In addition, if we are a smaller reporting company with less than \$100 million in annual revenue, we would not be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404.

We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act permits an EGC to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to use the extended transition period for complying with new or revised accounting standards and will do so until such time that we either (1) irrevocably elect to "opt out" of such extended transition period or (2) no longer qualify as an EGC. As a result of this election, our consolidated financial statements may not be comparable to companies that comply with public company Financial Accounting Standards Board standards' effective dates.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an EGC or a smaller reporting company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs, particularly as we hire additional financial and accounting employees to meet public company internal control and financial reporting requirements, and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We are evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an EGC or a smaller reporting company with less than \$100 million in revenue, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, including through hiring additional financial and accounting personnel, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement

process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Our certificate of incorporation that will become effective upon the closing of this offering designates the state courts in the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against the company and our directors, officers and employees.

Our certificate of incorporation that will become effective upon the closing of this offering provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) will, to the fullest extent permitted by law, be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or stockholders to our company or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware or (4) any action asserting a claim arising pursuant to any provision of our certificate of incorporation or bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine. These choice of forum provisions will not apply to claims arising under the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, or any other claim for which federal courts have exclusive jurisdiction. Furthermore, our certificate of incorporation that will become effective upon the closing of this offering provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any claims arising under the Securities Act of 1933, as amended.

These exclusive forum provisions may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees. If a court were to find such provisions contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect our business, financial condition and operating results.

### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this prospectus, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "project," "should," "target," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this prospectus include, among other things, statements about:

- the timing of our planned IND and CTA submissions for INZ-701;
- the timing and conduct of our planned Phase 1/2 clinical trials of INZ-701 for ENPP1 and ABCC6 deficiencies, including statements
  regarding the timing of initiation and completion of the clinical trials and the period during which the results of the clinical trials will
  become available;
- · the timing and conduct of our planned later stage clinical trials of INZ-701 for patients with ENPP1 and ABCC6 deficiencies;
- our plans to conduct research and preclinical testing of INZ-701 for additional indications;
- our plans to conduct research and preclinical testing of other product candidates;
- the timing of, and our ability to obtain and maintain, marketing approvals of INZ-701, and the ability of INZ-701 and our other product candidates to meet existing or future regulatory standards;
- our expectations regarding our ability to fund our operating expenses and capital expenditure requirements with our cash, cash equivalents
  and short-term investments and net proceeds of this offering;
- · the potential advantages of our product candidates;
- the rate and degree of market acceptance and clinical utility of our product candidates;
- our estimates regarding the potential market opportunity for our product candidates;
- our commercialization and manufacturing capabilities and strategy;
- our intellectual property position;
- the impact of COVID-19 on our business and operations;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- our expectations related to the use of net proceeds from this offering;
- · our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the impact of government laws and regulations;

- our competitive position; and
- · our expectations regarding the time during which we will be an emerging growth company under the JOBS Act.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this prospectus, particularly in the "Risk Factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments we may make or enter into.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this prospectus are made as of the date of this prospectus, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

This prospectus includes statistical and other industry and market data that we obtained from industry publications, research, surveys and studies conducted by third parties as well as our own estimates of potential market opportunities based on our analysis of these data, research, surveys and studies. All of the market data used in this prospectus involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our estimates of the potential market opportunities for our product candidates include a number of key assumptions based on our industry knowledge, industry publications and third-party research, surveys and studies, which may be based on a small sample size and fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions.

## USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of 5,000,000 shares of our common stock in this offering will be approximately \$66.5 million, assuming an initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional shares of our common stock in full, we estimate that the net proceeds from this offering will be approximately \$76.9 million.

A \$1.00 increase (decrease) in the assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by approximately \$4.7 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by approximately \$14.0 million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We estimate that we had cash, cash equivalents and short-term investments of approximately \$63.9 million as of June 30, 2020. This estimate was prepared by management in good faith based upon internal reporting, is preliminary, and unaudited, and may be revised as a result of management's further review of our results as of and for the three months ended June 30, 2020. We have not yet completed our normal interim review procedures as of and for the period ended June 30, 2020.

We currently estimate that we will use the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, as follows:

- approximately \$45 million for the completion of our IND and CTA submissions and conduct of our Phase 1/2 clinical trial of INZ-701 for ENPP1 deficiency;
- approximately \$40 million for the completion of our CTA submission and conduct of our Phase 1/2 clinical trial of INZ-701 for ABCC6 deficiency; and
- the remainder for preclinical studies for research stage programs, working capital and other general corporate purposes.

This expected use of net proceeds from this offering and our existing cash, cash equivalents and short-term investments represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from clinical trials, the timing of regulatory submissions and the outcome of regulatory review, as well as any collaborations that we may enter into with third parties for our product candidates, and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Based on our planned use of the net proceeds from this offering and our existing cash, cash equivalents and short-term investments, we estimate that such funds will be sufficient to enable us to complete our planned Phase 1/2 clinical trials of INZ-701 for both ENPP1 and ABCC6 deficiencies, and to fund our operating expenses and capital expenditure requirements at least into the second half of 2022. We have based these estimates on assumptions that may prove to be wrong and we could use our capital resources sooner than we currently expect.

We may also use a portion of the net proceeds from this offering for the future acquisition or in-license of other products, product candidates, businesses or technologies, although we have no current agreements or commitments for any such material acquisitions or licenses of any products, businesses or technologies. Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

## DIVIDEND POLICY

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business. We do not anticipate paying any cash dividends in the foreseeable future. Any future determination to declare and pay dividends will be made at the discretion of our board of directors and will depend on then-existing conditions, including our results of operations, financial condition, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

### CAPITALIZATION

The following table sets forth our cash, cash equivalents and short-term investments and our capitalization as of March 31, 2020:

- on an actual basis;
- on a pro forma basis to give effect to (1) our issuance and sale in June 2020 of an aggregate of 23,566,431 shares of our Series A-2 Convertible Preferred Stock for net proceeds of \$33.7 million and our issuance in July 2020 of an aggregate of 8,294,360 shares of our Series A-2 Convertible Preferred Stock to Alexion Pharmaceuticals, Inc., or Alexion, in consideration for the sale and assignment to us of specified patent rights and assets, (2) the automatic conversion of all outstanding shares of our preferred stock, including our shares of Series A-2 Convertible Preferred Stock issued in June 2020 and July 2020, into an aggregate of 13,953,850 shares of our common stock upon the closing of this offering and (3) the restatement of our certificate of incorporation upon the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 5,000,000 shares of our common stock in this offering at an assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma information assumes an as converted value per common share of \$15.00, which is the midpoint of the price range set forth on the cover page of this prospectus, for the shares of our Series A-2 Convertible Preferred Stock issued to Alexion that will automatically convert into 1,109,910 shares of our common stock upon the closing of this offering. The actual per share amount will be determined in connection with the issuance of our consolidated financial statements for the three months ended September 30, 2020. We will expense the assets acquired from Alexion as of the acquisition date because we will use them in our research and development activities and believe they have no alternative future uses. For a further description of our intellectual property asset acquisition from Alexion, see "Business—Alexion Intellectual Property Asset Acquisition."

The pro forma and pro forma as adjusted information below is illustrative only, and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read the information in this table together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus.

	As of March 31, 2020		
	Actual (in thousa	<u>Pro Forma</u> nds, except share a data)	Pro Forma As <u>Adjusted</u> and per share
Cash, cash equivalents and short-term investments	\$ 40,840	\$ 74,540	\$ 140,990
Series A Convertible Preferred Stock, \$0.0001 par value—48,850,000 shares authorized; 48,850,000 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	\$ 44,657	* —	\$ —
Series A-2 Convertible Preferred Stock, \$0.0001 par value—47,132,862 shares authorized; 23,566,431 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	33,270	_	_
Stockholders' equity:			
Preferred stock, \$0.0001 par value—no shares authorized, issued or outstanding, actual; 5,000,000 shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted	_	_	_
Common stock, \$0.0001 par value—129,000,000 shares authorized, 1,207,307 shares issued and outstanding, actual; 200,000,000 shares authorized, 15,161,157 shares issued and outstanding, pro forma;		1	2
200,000,000 shares authorized, 20,161,157 shares issued and outstanding, pro forma as adjusted	1.562	120.027	100 200
Additional paid in-capital	1,562	129,837	196,286
Accumulated other comprehensive income	28	28	28
Accumulated deficit	(42,390)	(59,039)	(59,039)
Total stockholders' equity	(40,800)	70,827	137,277
Total capitalization	\$ 37,127	\$ 70,827	\$ 137,277

A \$1.00 increase (decrease) in the assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents and short-term investments, additional paid-in capital, total stockholders' equity and total capitalization by \$4.7 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents and short-term investments, common stock, additional paid-in capital, total stockholders' equity and total capitalization by \$14.0 million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

## The table above excludes:

• 1,623,911 shares of our common stock issuable upon exercise of stock options outstanding as of March 31, 2020, at a weighted average exercise price of \$1.64 per share;

- 1,034,263 additional shares of our common stock reserved for future issuance under our existing Amended and Restated 2017 Equity Incentive Plan, as amended, as of March 31, 2020;
- 1,588,315 additional shares of our common stock that will be available for future issuance under our new 2020 Stock Incentive Plan that we are implementing in connection with this offering, of which we have granted options to purchase 768,380 shares of our common stock to our employees and non-employee directors effective upon the effectiveness of the registration statement of which this prospectus is a part; and
- 198,539 additional shares of our common stock that will be available for future issuance under our new 2020 Employee Stock Purchase Plan that we are implementing in connection with this offering.

## DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value (deficit) as of March 31, 2020 was \$(40.8) million, or \$(33.79) per share of common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and the carrying value of our preferred stock, which is not included within stockholders' (deficit) equity. Historical net tangible book value (deficit) per share represents historical net tangible book value (deficit) divided by the 1,207,307 shares of our common stock outstanding as of March 31, 2020.

Our pro forma net tangible book value as of March 31, 2020 was \$70.8 million, or \$4.67 per share of common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to (1) our issuance and sale in June 2020 of an aggregate of 23,566,431 shares of our Series A-2 Convertible Preferred Stock for net proceeds of \$33.7 million and our issuance in July 2020 of an aggregate of 8,294,360 shares of our Series A-2 Convertible Preferred Stock to Alexion Pharmaceuticals, Inc., or Alexion, in consideration for the sale and assignment to us of specified patent rights and assets (assuming an as converted value per common share of \$15.00, which is the midpoint of the price range set forth on the cover page of this prospectus, for the shares of our Series A-2 Convertible Preferred Stock issued to Alexion that will automatically convert into 1,109,910 shares of our common stock upon the closing of this offering) and (2) the automatic conversion of all outstanding shares of our preferred stock, including our shares of Series A-2 Convertible Preferred Stock issued in June 2020 and July 2020, into an aggregate of 13,953,850 shares of our common stock upon the closing of this offering. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares of common stock outstanding as of March 31, 2020, after giving effect to the pro forma adjustments described above.

After giving further effect to our issuance and sale of 5,000,000 shares of our common stock in this offering at an assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2020 would have been \$137.3 million, or \$6.81 per share. This represents an immediate increase in pro forma as adjusted net tangible book value per share of \$2.14 to existing stockholders and immediate dilution of \$8.19 in pro forma as adjusted net tangible book value per share to new investors purchasing shares of our common stock in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share		\$15.00
Historical net tangible book value (deficit) per share as of March 31, 2020	\$ (33.79)	
Increase per share attributable to the pro forma adjustments described above	38.46	
Pro forma net tangible book value per share as of March 31, 2020	\$ 4.67	
Increase in pro forma as adjusted net tangible book value per share attributable to new investors purchasing shares of our		
common stock in this offering	2.14	
Pro forma as adjusted net tangible book value per share immediately after this offering	<u> </u>	\$ 6.81
Dilution per share to new investors purchasing shares of our common stock in this offering		\$ 6.81 \$ 8.19

The dilution information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. A \$1.00 increase (decrease) in the assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value per

share after this offering by \$0.23 and dilution per share to new investors purchasing shares of our common stock in this offering by \$0.77, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase our pro forma as adjusted net tangible book value per share after this offering by \$0.34 and decrease the dilution per share to new investors purchasing shares of our common stock in this offering by \$0.34, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A decrease of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease our pro forma as adjusted net tangible book value per share after this offering by \$0.37 and increase the dilution per share to new investors purchasing shares of our common stock in this offering by \$0.37, assuming no change in the assumed initial public offering price and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase additional shares in full, our pro forma as adjusted net tangible book value per share after this offering would be \$7.07, representing an immediate increase in pro forma as adjusted net tangible book value per share of \$2.40 to existing stockholders and immediate dilution in pro forma as adjusted net tangible book value per share of \$7.93 to new investors purchasing shares of our common stock in this offering, assuming an initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, as of March 31, 2020, on the pro forma as adjusted basis described above, the total number of shares of our common stock purchased from us on an as converted to common stock basis, the total consideration paid or to be paid and the average price per share paid or to be paid by existing stockholders and by new investors in this offering at an assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing shares of our common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid. The following table excludes our issuance in July 2020 of shares of our Series A-2 Convertible Preferred Stock to Alexion in consideration for the sale and assignment to us of specified patent rights and assets.

	Shares Purc	hased	Total Consid	leration_	Average Price		
	Number	Percent	Amount	Percentage	Pe	r Share	
Existing stockholders	14,051,247	74%	\$116,328,210	61%	\$	8.28	
Investors purchasing shares of our common stock in this offering	5,000,000	26%	\$ 75,000,000	39%	\$	15.00	
Total	19,051,247	100%	\$191,328,210	100%			

A \$1.00 increase (decrease) in the assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by \$5.0 million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by 1.5 percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by 1.6 percentage points, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by \$15.0 million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by 4.4 percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by 5.2 percentage points, assuming no change in the assumed initial public offering price.

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters exercise their option to purchase additional shares in full, the number of shares of our common stock held by existing stockholders would be reduced to 73% of the total number of shares of our common stock outstanding after this offering, and the number of shares of our common stock held by new investors purchasing shares of our common stock in this offering would be increased to 27% of the total number of shares of our common stock outstanding after this offering.

The table above is based on the number of shares of our common stock outstanding as of March 31, 2020 and after giving effect to (1) our issuance and sale in June 2020 of an aggregate of 23,566,431 shares of our Series A-2 Convertible Preferred Stock for net proceeds of \$33.7 million and our issuance in July 2020 of an aggregate of 8,294,360 shares of our Series A-2 Convertible Preferred Stock to Alexion in consideration for the sale and assignment to us of specified patent rights and assets (assuming an as converted value per common share of \$15.00, which is the midpoint of the price range set forth on the cover page of this prospectus, for the shares of our Series A-2 Convertible Preferred Stock issued to Alexion that will automatically convert into 1,109,910 shares of our common stock upon the closing of this offering) and (2) the automatic conversion of all outstanding shares of our preferred stock, including our shares of Series A-2 Convertible Preferred issued in June 2020 and July 2020, into an aggregate of 13,953,850 shares of our common stock upon the closing of this offering. The table above excludes:

- 1,623,911 shares of our common stock issuable upon exercise of stock options outstanding as of March 31, 2020, at a weighted average exercise price of \$1.64 per share;
- 1,034,263 additional shares of our common stock reserved for future issuance under our existing Amended and Restated 2017 Equity Incentive Plan, as amended, as of March 31, 2020;
- 1,588,315 additional shares of our common stock that will be available for future issuance under our new 2020 Stock Incentive Plan that we are implementing in connection with this offering, of which we have granted options to purchase 768,380 shares of our common stock to our employees and non-employee directors effective upon the effectiveness of the registration statement of which this prospectus is a part; and
- 198,539 additional shares of our common stock that will be available for future issuance under our new 2020 Employee Stock Purchase Plan that we are implementing in connection with this offering.

To the extent that outstanding stock options are exercised, new stock options are issued, or we issue additional shares of our common stock in the future, there will be further dilution to investors purchasing shares of our common stock in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

### SELECTED CONSOLIDATED FINANCIAL DATA

You should read the following selected consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus. We have derived the consolidated statements of operations data for the years ended December 31, 2018 and 2019 and the consolidated balance sheet data as of December 31, 2018 and 2019 from our audited consolidated financial statements appearing at the end of this prospectus. The consolidated interim statements of operations data for the three months ended March 31, 2019 and 2020 and the consolidated balance sheet data as of March 31, 2020 have been derived from our unaudited condensed consolidated financial statements appearing at the end of this prospectus and have been prepared on the same basis as the audited consolidated financial statements. Our historical results are not necessarily indicative of the results that may be expected in the future, and our results for any interim period are not necessarily indicative of results that should be expected for any full year.

	Years Ended December 31,			-	Three Months Ended March			
		<u>2018</u>	(in tho	2019 sands, except	share an	<u>2019</u> d per share d	ata)	<u>2020</u>
Consolidated Statements of Operations Data:			(111 11101	ounas, encept	onur e un	a per siture a	,	
Operating expenses:								
Research and development	\$	8,099	\$	16,220	\$	4,134	\$	6,406
General and administrative		3,494		4,586		1,030	_	1,500
Total operating expenses		11,593		20,806		5,164		7,906
Loss from operations		(11,593)		(20,806)		(5,164)		(7,906)
Other income (expense):								
Interest income		284		1,106		210		171
Other expense, net		(29)		(24)		(17)		(3)
Change in fair value of preferred stock tranche liability		4,374					_	
Other income (expense), net		4,629		1,082		193		168
Net loss	\$	(6,964)	\$	(19,724)	\$	(4,971)	\$	(7,738)
Net loss per share attributable to common stockholders—basic and diluted(1)	\$	(6.63)	\$	(16.67)	\$	(4.27)	\$	(6.42)
Weighted-average common shares outstanding—basic and diluted(1)	1,	,050,706		1,183,144	1	,164,173		1,205,346
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited)(1)			\$	(1.30)			\$	(0.51)
Pro forma weighted-average common shares outstanding—basic and dilutes (unaudited)(1)			1	5,136,994			_	15,159,196

(1) See Note 10 to our consolidated financial statements appearing at the end of this prospectus for a description of the method used to calculate basic and diluted net loss per share and unaudited pro forma basic and diluted net loss per share as well as the weighted-average number of common shares used in the calculation of the per share amounts.

	As of December 31,			As of March 31,	
	2018 2019			2020	
		(in thousands)			
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	\$ 43,163	\$ 47,132	\$	40,840	
Working capital(1)	40,878	44,224		36,354	
Total assets	43,543	47,944		42,036	
Convertible preferred stock	55,029	77,927		77,927	
Accumulated deficit	(14,928)	(34,652)		(42,390)	
Total stockholders' deficit	(13,875)	(33,219)		(40,800)	
Cash, cash equivalents and short-term investments Working capital(1) Total assets Convertible preferred stock Accumulated deficit	40,878 43,543 55,029 (14,928)	44,224 47,944 77,927 (34,652)	\$	36,354 42,036 77,927 (42,390	

<sup>(1)</sup> We define working capital as current assets less current liabilities. See our consolidated financial statements for further details regarding our current assets and current liabilities.

### MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the "Selected Consolidated Financial Data" section of this prospectus and our consolidated financial statements and the related notes appearing at the end of this prospectus. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by these forward-looking statements. For convenience of presentation some of the numbers have been rounded in the text below.

#### Overview

We are a rare disease biopharmaceutical company developing novel therapeutics for the treatment of diseases of abnormal mineralization impacting the vasculature, soft tissue and skeleton. Through our in-depth understanding of the biological pathways involved in mineralization, we are pursuing the development of therapeutics to address the underlying causes of these debilitating diseases. It is well established that two genes, ENPP1 and ABCC6, play key roles in a critical mineralization pathway and that defects in these genes lead to abnormal mineralization. We are initially focused on developing a novel therapy to treat the rare genetic diseases of ENPP1 and ABCC6 deficiencies.

Our lead product candidate, INZ-701, is a soluble, recombinant, or genetically engineered, fusion protein that is designed to correct a defect in the mineralization pathway caused by ENPP1 and ABCC6 deficiencies. This pathway is central to the regulation of calcium deposition throughout the body and is further associated with neointimal proliferation, or the overgrowth of smooth muscle cells inside blood vessels. We have generated robust preclinical proof of concept data demonstrating that in animal models INZ-701 prevented pathological calcification, led to improvements in overall health and survival and prevented neointimal proliferation. In addition, an earlier murine research version of INZ-701 achieved survival benefit in a mouse model. We plan to file an Investigational New Drug Application, or IND, with the U.S. Food and Drug Administration, or FDA, and Clinical Trial Authorizations, or CTAs, with regulatory authorities in Europe for INZ-701 in the second half of 2020. We plan to advance INZ-701 into two separate Phase 1/2 clinical trials, one in patients with ENPP1 deficiency in the United States and in Europe and another in patients with ABCC6 deficiency in Europe. The FDA and the European Medicines Agency, or EMA, have granted orphan drug designation to INZ-701 for the treatment of ENPP1 deficiency. Subject to successfully completing clinical development of INZ-701 in these indications, we plan to seek marketing approvals for INZ-701 on a worldwide basis. Beyond our development focus on INZ-701, we believe that our therapeutic approach has the potential to benefit patients suffering from additional diseases of abnormal mineralization, including those without a clear genetic basis.

We were formed as a limited liability company in September 2015 and converted into a Delaware corporation in January 2017. We have not yet commercialized any products or generated any revenue from product sales. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, securing intellectual property rights, conducting research and development activities, establishing arrangements for the manufacture of INZ-701 and longer term planning for potential commercialization. All of our product candidates are still in preclinical development. To date, we have funded our operations primarily with proceeds from the sales of convertible preferred stock. Through March 31, 2020, we had received net proceeds of \$77.9 million from the sales of our convertible preferred stock. In June 2020, we received additional net proceeds of \$33.7 million upon the sale of our convertible preferred stock. Since inception, we have incurred significant operating losses. Our ability to generate revenue from product sales sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of INZ-701 or one or more of our future product candidates and programs. Our net losses were \$7.0 million and \$19.7 million for the years ended December 31, 2018 and 2019, respectively, and \$5.0 million and \$7.7 million for the three months ended March 31, 2019 and 2020, respectively. As of March 31, 2020, we had an accumulated deficit of \$42.4 million.

Our total operating expenses were \$11.6 million and \$20.8 million for the years ended December 31, 2018 and 2019, respectively, and \$5.2 million and \$7.9 million for the three months ended March 31, 2019 and 2020, respectively. We expect to continue to incur significant expenses for the foreseeable future. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance our preclinical activities and clinical trials. In addition, if we obtain marketing approval for INZ-701 or any other product candidate we develop, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company.

As a result, we will need to obtain substantial additional funding to support our continuing operations. Until such time, if ever, as we can generate significant revenues from product sales we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution and licensing arrangements, including the anticipated net proceeds from this offering. We do not have any committed external source of funds. If we are unable to raise capital or obtain adequate funds when needed or on acceptable terms, we may be required to delay, limit, reduce or terminate our research and development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and distract from our research and development efforts.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or even continue our operations.

As of March 31, 2020, we had cash, cash equivalents and short-term investments of approximately \$40.8 million. We have experienced negative cash flows from operations during fiscal 2018 and 2019, as well as during the three months ended March 31, 2020. We expect to incur substantial operating losses and negative cash flows from operations for the foreseeable future. As a result, there is a significant degree of uncertainty as to how long our existing cash, cash equivalents and short-term investments will be sufficient to fund our operations. These conditions raise substantial doubt about our ability to continue as a going concern for a period of at least one year from the date our consolidated financial statements for the year ended December 31, 2019 and our consolidated financial statements for the three months ended March 31, 2020 were issued. See Note 1 to our consolidated financial statements appearing at the end of this prospectus for additional information on our assessment of our ability to continue as a going concern.

We believe that the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments as of March 31, 2020 and the net proceeds from the sale of additional shares of convertible preferred stock in June 2020 of \$33.7 million, will enable us to fund our operating expenses and capital expenditure requirements at least into the second half of 2022. We have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. See "—Liquidity and Capital Resources."

To finance our operations beyond that point, we will need to raise additional capital, which cannot be assured.

We anticipate that our expenses will increase substantially if and as we:

• prepare for, initiate and conduct a planned Phase 1/2 clinical trial of INZ-701 for ENPP1 deficiency;

- prepare for, initiate and conduct a planned Phase 1/2 clinical trial of INZ-701 for ABCC6 deficiency;
- prepare for, initiate and conduct later stage clinical trials of INZ-701 for patients with ENPP1 and ABCC6 deficiencies;
- conduct research and preclinical testing of INZ-701 for additional indications;
- · conduct research and preclinical testing of other product candidates;
- advance INZ-701 for additional indications or any other product candidate into clinical development;
- · seek marketing approval for INZ-701 or any other product candidate if it successfully completes clinical trials;
- scale up our manufacturing processes and capabilities to support clinical trials of INZ-701 or any other product candidates we develop and for commercialization of any product candidate for which we may obtain marketing approval;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;
- in-license or acquire additional technologies or product candidates;
- · make any payments to Yale University, or Yale, under our license agreement or sponsored research agreement with Yale;
- maintain, expand, enforce and protect our intellectual property portfolio;
- hire additional clinical, regulatory, quality control and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our research, product development and planned future commercialization efforts and our operations as a public company.

### License and Sponsored Research Agreements

In January 2017, we entered into a license agreement with Yale, which was amended in May 2020 and July 2020, under which we licensed certain intellectual property related to ectonucleotide pyrophosphatase/phosphodiesterase enzymes, or ENPPs, that is the basis for our INZ-701 development program. Pursuant to the license agreement, as partial upfront consideration, we made a payment of approximately \$60,000 to Yale, which amount reflected unreimbursed patent expenses incurred by Yale prior to the date of the license agreement. We are responsible for paying Yale an annual license maintenance fee in varying amounts throughout the term ranging from the low tens of thousands of dollars to the high tens of thousands of dollars. As of March 31, 2020, we have incurred a total of \$42,500 in license maintenance fees to Yale. We are required to pay Yale \$3.0 million, based on the achievement of a specified net product sales milestone or specified development and commercialization milestones, for each therapeutic and prophylactic licensed product developed. We are required to pay Yale an amount in the several hundreds of thousands of dollars, based on the achievement of a specified net product sales milestone or specified development and commercialization milestones, for each diagnostic licensed product developed. While the agreement remains in effect, we are required to pay Yale low single-digit percentage royalties on aggregate worldwide net sales of certain licensed products. Yale is guaranteed a

minimum royalty payment amount (ranging in dollar amounts from the mid six figures to low seven figures) for each year after the first sale of a therapeutic or prophylactic licensed product that results in net sales. Yale is guaranteed a minimum royalty payment amount (ranging from the low tens of thousands of dollars to the mid tens of thousands of dollars) for each year after the first sale of a diagnostic licensed product that results in net sales. We must also pay Yale a percentage in the twenties of certain types of income we receive from sublicensees. We are also responsible for costs relating to the prosecution and maintenance of the licensed patents. Finally, subject to certain conditions, all payments due by us to Yale will be tripled following any patent challenge or challenge to a claim by Yale that a product is a licensed product under the agreement made by us against Yale if Yale prevails in such challenge.

In January 2017, we also entered into a corporate sponsored research agreement with Yale, which was amended in February 2019, under which we agreed to provide research support funding in the aggregate amount of \$2.4 million over the five year period from contract inception through the fourth quarter of 2021. We recorded research and development expenses associated with this arrangement of \$0.4 million and \$0.5 million in the years ended December 31, 2018 and 2019, respectively, and \$0.1 million and \$0.2 million in the three months ended March 31, 2019 and 2020, respectively.

We recorded research and development expense associated with other arrangements with Yale of \$0.3 million and \$0.4 million in the years ended December 31, 2019 and 2018, respectively, and \$0.2 million and none in the three months ended March 31, 2019 and 2020, respectively.

## **Financial Operations Overview**

### Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the foreseeable future. If development efforts for our product candidates are successful and result in regulatory approval or we enter into collaboration or similar agreements with third parties, we may generate revenue from those product candidates.

## Research and Development Expenses

Research and development expenses primarily consist of costs incurred in connection with the discovery and development of our lead product candidate, INZ-701.

We expense research and development costs as incurred. These expenses include:

- · fees and expenses incurred in connection with the in-license of technology and intellectual property rights;
- expenses incurred under agreements with third parties, including contract research organizations, or CROs, and other third parties that
  conduct research, preclinical and clinical activities on our behalf as well as third parties that manufacture our product candidates for use in
  our preclinical studies and planned clinical trials;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical trial materials, including manufacturing validation batches;
- employee-related expenses, including salaries, related benefits, travel and stock-based compensation expense for employees engaged in research and development functions;
- the costs of laboratory supplies and acquiring, developing preclinical studies and clinical trial materials;

- costs related to compliance with regulatory requirements; and
- facilities costs, which include depreciation costs of equipment and allocated expenses for rent, utilities and other operating costs.

We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers.

Research and development activities are central to our business model. We are still in the early stages of development of INZ-701 and expect to file applications with regulatory authorities in the United States and Europe in the second half of 2020 to allow us to initiate clinical development. Product candidates in later stages of clinical development generally have higher development costs than those in preclinical development or in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. From inception through March 31, 2020, we have incurred \$35.3 million of research and development costs for INZ-701. We expect that our research and development costs will continue to increase substantially for the foreseeable future as we initiate additional clinical trials of INZ-701, scale our manufacturing processes and advance development of INZ-701 for additional indications and potentially additional product candidates.

The successful development of INZ-701 and other potential future product candidates is highly uncertain. Accordingly, at this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the development of any product candidate. We are also unable to predict when, if ever, we will generate revenue and material net cash inflows from the commercialization and sale of any of our product candidates for which we may obtain marketing approval. We may never succeed in achieving marketing approval for any of our product candidates. The success of INZ-701 and any other product candidate we develop will depend on a variety of factors, including:

- successfully completing preclinical studies and initiating clinical trials, including acceptance of our IND for INZ-701 by the FDA and similar applications by regulatory authorities in Europe to allow us to initiate clinical development of INZ-701;
- successfully enrolling patients in and completing clinical trials:
- scaling up manufacturing processes and capabilities to support clinical trials of INZ-701 and any other product candidates we develop;
- applying for and receiving marketing approvals from applicable regulatory authorities;
- obtaining and maintaining intellectual property protection and regulatory exclusivity for INZ-701 and any other product candidates we develop;
- making arrangements for commercial manufacturing capabilities;
- establishing sales, marketing and distribution capabilities and launching commercial sales of INZ-701 and any other product candidates we develop, if and when approved, whether alone or in collaboration with others;
- acceptance of INZ-701 and any other product candidates we develop, if and when approved, by patients, the medical community and third-party payors;
- · effectively competing with other therapies;
- · obtaining and maintaining coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;

- maintaining, enforcing, defending and protecting our rights in our intellectual property portfolio;
- · not infringing, misappropriating or otherwise violating others' intellectual property or proprietary rights; and
- maintaining a continued acceptable safety profile of our products following receipt of any marketing approvals.

A change in the outcome of any of these variables with respect to the development, manufacture or commercialization activities of any of our product candidates could mean a significant change in the costs, timing and viability associated with the development of that product candidate. For example, if we are required to conduct additional clinical trials or other testing beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development.

## General and Administrative Expenses

General and administrative expenses consist primarily of salaries, related benefits, travel and stock-based compensation expense for personnel in executive, finance and administrative functions. General and administrative expenses also include professional fees for legal, consulting, accounting, tax and audit services, and information technology infrastructure costs. We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We also anticipate that we will incur increased costs associated with being a public company, including costs of accounting, audit, legal, regulatory, compliance and tax-related services related to maintaining compliance with requirements of Nasdaq and the Securities and Exchange Commission, or SEC; director and officer insurance costs; and investor and public relations costs. We anticipate the additional costs for these services will substantially increase our general and administrative expenses. Additionally, we may experience an increase in payroll and expense as a result of our preparation for potential commercial operations, especially as it relates to sales and marketing costs.

#### **Interest Income**

Interest income consists of income from bank deposits and short-term investments.

## Other Expense

Other expense primarily consists of foreign exchange gains or losses.

## Change in Fair Value of Preferred Stock Tranche Liability

As described in Note 8 of the accompanying consolidated financial statements, in 2017, we entered into a Series A Convertible Preferred Stock Purchase Agreement, which, as amended and restated, we refer to as the Series A Agreement, under which we agreed to issue up to 48,750,000 shares of Series A Convertible Preferred Stock in two tranches. Under the Series A Agreement, we initially issued 27,083,333 shares at a price of \$1.00 per share for net cash proceeds of \$26.7 million. The Series A Agreement provided for a second tranche closing based on the achievement of a defined milestone or upon waiver of the milestone, or the Tranche Right. In November 2018, we sold an additional 21,666,667 shares of Series A Convertible Preferred Stock at a price of \$1.00 per share under the Tranche Right.

The Tranche Right was classified as a liability and initially recorded at fair value. The liability was subject to revaluation at each balance sheet date prior to the exercise or expiration of the Tranche Right. The

change in the preferred stock tranche liability consists of the re-measurement gains or losses associated with changes in the fair value of the Tranche Right. Upon issuance of the additional shares of Series A Convertible Preferred Stock in November 2018, the Tranche Right was settled.

## **Critical Accounting Policies and Use of Estimates**

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in conformity with accounting principles generally accepted in the United States of America. The preparation of these consolidated financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience, known trends and events, and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing at the end of this prospectus, we believe the following accounting policies are the most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

## Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing purchase orders and open contracts, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the services when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by CROs and contract manufacturing organizations, or CMOs, among others, in connection with research and development activities for which we have not yet been invoiced.

We contract with CROs and CMOs to conduct clinical and manufacturing and other research and development services on our behalf. We base our expenses related to CROs and CMOs on our estimates of the services received and efforts expended pursuant to quotes and contracts with them. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our CROs or CMOs will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or amount of prepaid expense accordingly. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services

performed may vary and may result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

## **Stock-Based Compensation**

Stock-based compensation expense represents the cost of the grant date fair value of employee and non-employee stock option grants and restricted stock awards recognized over the requisite service period of the awards on a straight-line basis. For service-based awards that are subject to graded vesting, companies have the option to recognize compensation expense either on a straight-line or accelerated basis. We have elected to recognize compensation expense for these awards on a straight-line basis.

We accounted for stock options to non-employees using the fair value approach through December 31, 2017. On January 1, 2018, we early adopted Financial Accounting Standards Board, or FASB, Accounting Standards Update, or ASU, No. 2018-07, *Compensation – Stock Compensation*, or ASU 2018-07, and as a result, the fair value of unvested non-employee awards as of December 31, 2017 is no longer remeasured each reporting period. All future expense related to these awards will be recorded based on the fair value measured as of December 31, 2017, the last period prior to the adoption of ASU 2018-07. We classify stock-based compensation expense in our consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's salary and related costs are classified or in which the award recipient's service payments are classified.

## Fair Value of Stock-Based Awards

We estimate the fair value of our stock options using the Black-Scholes option-pricing model, which requires inputs of subjective assumptions, including: (1) the expected volatility of our common stock; (2) the expected term of the award; (3) the risk-free interest rate; (4) expected dividends; and (5) the fair value of common stock. Due to the lack of a public market for our common stock and a lack of company-specific historical and implied volatility data, we have based our computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to us, including stage of product development, life science industry focus, length of trading history and similar vesting provisions. The historical volatility data is calculated based on a period of time commensurate with the expected term assumption. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available or until circumstances change, such that the identified entities are no longer representative companies. In the latter case, more suitable, similar entities whose share prices are publicly available would be utilized in the calculation. We estimate the expected term of our stock options granted to employees using the simplified method, whereby the expected term equals the average of the vesting term and the original contractual term of the option. We utilize this method as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. For stock options granted to non-employees, we utilize the contractual term of the option as the basis for the expected term assumption. The risk-free interest rate is based on a U.S. Treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero as we have never paid dividends and have no current plans to pay any dividends on our commo

The fair value of stock options granted to employees was estimated on the date of grant using the Black-Scholes option-pricing model, with the following range of assumptions:

	Years Ended I	Years Ended December 31,		
	2018	2019	2019	2020
Risk-free interest rate	2.35% to 3.01%	1.63% to 2.51%	2.51%	2020 N/A
Expected dividend yield	0%	0%	0%	N/A
Expected term (in years)	6.08	6.78	6.78	N/A
Expected volatility	100.11% to 103.48%	85.02% to 103.76%	85.02%	N/A

The fair value of stock options granted to non-employees was estimated on the date of grant and as the grants are remeasured over the vesting period using the Black-Scholes option-pricing model, with the following range of assumptions:

	Years Ended Decemb	er 31,
	2018	2019
Risk-free interest rate	2.18%	1.84%
Expected dividend yield	0%	0%
Expected term (in years)	10.00	10.00
Expected volatility	101.87%	85.02%

There were no stock options granted to non-employees during the three months ended March 31, 2019 and 2020.

We determine the fair value of restricted stock awards based on the estimated fair value of our common stock on the date of grant, less any applicable purchase price.

In the first quarter of the year ended December 31, 2018, we made an accounting policy election to recognize forfeitures as they occur upon adoption of guidance per ASU No. 2016-09, *Compensation—Stock Compensation*, or ASU 2016-09. The adoption of ASU 2016-09 did not have a material impact on our consolidated financial statements. In reporting periods prior to the year ended December 31, 2018, we estimated forfeitures at the time of grant and revised the forfeitures rate in subsequent periods as necessary if actual forfeitures differed from estimates.

The following table presents the grant dates, number of underlying shares of common stock and the per share exercise prices of stock options granted between January 1, 2017 and July 17, 2020, along with the fair value per share utilized to calculate stock-based compensation expense:

Grant Date	Type of Award	Number of Common Shares	Per Share Exercise Price of Award(1)	Va Comi on	hare Fair alue of non Stock Grant ate(2)	Esti Fair	Share imated Value of vard(3)
June 28, 2017	Option	469,268	\$ 0.98	\$	0.98	\$	0.83
September 7, 2017	Option	155,559	\$ 0.98	\$	0.98	\$	0.75
January 8, 2018	Option	87,672	\$ 0.98	\$	1.20(4)	\$	1.20
April 15, 2018	Option	43,489	\$ 0.98	\$	1.20(4)	\$	1.20
December 13, 2018	Option	66,569	\$ 1.87	\$	1.87	\$	1.35
March 7, 2019	Option	8,195	\$ 1.87	\$	1.87	\$	1.42
June 20, 2019	Option	673,755	\$ 2.02	\$	2.02	\$	1.50
September 20, 2019	Option	75,604	\$ 2.02	\$	2.02	\$	1.50
September 26, 2019	Option	160,578	\$ 2.02	\$	2.02	\$	1.50
December 12, 2019	Option	90,993	\$ 2.02	\$	2.02	\$	1.50
April 23, 2020	Option	492,838	\$ 2.77	\$	2.77	\$	2.25
May 28, 2020	Option	115,347	\$ 2.77	\$	2.77	\$	2.25

<sup>(1)</sup> The Per Share Exercise Price of Award represents the fair value of our common stock on the date of grant, as determined by our board of directors, after taking into account our most recently available contemporaneous valuations of our common stock as well as additional factors that may have changed since the date of such contemporaneous valuations through the date of grant.

<sup>(2)</sup> The Per Share Fair Value of Common Stock on Grant Date is based upon a third-party valuation analysis and represents what we believed was the fair value of our common stock on the respective grant dates. Valuations were performed as of April 30, 2017, December 31, 2017, November 30, 2018, May 31, 2019 and March 31, 2020.

- (3) The Per Share Estimated Fair Value of Award reflects the fair value of options as estimated at the date of grant using the Black-Scholes option-pricing model.
- (4) At the time of the option grants on January 8, 2018 and April 15, 2018, our board of directors determined that the fair value of our common stock of \$0.98 per share calculated in the contemporaneous valuation as of April 30, 2017 reasonably reflected the per share fair value of our common stock as of the grant date. However, as described below, the fair value of our common stock at the date of these grants was adjusted to \$1.20 per share in connection with a retrospective fair value assessment for accounting purposes.

In preparing for the issuance of our consolidated financial statements for the year ended December 31, 2017, we performed a retrospective fair value assessment and concluded that the fair value of our common stock underlying stock options that we granted on January 8, 2018 and April 15, 2018, with an exercise price of \$0.98 per share, was \$1.20 per share for accounting purposes. That value of \$1.20 per share, which we applied to determine the per share estimated fair value of the January 8, 2018 and April 15, 2018 awards for accounting purposes, was based upon our board of directors' determination of the fair value of our common stock as of December 31, 2017.

Effective upon the effectiveness of the registration statement of which this prospectus is a part, we granted options to purchase an aggregate of 768,380 shares of our common stock at an exercise price per share equal to the initial public offering price per share of our common stock in this offering.

The following table summarizes the classification of our stock-based compensation expense recognized in our consolidated statements of operations and comprehensive loss (in thousands):

	Years Ended December 31,					Three Month	ıs Ended Ma	rch 31 <u>,</u>
	201	18	2	2019	20	019		2020
Research and development	\$	322	\$	150	\$	27	\$	65
General and administrative		122		151		14		64
Total	\$	444	\$	301	\$	41	\$	129

As of December 31, 2019, we had \$1.5 million of unrecognized compensation expense related to stock option awards, which is expected to be recognized over weighted-average remaining vesting periods of approximately 3.0 years. As of March 31, 2020, we had \$1.3 million of unrecognized compensation expense related to stock option awards, which is expected to be recognized over weighted-average remaining vesting periods of approximately 2.3 years. In future periods, we expect stock-based compensation expense to increase, due in part to our existing unrecognized stock-based compensation expense, potential increases in the value of our common stock and expected issuance of additional stock-based awards to continue to attract and retain our employees.

### Determination of Fair Value of Common Stock

As a private company with no active public market for our common stock, our board of directors has historically determined the fair value of our common stock on each date of each option grant, with input from management, considering our most recent contemporaneous third party valuation and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. The additional factors considered when determining any changes in fair value of our common stock between the most recent contemporaneous valuation and the grant dates included the status of our stage of research and development, our operating and financial performance and current business conditions. The third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, or the Practice Aid. Once a public trading market for our common stock has been established in connection with the completion of this

offering, it will no longer be necessary for us to estimate the fair value of our common stock in connection with our accounting for stock options, as the fair value of our common stock will be its trading price on The Nasdaq Stock Market.

We performed contemporaneous valuations, with the assistance of a third-party valuation specialist, as of April 30, 2017, December 31, 2017, November 30, 2018, May 31, 2019 and March 31, 2020, which resulted in valuations of our common stock of \$0.98, \$1.20, \$1.87, \$2.02, and \$2.77 per share, respectively. In conducting each valuation, we considered all objective and subjective factors that we believed to be relevant, including our best estimate of our business condition, prospects and operating performance at each valuation date. Within the valuations performed, a range of factors, assumptions and methodologies were used. The significant factors included:

- the lack of an active public market for our common stock and convertible preferred stock;
- the prices at which we sold shares of our convertible preferred stock in arm's length transactions and the superior rights, preferences and privileges of the convertible preferred stock relative to our common stock, including the liquidation preferences of our convertible preferred stock;
- · our results of operations and financial condition, including cash on hand;
- the material risks related to our business;
- our stage of development and business strategy;
- the composition of, and changes to, our management team and board of directors;
- the market performance of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed initial public offerings, or IPOs, of companies in the life sciences and biotechnology sectors; and
- the likelihood of achieving a liquidity event such as an IPO given prevailing market conditions.

There are significant judgments and estimates inherent in the determination of the fair value of our common stock. These judgments and estimates are management's best estimates and include assumptions regarding our future operating performance, the time to completing an IPO or other liquidity event, the related company valuations associated with such events and the determinations of the appropriate valuation methods. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per common share could have been different.

### Common Stock Valuation Methodologies

Our contemporaneous common stock valuations were prepared in accordance with the guidelines in the Practice Aid, which prescribes several valuation approaches for determining the value of an enterprise, such as the cost, market and income approaches, and various methodologies for allocating the value of an enterprise to its capital structure and specifically the common stock.

Our common stock valuations through May 31, 2019 were prepared using the backsolve method to calculate the total equity value and the option-pricing method, or OPM, to allocate the total equity value. The backsolve method derives the implied equity value for one type of equity security from a contemporaneous transaction involving another type of security. Our common stock valuation as of March 31, 2020 was prepared using the hybrid method as described below.

Option-Pricing Method (OPM). The OPM treats each class of common stock and convertible preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceed the value of the convertible preferred stock liquidation preferences at the time of a liquidity event, such as a strategic sale, merger or IPO. The common stock is modeled as a call option on the underlying equity value at a predetermined exercise price. In the model, the exercise price is based on a comparison with the total equity value rather than, as in the case of a regular call option, a comparison with a per share stock price. Thus, common stock is considered to be a call option with a claim on the enterprise at an exercise price equal to the remaining value immediately after the convertible preferred stock liquidation preference is paid.

The OPM uses the Black-Scholes option-pricing model to price the call options. This model defines the securities' fair values as functions of the current fair value of a company and uses assumptions, such as the anticipated timing of a potential liquidity event and the estimated volatility of the equity securities. The aggregate value of the common stock derived from the OPM is then divided by the number of shares of common stock outstanding to arrive at the per share value.

We used the OPM backsolve approach to estimate enterprise value under the OPM. The OPM backsolve approach uses the OPM to calculate the implied equity value based on recent sales of our securities. For the OPM, we based our assumed volatility factor on the historical trading volatility of our publicly traded peer companies. At each valuation date, we determined the appropriate volatility to be used, considering such factors as our expected time to a liquidity event and our stage of development.

To derive the fair value of our common stock using the OPM, we calculated the proceeds to the common stockholders based on the preferences and priorities of the convertible preferred and common stock. We then applied a discount for lack of marketability to the common stock to account for the lack of access to an active public market.

Probability-Weighted Expected Return Method (PWERM). The probability weighted expected return method, or PWERM, is a scenario-based methodology that estimates the fair value of common stock-based upon an analysis of future values for us, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. A discount for lack of marketability is then applied to the common stock to account for the lack of access to an active public market.

Hybrid Method. The hybrid method is a PWERM where the equity value in one of the scenarios is calculated using an OPM. In the hybrid method used by us, we considered two types of future-event scenarios: an IPO and an unspecified liquidity event. The equity value for the IPO scenario was determined using the guideline public company method, or GPC, which includes comparisons to publicly traded companies in our industry that recently completed IPOs. The equity value for the unspecified liquidity event scenario was determined using a backsolve method. The relative probability of each type of future-event scenario was determined based on an analysis of market conditions at the time, including then-current IPO valuations of similarly situated companies, and our expectations as to the timing and likely prospects of the future-event scenarios. A discount for lack of marketability is then applied to the common stock to account for the lack of access to an active public market.

To derive the fair value of the common stock for each scenario using the hybrid method, we calculated the proceeds to the common stockholders based on the preferences and priorities of the convertible preferred and common stock. We then applied a discount for lack of marketability to the common stock to account for the lack of access to an active public market.

In connection with this offering, all outstanding shares of our preferred stock will be converted to common stock.

### **Results of Operations**

## Comparison of the Three Months Ended March 31, 2019 and 2020

The following table summarizes our results of operations for the three months ended March 31, 2019 and 2020 (in thousands):

		Three Months Ended March 31,		
	<u>2019</u>	2020	Increase (Decrease)	
Operating expenses:				
Research and development	\$ 4,134	\$ 6,406	\$ 2,272	
General and administrative	1,030	1,500	470	
Total operating expenses	5,164	7,906	2,742	
Loss from operations	(5,164)	(7,906)	2,742	
Other income (expense):				
Interest income	210	171	(39)	
Other expense, net	(17)	(3)	14	
Other income (expense), net	193	168	(25)	
Net loss	\$(4,971)	\$(7,738)	\$ 2,717	

## Research and Development Expense

Research and development expense increased by \$2.3 million to \$6.4 million for the three months ended March 31, 2020 from \$4.1 million for the three months ended March 31, 2019. The increase in research and development expense was primarily attributable to the following:

- our manufacturing costs increased \$0.7 million as a result of the manufacture of pre-engineering, engineering, and clinical trial batches of product for INZ-701 as we scaled our manufacturing process and manufactured material for our clinical trials;
- our toxicology costs increased \$0.9 million as a result of the conduct of increased preclinical toxicology studies in preparation for the planned filing of an IND for INZ-701; and
- an increase of \$0.7 million due to increases for consulting and professional fees as we engaged various third parties to assist in areas such as quality and regulatory, for the planned filing of an IND for INZ-701.

We expect that our research and development costs will continue to increase for the foreseeable future as we prepare for clinical trials of INZ-701, further scale our manufacturing processes and advance development of INZ-701 for additional indications or of additional product candidates.

## General and Administrative Expense

General and administrative expense increased by \$0.5 million to \$1.5 million for the three months ended March 31, 2020 from \$1.0 million for the three months ended March 31, 2019. The increase in general and administrative expense was primarily attributable to an increase in our employee compensation, including stock-

based compensation, and benefits related to an increase in the number of general administrative employees, an increase in legal fees related to patents and new contracts, and generally higher fees in areas such as audit, tax and information technology to support our growth. We expect that our general and administrative expense will increase in future periods as we expand our operations and incur additional costs in connection with being a public company.

### Interest Income

Interest income decreased by \$39 thousand to \$171 thousand for the three months ended March 31, 2020 from \$210 thousand for the three months ended March 31, 2019. The decrease was primarily attributable to lower average cash and investment balances during the three months ended March 31, 2020 as compared to the three months ended March 31, 2019.

## Other Expense, net

Other expense, net, consisting primarily of foreign exchange losses for the three months ended March 31, 2020, was consistent with the three months ended March 31, 2019.

## Comparison of the Years Ended December 31, 2018 and 2019

The following table summarizes our results of operations for the years ended December 31, 2018 and 2019 (in thousands):

	Years Decem		
	2018	2019	Increase (Decrease)
Operating expenses:			
Research and development	\$ 8,099	\$ 16,220	\$ 8,121
General and administrative	3,494	4,586	1,092
Total operating expenses	11,593	20,806	9,213
Loss from operations	(11,593)	(20,806)	9,213
Other income (expense):			
Interest income	284	1,106	822
Other expense, net	(29)	(24)	5
Change in fair value of preferred stock tranche liability	4,374		(4,374)
Other income (expense), net	4,629	1,082	(3,547)
Net loss	\$ (6,964)	\$(19,724)	\$ 12,760

## Research and Development Expense

Research and development expense increased by \$8.1 million to \$16.2 million for the year ended December 31, 2019 from \$8.1 million for the year ended December 31, 2018. The increase in research and development expense was primarily attributable to the following:

- our manufacturing costs increased \$3.2 million as a result of the manufacture of pre-engineering, engineering, and clinical trial batches of product for INZ-701 as we scaled our manufacturing process and manufactured material for our clinical trials;
- our toxicology costs increased \$2.1 million as a result of the conduct of increased preclinical toxicology studies in preparation for the planned filing of an IND for INZ-701;

- our employee compensation, including stock-based compensation, benefits and related recruiting costs increased \$1.3 million primarily
  due to an overall increase in research and development headcount from 11 employees at December 31, 2018 to 16 employees at
  December 31, 2019; and
- an increase of \$1.5 million due to increases of \$0.8 million for consulting and professional fees as we engaged various third-parties to assist in areas such as quality and regulatory, \$0.3 million for lab supplies, \$0.2 million for rent and \$0.2 million for travel.

General and Administrative Expense

General and administrative expense increased by \$1.1 million to \$4.6 million for the year ended December 31, 2019 from \$3.5 million for the year ended December 31, 2018. The increase in general and administrative expense was primarily attributable to an increase in our employee compensation, including stock-based compensation, benefits and recruiting fees related to an increase in the number of general administrative employees.

Interest Income

Interest income increased by \$0.8 million to \$1.1 million for the year ended December 31, 2019 from \$0.3 million for the year ended December 31, 2018. The increase was primarily attributable to higher average cash and investment balances during 2019 as compared to 2018.

Other Expense, net

Other expense, net, consisting primarily of foreign exchange losses for the year ended December 31, 2019, was consistent with the year ended December 31, 2018.

Change in Fair Value of Preferred Stock Tranche Liability

Change in fair value of preferred stock tranche liability decreased from \$4.4 million for the year ended December 31, 2018 to zero for the year ended December 31, 2019. The change in fair value of the Series A Convertible Preferred Stock tranche liability consists of the re-measurement gains associated with changes in the fair value of the Tranche Right. Upon issuance of the additional shares of Series A Convertible Preferred Stock in November 2018, the Tranche Right was settled, and therefore, there were no gains or losses during the year ended December 31, 2019.

## **Liquidity and Capital Resources**

# Sources of Liquidity

Since our inception, we have not generated any revenue and have incurred significant operating losses and negative cash flows from our operations. To date, we have funded our operations primarily with proceeds from the sales of convertible preferred stock. Through March 31, 2020, we had received net cash proceeds of \$77.9 million from sales of our convertible preferred stock. As of March 31, 2020, we had cash, cash equivalents and short-term investments of approximately \$40.8 million.

The Series A-2 Convertible Preferred Stock Purchase Agreement provides for a second tranche closing of \$33.7 million based on the achievement of a defined milestone or earlier upon board of directors and requisite stockholder approval to waive such requirement, pursuant to which the investors are required to purchase, and we to sell, an additional 23,566,431 shares of Series A-2 Convertible Preferred Stock at \$1.43 per share upon the achievement of the defined milestone. As of March 31, 2020, that milestone was not achieved. In June 2020, our board of directors and requisite stockholders approved a waiver of this milestone and we sold 23,566,431 shares of Series A-2 Convertible Preferred Stock for net proceeds of \$33.7 million.

Cash in excess of immediate requirements is invested primarily with a view to liquidity and capital preservation. The following table provides information regarding our total cash, cash equivalents and short-term investments at December 31, 2018, December 31, 2019 and March 31, 2020 (in thousands):

	Decen	December 31,		
	2018	2019	2020	
Cash and cash equivalents	\$35,966	\$ 31,605	\$ 21,937	
Short-term investments	7,197	15,527	18,903	
Total cash, cash equivalents and short-term investments	\$43,163	\$ 47,132	\$ 40,840	

#### Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2018 and 2019, and for the three months ended March 31, 2019 and 2020 (in thousands):

	Years Ended December 31,		Three Months Ended March 31,	
	2018	2019	2019	2020
Net cash used in operating activities	\$ (9,437)	\$(18,810)	\$ (5,288)	\$(6,265)
Net cash provided by (used in) investing activities	9,006	(8,391)	1,758	(3,408)
Net cash provided by financing activities	31,945	22,970	22,932	5
Net increase (decrease) in cash, cash equivalents and restricted cash	\$31,514	\$ (4,231)	\$19,402	\$(9,668)

Net Cash Used in Operating Activities

The cash used in operating activities resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital.

Net cash used in operating activities was \$5.3 million for the three months ended March 31, 2019 compared to \$6.3 million for the three months ended March 31, 2020. The increase in cash used in operating activities of \$1.0 million was primarily attributable to the increase in our net loss, adjusted for non-cash items, of \$2.7 million, primarily due to increased research and development expenses, offset by an increase in accounts payable and accruals of \$1.7 million.

Net cash used in operating activities was \$9.4 million for the year ended December 31, 2018 compared to \$18.8 million for the year ended December 31, 2019. The increase in cash used in operating activities of \$9.4 million was primarily attributable to the increase in our net loss, adjusted for non-cash items, of \$8.5 million, primarily due to increased research and development expenses.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was \$1.8 million for the three months ended March 31, 2019 compared to net cash used in investing activities of \$3.4 million for the three months ended March 31, 2020. The decrease in cash flows from investing activities of \$5.2 million was primarily attributable to a net increase in purchases of short-term investments as we converted excess cash to short-term investments.

Net cash provided by investing activities was \$9.0 million for year ended December 31, 2018 compared to net cash used in investing activities of \$8.4 million for the year ended December 31, 2019. The decrease in cash flows from investing activities of \$17.4 million was primarily attributable to a net increase in purchases of short-term investments as we converted excess cash to short-term investments.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$22.9 million for the three months ended March 31, 2019 compared to \$5 thousand for the three months ended March 31, 2020. The decrease in cash provided by financing activities of \$22.9 million primarily reflects the proceeds from issuances of convertible preferred stock in 2019. During the three months ended March 31, 2019, we received net proceeds of \$22.9 million from the issuance of Series A-2 Convertible Preferred Stock, as compared to net proceeds of \$5 thousand from the exercise of stock options during the three months ended March 31, 2020.

Net cash provided by financing activities was \$31.9 million for the year ended December 31, 2018 compared to \$23.0 million for year ended December 31, 2019. The decrease in cash provided by financing activities of \$9.0 million reflects changes in the amounts of proceeds from issuances of convertible preferred stock. During the year ended December 31, 2018, we received net proceeds of \$21.6 million and \$10.4 million from the issuance of Series A and Series A-2 Convertible Preferred Stock, respectively, as compared to net proceeds from the issuance of Series A-2 Convertible Preferred Stock during the year ended December 31, 2019 of \$22.9 million.

## **Funding Requirements**

We expect to devote substantial financial resources to our ongoing and planned activities, particularly as we prepare for, initiate and conduct our planned Phase 1/2 clinical trials of INZ-701 for ENPP1 and ABCC6 deficiencies, and continue research and development and initiate additional clinical trials of, and seek marketing approval for, INZ-701 and any other product candidate we develop. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance our preclinical activities and clinical trials. In addition, if we obtain marketing approval for INZ-701 or any other product candidates we develop, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital or obtain adequate funds when needed or on acceptable terms, we may be required to delay, limit, reduce or terminate our research and development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and distract from our research and development efforts.

Our future capital requirements will depend on many factors, including:

- the progress, costs and results of our planned Phase 1/2 clinical trials of INZ-701 for ENPP1 and ABCC6 deficiencies and any future clinical development of INZ-701 for these indications;
- the scope, progress, costs and results of research, preclinical testing and clinical trials of INZ-701 for additional indications;
- the number of and development requirements for additional indications for INZ-701 or for any other product candidates we develop;
- our ability to scale up our manufacturing processes and capabilities to support clinical trials of INZ-701 and any other product candidates we develop;
- the costs, timing and outcome of regulatory review of INZ-701 and any other product candidates we develop;
- potential changes in the regulatory environment and enforcement rules;

- · our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the payment of license fees and other costs of our technology license arrangements;
- the costs and timing of future commercialization activities, including product manufacturing, sales, marketing and distribution, for INZ-701 and any other product candidates we develop for which we may receive marketing approval;
- the amount and timing of revenue, if any, received from commercial sales of INZ-701 and any other product candidates we develop for which we receive marketing approval;
- · potential changes in pharmaceutical pricing and reimbursement infrastructure;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property-related claims; and
- · the extent to which we in-license or acquire additional technologies or product candidates.

As of March 31, 2020, we had cash, cash equivalents and short-term investments of approximately \$40.8 million. We believe that the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments as of March 31, 2020, together with the net proceeds from the sale of additional shares of convertible preferred stock in June 2020 of \$33.7 million, will enable us to fund our operating expenses and capital expenditure requirements at least into the second half of 2022. However, we have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. In addition, changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. As a result, we could deplete our capital resources sooner than we currently expect. In addition, because the successful development of INZ-701 and any other product candidates that we pursue is highly uncertain, at this time we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the development of any product candidate.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. We will not generate commercial revenues unless and until we can achieve sales of products, which we do not anticipate for a number of years, if at all. Accordingly, we will need to obtain substantial additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all, and may be impacted by the economic climate and market conditions. For example, market volatility resulting from the COVID-19 pandemic or any other future infectious diseases, epidemics or pandemics could also adversely impact our ability to access capital as and when needed.

Until such time, if ever, as we can generate substantial revenues from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our operations and ability to take specific actions, such as incurring additional debt, making acquisitions, engaging in acquisition, merger or collaboration transactions, selling or licensing our assets, making capital expenditures, redeeming our stock, making certain investments or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

## **Contractual Obligations**

The following table summarizes our significant contractual obligations as of payment due date by period at December 31, 2019 (in thousands):

		Less			
		than	1 to 3		More than 5
	<u>Total</u>	1 year	years	3 to 5 years	years
Minimum operating lease payments(1)	\$2,994	\$512	\$1,056	\$ 1,099	\$ 327
Sponsored research agreements(2)	1,000	500	500	_	
Minimum license obligations(3)	50	50	_	_	_

- (1) Represents future minimum lease payments under our non-cancelable operating leases for office and laboratory space that expire between August 2020 and the second half of 2025. The minimum lease payments above do not include any related common area maintenance charges or real estate taxes.
- (2) Represents payments due under research agreements based on the terms of agreements.
- (3) Represents minimum annual license fees under our license agreement with Yale. See "Business—Yale University License Agreement" for additional information about the license agreement with Yale, including with respect to other potential payments thereunder.

The table above, which is presented as of December 31, 2019, does not include the non-cancelable operating lease for laboratory space in Boston entered into by us in May 2020. The lease term will begin following the substantial completion of the construction work, which is anticipated in late 2020, and ends in late 2025. The total future lease commitments under the operating lease are \$2.3 million.

We enter into agreements in the normal course of business with CROs for preclinical studies and clinical trials, CMOs for clinical supply manufacturing, professional consultants for expert advice and other vendors for other services for operating purposes. We have not included these payments in the table of contractual obligations above since the contracts do not contain any minimum purchase commitments and provide for termination on notice by us and we believe that our non-cancelable obligations under these agreements are not material.

In addition, under our license agreement with Yale, we will be required to make milestone payments and pay royalties and other amounts. We have not included any contingent payment obligations, such as milestones or royalties, in the table above as the amount, timing and likelihood of such payments are not known.

## **Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.

# Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk related to changes in interest rates. As of March 31, 2020, our cash equivalents consisted of primarily of short-term money market funds. As of March 31, 2020, our short-term investments consisted of commercial paper, corporate debt securities and government agency securities with maturities of less than one year. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term nature of the investments in our

portfolio and the low risk profile of our investments, an immediate change of 100 basis points in interest rates would not have a material effect on the fair market value of our investment portfolio or on our financial position or results of operations.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we have contracted with and may continue to contract with foreign vendors that are located in Europe. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years ended December 31, 2018 and 2019, or the three months ended March 31, 2019 and 2020.

## **Emerging Growth Company Status**

We are an "emerging growth company," or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We may remain an EGC until the last day of the fiscal year in which the fifth anniversary of the closing of this offering occurs, although if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of any June 30 before that time or if we have annual gross revenues of \$1.07 billion or more in any fiscal year, we would cease to be an EGC as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than \$1 billion of non-convertible debt over a three-year period.

For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. These exemptions include being permitted to provide only two years of audited financial statements in this prospectus, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure; not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting; not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements and reduced disclosure obligations regarding executive compensation; and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

In addition, the JOBS Act permits an EGC to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to use the extended transition period for complying with new or revised accounting standards and will do so until such time that we either (1) irrevocably elect to "opt out" of such extended transition period or (2) no longer qualify as an EGC. As a result of this election, our consolidated financial statements may not be comparable to companies that comply with public company FASB standards' effective dates.

#### BUSINESS

#### Overview

We are a rare disease biopharmaceutical company developing novel therapeutics for the treatment of diseases of abnormal mineralization impacting the vasculature, soft tissue and skeleton. Through our in-depth understanding of the biological pathways involved in mineralization, we are pursuing the development of therapeutics to address the underlying causes of these debilitating diseases. It is well established that two genes, ENPP1 and ABCC6, play key roles in a critical mineralization pathway and that defects in these genes lead to abnormal mineralization. We are initially focused on developing a novel therapy to treat the rare genetic diseases of ENPP1 and ABCC6 deficiencies.

Our lead product candidate, INZ-701, is a soluble, recombinant, or genetically engineered, fusion protein that is designed to correct a defect in the mineralization pathway caused by ENPP1 and ABCC6 deficiencies. This pathway is central to the regulation of calcium deposition throughout the body and is further associated with neointimal proliferation, or the overgrowth of smooth muscle cells inside blood vessels. We have generated robust preclinical proof of concept data demonstrating that in animal models INZ-701 prevented pathological calcification, led to improvements in overall health and survival and prevented neointimal proliferation. In addition, an earlier murine research version of INZ-701 achieved survival benefit in a mouse model. We plan to file an Investigational New Drug Application, or IND, with the U.S. Food and Drug Administration, or FDA, and Clinical Trial Authorizations, or CTAs, with regulatory authorities in Europe for INZ-701 in the second half of 2020. We plan to advance INZ-701 into two separate Phase 1/2 clinical trials, one in patients with ENPP1 deficiency in the United States and in Europe and another in patients with ABCC6 deficiency in Europe. The FDA and the European Medicines Agency, or EMA, have granted orphan drug designation to INZ-701 for the treatment of ENPP1 deficiency. Subject to successfully completing clinical development of INZ-701 in these indications, we plan to seek marketing approvals for INZ-701 on a worldwide basis. Beyond our development focus on INZ-701, we believe that our therapeutic approach has the potential to benefit patients suffering from additional diseases of abnormal mineralization, including those without a clear genetic basis.

A metabolic pathway that has been conserved throughout evolution in higher organisms is the key to regulating mineralization in the human body. If the proper function of this pathway is altered or disturbed, then both genetic and non-genetic diseases and conditions involving abnormal mineralization can result. In a properly functioning mineralization pathway, ENPP1 is responsible for converting extracellular molecules of adenosine triphosphate, or ATP, to pyrophosphate, or PPi, a regulator of calcium deposition throughout the body. ENPP1 is also responsible for converting extracellular ATP into a precursor of adenosine, a regulator of neointimal proliferation. A defect in the ENPP1 gene results in low levels of PPi, leading to abnormal mineralization in the vasculature and soft tissues, and in low levels of adenosine, leading to neointimal proliferation and narrowing of blood vessels and potential development of cardiovascular disease. In a properly functioning mineralization pathway, ABCC6 is responsible for transporting ATP from inside a cell to outside the cell. A defect in the ABCC6 gene reduces the extracellular ATP available to be used by ENPP1, thus also resulting in low levels of PPi and adenosine and leading to abnormal mineralization and neointimal proliferation.

ENPP1 and ABCC6 deficiencies are systemic, progressive and continuous diseases occurring over the course of a patient's lifetime, starting as early as fetal development and spanning into adulthood. These diseases represent a significant unmet medical need, with high mortality rates for infants with ENPP1 deficiency and high levels of morbidity occurring for patients with these diseases throughout their life. ENPP1 deficiency is estimated to occur in approximately one in 200,000 births, and we believe there are between 11,000 and 12,000 patients worldwide with ENPP1 deficiency. In the United States, Europe and other major markets, including Australia, Brazil, Canada, Japan and Russia, we believe there are approximately 3,500 patients with ENPP1 deficiency. ABCC6 deficiency is estimated to afflict approximately one per 50,000 individuals, and we believe there are more than 67,000 patients worldwide with ABCC6 deficiency. In the United States, Europe and other major markets, including Australia, Brazil, Canada, Japan and Russia, we believe there are approximately 20,000

patients with ABCC6 deficiency. There are currently no approved therapies for either ENPP1 or ABCC6 deficiency. Currently available treatments are only palliative, seeking to minimize the symptoms of these diseases.

We conducted what we believe is the largest retrospective, cross-sectional natural history study of 127 patients with a presumed diagnosis of ENPP1 deficiency. Preliminary results from this study suggest that the spectrum of manifestations for ENPP1 deficiency includes an infantile phase, a pediatric phase and an adult phase. Infants with ENPP1 deficiency have pathological vascular calcification, which has been referred to in the medical literature as generalized arterial calcification of infancy, or GACI, in which abnormal mineralization and neointimal proliferation result in narrowed blood vessels that can cause heart and kidney failure. Approximately 45% to 50% of infants with ENPP1 deficiency die within 12 months of birth. Children with ENPP1 deficiency who survive beyond infancy develop rickets, which has been referred to in the medical literature as autosomal-recessive hypophosphatemic rickets type 2, or ARHR2. Rickets leads to severe skeletal deformities, short stature, severe bone pain and increased bone fractures. These children also experience continuing vascular and organ calcification. In adults, in addition to further vascular and organ calcification, ENPP1 deficiency manifests as a condition referred to as osteomalacia. Osteomalacia leads to severe bone pain, fatigue, muscle weakness and risk of recurring bone fractures. We plan to conduct a prospective, longitudinal natural history study of patients with ENPP1 deficiency designed to test and validate our findings from the retrospective natural history study.

ABCC6 deficiency is associated with pathological mineralization in blood vessels and soft tissues throughout the body resulting in significant morbidity, including blindness, potentially life-threatening cardiovascular complications and skin calcification. Some infants with ABCC6 deficiency are diagnosed with a vascular calcification condition resembling the acute infantile form of ENPP1 deficiency. In older patients, ABCC6 deficiency presents as pseudoxanthoma elasticum, or PXE, a rare disorder in which individuals develop calcification of soft connective tissues, including in the eyes, cardiovascular system and skin.

Our lead product candidate, INZ-701, targets the restoration of a normal balance in PPi and adenosine. In our preclinical studies conducted in ENPP1-deficient mouse models, dosing with INZ-701 resulted in increased plasma PPi levels, reduction in calcium deposits in a variety of tissues, prevention of calcification in the heart and aorta, and improvements in overall health. In ABCC6-deficient mouse models, dosing with INZ-701 also increased plasma PPi levels. Further, overexpressing ENPP1 in an ABCC6-deficient mouse model reduced calcification in key tissues. In addition to normalizing levels of PPi, in preclinical studies, INZ-701 prevented neointimal proliferation in both wild-type and ENPP1-deficient mice, which we believe is attributable to increased levels of adenosine.

Beyond ENPP1 and ABCC6 deficiencies, we believe that INZ-701 has the potential to provide therapeutic benefit to patients suffering from additional diseases of abnormal mineralization related to low PPi levels and diseases of neointimal proliferation related to low levels of adenosine, including diseases without a clear genetic basis. For example, calciphylaxis, a manifestation of chronic kidney disease, or CKD, may represent a particularly attractive area for drug development for abnormal mineralization. Calciphylaxis is characterized by pathological calcification of the vasculature in the skin and fat leading to blood clots and skin ulcers, likely as a result of low PPi levels. There are currently no approved therapies for calciphylaxis, and the condition has a reported one-year survival rate of approximately 50%. We are currently in the early stages of development of INZ-701 for the treatment of calciphylaxis and are aware of competition at a more advanced stage of clinical development for this disease.

We hold development and commercialization rights to our pipeline and programs, including INZ-701, on a worldwide basis. Our current development programs are protected through exclusive intellectual property rights, including with filed and issued patents covering composition of matter for ENPP1-Fc fusion proteins, including INZ-701, and methods of treatment. We obtained an exclusive, worldwide license to our foundational intellectual property rights from Yale University, or Yale, in January 2017.

We have assembled a leadership team with a strong track record and experience in building and managing biopharmaceutical companies and in rare disease research, development and commercialization. Our executives have experience, in particular, in developing new markets, obtaining marketing approval for and commercializing therapies for rare diseases that had not previously been the focus for drug development. Axel Bolte, our President and Chief Executive Officer and a co-founder of our company, previously had a successful career in healthcare venture capital, investing in and serving on the boards of directors of multiple private and public biopharmaceutical companies. Members of our science and medical leadership team previously led various discovery, development and manufacturing programs at Genzyme Corp., Shire Human Genetic Therapies, BioMarin Pharmaceutical, Inc., Alexion Pharmaceuticals, Inc., Pfizer Inc. and Ultragenyx Pharmaceutical Inc., among other companies. To date, we have funded our operations primarily with proceeds from sales of convertible preferred stock to investors that include Longitude Venture Partners, New Enterprise Associates, Novo Holdings A/S, Pivotal bioVenture Partners, RA Capital Healthcare Fund and Sofinnova Venture Partners.

## Strategy

Our goal is to develop and commercialize safe and effective therapies for the treatment of patients suffering from a broad range of genetic and non-genetic diseases of abnormal mineralization. The critical components of our strategy to achieve this goal include:

- Efficiently advance clinical development for our lead product candidate, INZ-701, with an initial focus on ENPP1 and ABCC6 deficiencies. We have generated robust preclinical proof of concept data and plan to file an IND with the FDA and CTAs with the regulatory authorities in Europe for INZ-701 in the second half of 2020. We plan to advance INZ-701 into two separate Phase 1/2 clinical trials, one in patients with ENPP1 deficiency and another in patients with ABCC6 deficiency. We believe that our clinical strategy of linking the restoration of plasma PPi levels to measures of physiological and clinical efficacy may provide an efficient path for development and availability of clinical data.
- Expand our research and development efforts for INZ-701 in additional diseases of abnormal mineralization and for other therapies beyond INZ-701. Based on its mechanism of action, we believe that INZ-701 has the potential to normalize plasma PPi levels and provide therapeutic benefit to patients beyond those with monogenic defects in the ENPP1 or ABCC6 gene, including patients with calciphylaxis. As a science-driven company, we also plan to continue to apply our expertise to identify and develop new therapeutics for diseases of abnormal mineralization. For example, we are currently exploring the potential for development of a gene therapy for ENPP1 deficiency.
- Establish commercialization infrastructure for the marketing and sale of INZ-701 for rare indications. We hold development and commercialization rights to INZ-701 on a worldwide basis. Given the limited number of specialists who treat the rare diseases we are initially pursuing, we believe that we will be able to commercialize INZ-701, if approved, in these indications with a small, targeted, internal sales and commercial organization in the United States and other major markets. Our executives have a strong track record and experience in developing new markets, obtaining marketing approval for and commercializing therapies for rare diseases that had not previously been the focus for drug development. We may explore the use of a variety of types of collaboration, co-promotion, distribution and other marketing arrangements with one or more third parties to commercialize our product candidates in smaller markets outside the United States or for other situations in which a larger sales and marketing organization is required.
- **Build a patient-focused company to treat diseases of abnormal mineralization.** We intend to continue to engage with patient advocacy groups, medical centers of excellence and medical

specialists in an effort to expeditiously bring our therapy to patients. In building a patient-focused company to address the needs of both genetically defined and broader patient populations, we are working with clinicians and patient organizations to better understand the symptoms and consequences of diseases of abnormal mineralization and to increase awareness of the commonalities among these diseases. We have completed a retrospective, cross-sectional natural history study of patients with ENPP1 deficiency and have several ongoing and planned programs, including a burden of disease study and a prospective natural history study. We believe that the findings from these studies and others like them will be important in supporting future trial design and patient enrollment.

• Continue to expand our scientific understanding of abnormal mineralization, our related intellectual property portfolio and our rights to complementary technologies. We intend to continue to pursue new scientific and therapeutic insights to position ourselves as leaders in the treatment of diseases of abnormal mineralization impacting the vasculature, soft tissue and skeleton. Both in our company laboratory and in collaboration with academic and research institutions, we plan to continue to conduct translational experiments, validate disease models and evaluate new treatment modalities in our area of focus. Our current development programs are protected through exclusive intellectual property rights, including with filed and issued patents covering composition of matter for ENPP1-Fc fusion proteins, including INZ-701, and methods of treatment. We expect to expand the breadth of our intellectual property portfolio over time to incorporate novel insights we obtain through our research. In addition, we may further expand our development pipeline by opportunistically in-licensing or acquiring the rights to complementary technologies and product candidates. For example, in July 2020, we expanded our intellectual property portfolio when we acquired from Alexion Pharmaceuticals, Inc., or Alexion, specified patent rights and other specified assets related to ENPP1.

## **Pipeline**

Our lead development programs, for which we hold development and commercialization rights on a worldwide basis, are summarized in the table below.

			STAGE OF DEVELOPMENT				
PROGRAM	ASSET	Research	IND Enabling	Phase 1/2	Phase 2/3	ANTICIPATED MILESTONE	
GENETIC DISEASES							
ENPP1 Deficiency	INZ-701 (ENPP1-Fc)					File IND and CTA 2H 2020	
ABCC6 Deficiency	INZ-701 (ENPP1-Fc)					File CTA 2H 2020	
ADDITIONAL DISEASES							
Calciphylaxis	INZ-701 (ENPP1-Fc)					Generate pre-clinical proof of concept	
Diseases of Neointimal Proliferation	INZ-701 (ENPP1-Fc)					Generate pre-clinical proof of concept	

## Pathological Diseases of Abnormal Mineralization: A Significant Unmet Need

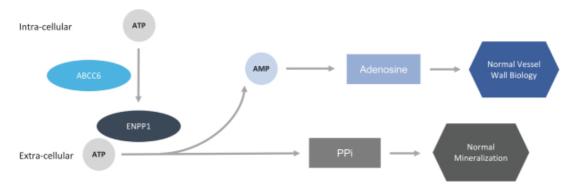
Mineralization is a biological process during which an organism deposits calcium salt crystals, typically calcium polyphosphates, onto an organic extracellular matrix that gives rise to essential structures, such as bone and teeth in humans. In human development, this normal mineralization process begins as early as fetal development and continues throughout life. Diseases of abnormal mineralization have high levels of morbidity and mortality and can have a genetic and non-genetic basis.

### The Mineralization Pathway

A metabolic pathway that has been conserved throughout evolution in higher organisms is the key to regulating mineralization in the human body. Multiple enzymes and other proteins perform sequential reactions in this pathway as part of a normal mineralization process.

In a properly functioning mineralization pathway, the protein encoded by the ABCC6 gene (ATP-Binding Cassette in the C6 family) located on the cellular membrane is responsible for transporting adenosine triphosphate, or ATP, from inside a cell to outside the cell. The enzyme encoded by the ENPP1 gene (ectonucleotide pyrophosphatase/phosphodiesterase 1) then cleaves ATP into pyrophosphate, or PPi, and adenosine monophosphate, or AMP. PPi is a potent regulator of mineralization and, in particular, controls the rate of calcium crystal deposition in bone. AMP is further metabolized into adenosine, a potent regulator of cellular proliferation that, in particular, modulates a blood vessel's response to injury and is responsible for preventing neointimal proliferation, or the overgrowth of smooth muscle cells inside blood vessels.

The normal function of this mineralization pathway is depicted in the figure below.

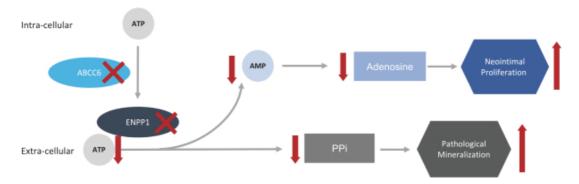


## Pathology of Diseases of Abnormal Mineralization

If the proper function of the key mineralization pathway is altered or disturbed, then both genetic and non-genetic diseases and conditions involving abnormal mineralization can result. Genetic mutations affecting ENPP1, a critical enzyme in the mineralization pathway, result in low levels of PPi and AMP, a precursor of adenosine. Genetic mutations affecting ABCC6, a critical protein in the mineralization pathway, decrease the availability of extracellular ATP required for proper ENPP1 function and give rise indirectly to low levels of PPi and AMP, a precursor of adenosine.

Low levels of PPi lead to abnormal mineralization and pathological calcification in areas of the body where it should not occur, referred to as ectopic calcification. This ectopic calcification occurs in the vasculature and soft tissue, including multiple organ systems, and results in disease. The heart, kidney and skin are especially vulnerable to the effects of abnormal mineralization and pathological, ectopic calcification. Pathological, ectopic calcification in blood vessels inside bones can also interfere with normal skeletal mineralization. Low levels of adenosine lead to the narrowing and obstruction of blood vessels caused by neointimal proliferation and potential development of cardiovascular disease. ENPP1 and ABCC6 deficiencies are systemic, progressive and continuous diseases occurring over the course of a patient's lifetime, starting as early as fetal development and spanning into adulthood.

The consequences of genetic mutations affecting either ENPP1 or ABCC6 are depicted in the figure below.



## **ENPP1 Deficiency and Disease Manifestations**

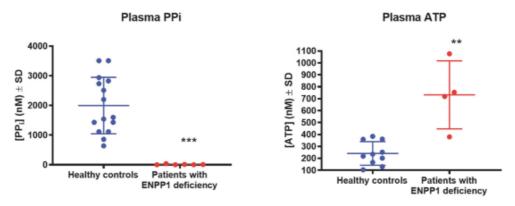
ENPP1 deficiency is a rare, inherited, genetic inborn error of metabolism caused by mutations in the ENPP1 gene. The condition is inherited as a recessive trait in which mutations in the ENPP1 gene result in decreased or absent activity of the ENPP1 enzyme. ENPP1 deficiency results in low plasma levels of PPi and neointimal proliferation, and is a single, systemic, progressive and continuous disease with high mortality and morbidity. The spectrum of manifestations for ENPP1 deficiency includes an infantile phase, a pediatric phase and an adult phase.

In the acute infantile phase, which has been referred to as GACI in the medical literature, ENPP1 deficiency is characterized by narrowing of large and medium arteries caused by severe and pathological vascular calcification and neointimal proliferation, resulting in dysfunction and potential failure of major organs, such as the heart and kidneys. The disease can be diagnosed prenatally when an ultrasound shows characteristic calcifications in the fetus. Infants with ENPP1 deficiency have clinical signs of hypertension, heart disease and kidney disease even at birth. Mortality caused by ENPP1 deficiency is at the highest during the infantile phase and occurs predominantly in the first 12 months of life. Approximately 45% to 50% of infants with ENPP1 deficiency die within 12 months of birth. If they survive the crisis of infancy during the first 12 months of life, individuals with ENPP1 deficiency are likely to survive through adolescence and beyond, but with significant morbidity and a low quality of life.

In the progressive pediatric phase, in addition to continuing vascular and organ calcification, ENPP1 deficiency is characterized by the onset of rickets, which has been referred to in the medical literature as autosomal-recessive hypophosphatemic rickets type 2, or ARHR2. The continuing calcification of arteries in bones induces the bone to produce a hormone known as fibroblast growth factor-23 (FGF23), which in turn causes the kidneys to waste phosphate, giving rise to rickets. Rickets leads to severe skeletal deformities, short stature, severe bone pain and increased risk of bone fractures. In addition, children with ENPP1 deficiency may experience excess calcification in joints and dental problems caused by deformities in the growth of adult teeth. Early onset of hearing loss has also been reported in these children. Patients with pediatric ENPP1 deficiency experience impaired growth and development and generally decreased quality of life, including impaired activities of daily living.

In the adult phase following closure of the bone growth plates at the end of adolescence, in addition to continuing vascular and organ calcification, ENPP1 deficiency manifests as osteomalacia. Osteomalacia leads to severe bone pain, fatigue, muscle weakness and risk of recurring bone fractures. Adults with ENPP1 deficiency experience significant functional and cognitive impairment and generally decreased quality of life, including impaired activities of daily living.

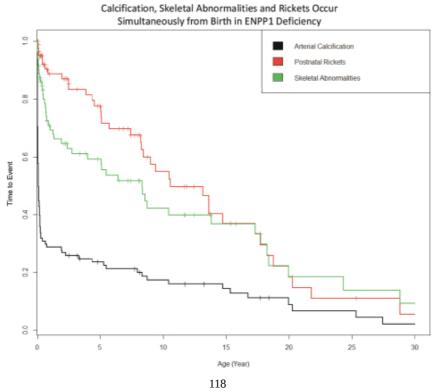
The graphs below, adapted from a third-party study, show that patients with ENPP1 deficiency have decreased levels of PPi and elevated levels of ATP in the plasma. This study measured plasma levels of PPi and plasma levels of ATP in healthy volunteers between 19 and 40 years of age and in patients with ENPP1 deficiency between the ages of one month and 19 years of age. A p-value is a conventional statistical method for measuring the statistical significance of clinical results. A p-value of less than 0.05 is generally considered to represent statistical significance, meaning that there is a less than 5% likelihood that the observed results occurred by chance. Values are presented as the mean ± standard deviation (SD). In these graphs, the symbol \*\* represents a p-value of less than 0.005 and the symbol \*\*\* represents a p-value of less than 0.001.



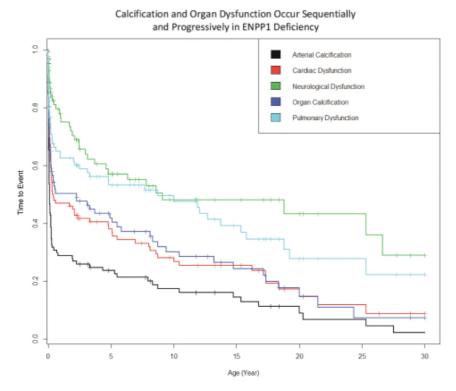
# Retrospective Natural History Study

We conducted what we believe is the largest retrospective, cross-sectional, natural history study of infants, children and adults with a presumed diagnosis of ENPP1 deficiency, including subjects with the acute form of ABCC6 deficiency who may have been diagnosed as ENPP1 infants. The U.S. National Institutes of Health, or NIH, and the University of Münster in Germany contributed data on 127 subjects across 18 countries to this natural history study. Preliminary results from the study suggest that ENPP1 deficiency, regardless of its phenotypic manifestation or original diagnosis as GACI or ARHR2, appears to be a systemic, progressive and continuous disease that occurs over the course of a patient's lifetime.

As shown in the graph below, in our natural history study, arterial calcification preceded skeletal abnormalities, which preceded postnatal rickets. This data is shown using a Kaplan–Meier curve, also known as the product limit estimator, a non-parametric statistic used to estimate the probability of an event occurring given a defined time frame. While they occur at a defined rate, these manifestations occur simultaneously and concurrently following birth. The data indicate that the condition referred to as GACI in the medical literature is not independent of the condition referred to as ARHR2 in the medical literature. Preliminary results from our study suggest that arterial calcification and rickets are inseparable and dependent phenomena of ENPP1 deficiency.



The data also suggest that patients who survive their first 12 months of life continue developing a systemic, progressive disease involving arterial, skeletal and other organ calcifications, leading to physiological dysfunction across many systems. The graph below shows the Kaplan–Meier curve demonstrating systemic progression of the disease. The following manifestations of disease occur in progression: arterial calcification, cardiac dysfunction, organ calcification, pulmonary dysfunction and neurological dysfunction.



The data suggest that arterial calcification, organ calcification and organ dysfunction proceed in a progressive manner, with organ-specific symptoms emerging sequentially with time well into adulthood.

Based on our retrospective natural history study, we believe that ENPP1 deficiency is characterized by concurrent onset of manifestations, albeit at different rates, and that ENPP1 deficiency is a systemic, progressive and continuous disease.

We plan to conduct a prospective, longitudinal natural history study of patients with ENPP1 deficiency designed to test and validate our findings from the retrospective natural history study.

## ENPP1 Deficiency Incidence and Prevalence; Current Standard of Care

ENPP1 deficiency is estimated to occur in approximately one in 200,000 births, and we believe there are between 11,000 and 12,000 patients worldwide with ENPP1 deficiency. In the United States, Europe and other major markets, including Australia, Brazil, Canada, Japan and Russia, we believe there are approximately 3,500 patients with ENPP1 deficiency. There are approximately 200 published cases of ENPP1 deficiency in the medical literature. To gather more information about patient symptoms and diagnoses of ENPP1 deficiency, we conducted an online physician survey in 2019. In our survey, which included select physician specialties in the United States, Canada and five major European countries, we identified 623 alive patients in these countries

affected by ENPP1 deficiency following completion of 1,001 patient surveys. We have also completed an epidemiological study that projects the worldwide prevalence of ENPP1 deficiency. Based on this study and our physician survey, we believe that there are approximately 11,850 patients worldwide with ENPP1 deficiency.

There are currently no approved therapies for ENPP1 deficiency. Currently available treatments are only palliative, seeking to minimize the symptoms of this disease. Some retrospective studies have reported potential therapeutic effect in infants of the bisphosphonate etidronate that is normally used to treat osteoporosis. However, these findings have been controversial due to selection bias in the study. In addition, etidronate has been discontinued in the United States, and bisphosphonate use generally has been further associated with longer term adverse effects on skeletal development. Administration of vitamin D3, oral phosphate and other agents are sometimes used to alleviate signs and symptoms of ENPP1 deficiency, although oral phosphate can actually increase the risk of pathological calcification. In a third-party healthy volunteer study, treating PPi deficiency by adjusting the diet was an inefficient process, with only a small fraction of dietary PPi being absorbed.

# ABCC6 Deficiency and Disease Manifestations

ABCC6 deficiency is a rare, inherited, genetic inborn error of metabolism caused by mutations in the ABCC6 gene. The systemic and progressively debilitating condition is inherited as a recessive trait in which mutations in the ABCC6 gene result in decreased or absent activity of the ABCC6 protein.

ABCC6 deficiency results in low plasma levels of PPi and is associated with pathological mineralization in blood vessels and soft tissues throughout the body, resulting in significant morbidity, including blindness, potentially life-threatening cardiovascular complications and skin calcification. The pathological mineralization associated with ABCC6 deficiency is the result of ectopic calcification in elastic fibers. Elastic fibers are a component of connective tissue, which provides strength and flexibility to structures throughout the body. Ectopic calcification can affect function in elastic fibers in the eyes, blood vessels and skin, and less frequently in other areas such as the digestive tract.

Some infants with ABCC6 deficiency are diagnosed with a vascular calcification condition resembling the acute infantile form of ENPP1 deficiency. In older patients, ABCC6 deficiency presents as pseudoxanthoma elasticum, or PXE, a rare disorder in which individuals develop calcification of soft connective tissues, including in the eyes, cardiovascular system and skin.

Individuals with PXE often have abnormalities in the eyes, such as a change in the pigmented cells of the retina or angioid streaks that occur when tiny cracks form in the elastic membrane, referred to as Bruch's membrane, under the retina. Subsequent bleeding and scarring of the retina known as choroidal neovascularization may also occur, which together with the damage to Bruch's membrane can cause vision loss. A recent report stated that 37% of PXE patients over the age of 50 experienced visual impairment and 15% were legally blind. Pathological mineralization of the blood vessels that carry blood from the heart to the rest of the body may cause other signs and symptoms of PXE. Ectopic calcification narrows blood vessels, particularly in the lower extremities, and leads to claudication, characterized by cramping and pain during exercise due to decreased blood flow to the arms and legs. Individuals with PXE may also have yellowish bumps called papules on their neck, underarms and other areas of the skin surrounding joint bends. These papules are painful, can impair joint movement and are an indication of a general systemic pathological soft tissue calcification process.

Neointimal proliferation is also a pathophysiological feature of PXE. Narrowing of blood vessels accelerates in PXE patients, resulting in higher than normal cardiovascular incidents, such as ischemic stroke and early myocardial infarctions. The number of PXE patients with cardiovascular involvement is estimated at more than 21,000 worldwide. Bleeding in the gastrointestinal tract, in particular the stomach, has been reported to occur in approximately 13% of PXE patients.

## ABCC6 Deficiency Incidence and Prevalence; Current Standard of Care

ABCC6 deficiency is estimated to afflict approximately one per 50,000 individuals, with the disease being diagnosed twice as frequently in females as in males, and we believe there are more than 67,000 patients worldwide with ABCC6 deficiency. In the United States, Europe and other major markets, including Australia, Brazil, Canada, Japan and Russia, we believe there are approximately 20,000 patients with ABCC6 deficiency.

There are currently no approved therapies for ABCC6 deficiency. Currently available treatments are only palliative, seeking to minimize the symptoms of this disease. Ophthalmic symptoms are typically treated with intravitreal injections of vascular endothelial growth factor inhibitors to slow the progression of choroidal neovascularization. However, damage to Bruch's membrane in these patients leads to continued and recurring choroidal neovascularization, causing vision loss. The current treatment approach for slowing or limiting the cardiovascular manifestations of PXE is based on the reduction of cardiovascular risk factors through lifestyle changes or in some cases by taking cholesterol-lowering agents. In the event of severe vascular disease, patients may undergo standard surgical bypass or angioplasty procedures.

## Non-genetic Implications of Pathological Mineralization

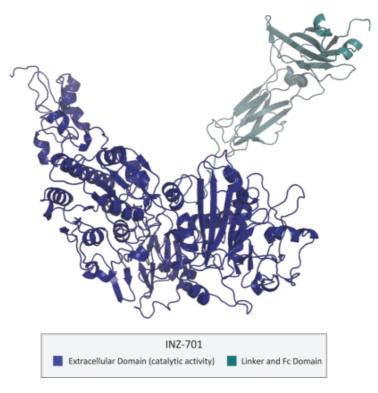
Abnormal mineralization and neointimal proliferation may also manifest in non-genetic diseases, such as calciphylaxis. Calciphylaxis, a manifestation of CKD, is associated with low levels of PPi and is characterized by pathological calcification of the vasculature in the skin and fat leading to blood clots and skin ulcers. This disease has a reported one-year survival rate of approximately 50%. Calciphylaxis affects between 1% and 4% of patients with end stage renal disease. The estimated incidence of calciphylaxis is at least 1,800 new patients per year in the United States. There are currently no approved therapies for calciphylaxis, although use of sodium thiosulfate, a chelating agent intended to lower calcium content in the blood, reportedly ameliorates symptoms. Patients also are often advised to maintain a low phosphate diet. Neointimal proliferation in the vasculature is a hallmark of a number of non-genetic diseases in which arteries have been damaged or disrupted by insertion of a stent, bypass graft occlusion, transplant vasculopathy or inflammation known as arteritis.

**Our Solution: INZ-701** 

# Overview of INZ-701

INZ-701 is a soluble, recombinant, or genetically engineered, protein containing the extracellular domain of native human ENPP1 fused, or linked, to the Fc domain, or crystallizable fragment, of the immunoglobulin IgG1. In its native form, ENPP1 is a transmembrane enzyme with a modular structure consisting of a short intracellular domain, a single transmembrane domain and an extracellular domain that contains a conserved catalytic site responsible for enzymatic activity. ENPP1 is expressed predominantly in the liver and, to a lesser extent, in the kidney and bone. INZ-701 contains the extracellular soluble domain of ENPP1 fused to the Fc domain of IgG1 to minimize immunogenicity, stabilize the construct, increase the plasma half-life and allow ease of purification.

The presumed crystal structure of INZ-701 is depicted in the figure below.



INZ-701 is designed to replace the lost enzymatic function of genetically deficient ENPP1 by restoring the normal balance in PPi and adenosine for ENPP1 deficiency and providing therapeutic effect to treat other diseases, like ABCC6 deficiency, involving low PPi levels. In contrast to native ENPP1, INZ-701 is a soluble protein that is designed to circulate throughout the body and access extracellular ATP and other nucleotide proteins. Like native ENPP1, INZ-701 cleaves ATP into PPi and AMP, a precursor of adenosine. Pharmacologically, INZ-701 is designed to have prolonged distribution and elimination phases, leading to steady-state concentrations in the blood over time and making dosing possible at infrequent intervals, potentially as long as weekly. INZ-701 is formulated for subcutaneous delivery.

In our preclinical studies conducted in ENPP1-deficient mouse models, dosing with INZ-701 resulted in increased plasma PPi levels, reduction in ectopic calcium deposits in a variety of tissues, prevention of calcification in the heart and aorta, and improvements in overall health. In ABCC6-deficient mouse models, dosing with INZ-701 also increased plasma PPi levels. Further, overexpressing ENPP1 in an ABCC6-deficient mouse model reduced calcification in key tissues. In addition to normalizing levels of PPi, in preclinical studies, INZ-701 prevented neointimal proliferation in both wild-type and ENPP1-deficient mice, which we believe is attributable to increased levels of adenosine. The nonclinical INZ-701 toxicology studies that we conducted in two animal species showed no systemic adverse effects at doses that significantly exceeded potential human doses.

The FDA and EMA have granted orphan drug designation to INZ-701 for the treatment of ENPP1 deficiency.

#### INZ-701: Preclinical Results and Data

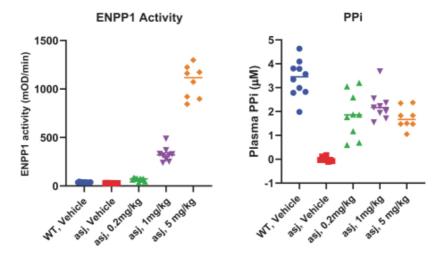
We determined preclinical proof of concept for INZ-701 using multiple mouse models containing inactivated genes for ENPP1. In these ENPP1-deficient mouse models, the animals have an increased propensity for vascular calcification and replicate key aspects of human disease due to ENPP1 deficiency. For example, an *asj* mouse contains a missense mutation in the ENPP1 gene and develops severe vascular calcification. In these mice, vascular calcification develops in newborn pups beginning around two weeks of age to fourteen weeks of age. This vascular calcification resembles that seen in human disease in infants due to ENPP1 deficiency, although in humans, extensive vascular calcification begins as early as fetal development.

In our preclinical studies, we also used an ABCC6 mouse model with targeted ablation of the ABCC6 gene. In these mice, ectopic calcification in tissues resembles that seen in human disease due to ABCC6 deficiency. ABCC6 is primarily expressed in the liver. In mice, ABCC6 is responsible for approximately 90% of the levels of extracellular ATP, the primary source of extracellular PPi. Mice in which the gene for ABCC6 has been inactivated exhibit significantly reduced levels of extracellular PPi in blood.

### Increase in PPi

As a result of an ENPP1 gene deletion, *asj* mice have very low or nondetectable levels of circulating PPi. Treatment of these mice with 0.2 mg/kg, 1 mg/kg or 5 mg/kg of INZ-701 by subcutaneous injection every other day for a period of eight weeks led to significant increases in ENPP1 enzyme activity and PPi levels in plasma to approximately wild-type levels. These increases compensated for the loss of ENPP1 activity in this strain of mice. Mice treated with vehicle control did not exhibit similar increases.

The results of these initial studies are shown in the graphs below.



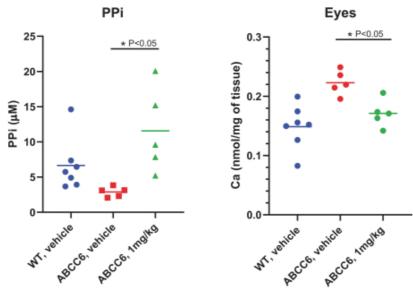
In addition to its ability to increase PPi levels in ENPP1-deficient mice, these initial studies showed that it is possible to administer doses of INZ-701 that normalized PPi levels in mice. We believe that increasing the amount of ENPP1 enzymatic activity by administration of INZ-701 could lead to further increases of PPi. We further believe this suggests that ENPP1 has the potential to provide therapeutic benefit in non-genetic diseases that involve ectopic calcification.

INZ-701 needs to show an impact on individuals who do and do not have mutations in the gene. We believe that our preclinical findings provide strong support for the eventual use of INZ-701 to treat patients with

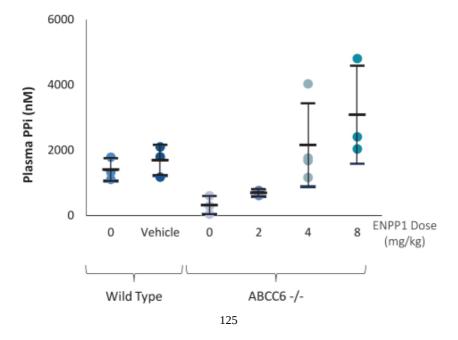
ABCC6 deficiency. Individuals with PXE have dysfunctional ABCC6 and decreased levels of plasma PPi due to deficiencies in exporting ATP from within the cell. In studies in mice with defects in the ABCC6 gene, plasma PPi levels are significantly reduced from wild-type mice but still higher than those seen in *asj* mice, which have an inactivated ENPP1 gene. In other studies, overexpression of ENPP1 in *asj* mice containing inactivated ENPP1 normalized plasma PPi levels. Addition of the same transgene of ENPP1 in ABCC6 mutant mice normalized PPi levels, suggesting that even in the case of limiting extracellular ATP, an increase in ENPP1 activity led to the formation of additional PPi.

Studies in mice with a genetic defect in ABCC6 led to the hypothesis that low levels of plasma PPi in patients with ABCC6 deficiency contributes to ectopic calcification. In studies in ABCC6-deficient mice, vascular calcification was correlated with plasma PPi level, with high levels of PPi resulting in significant reductions in cardiac calcium deposits. We believe this finding confirms the link between ABCC6, PPi and calcification. It also suggests that increasing plasma PPi in PXE patients offers potentially significant therapeutic benefit.

To further illustrate the potential of our approach, we dosed ABCC6-deficient mice with 1 mg/kg of INZ-701 and vehicle control for eight weeks. Treatment with INZ-701 resulted in an increase in plasma PPi levels consistent with those in normal healthy mice. The increase in plasma PPi levels was also associated with a decrease in pathological calcification of the eye, a target organ for ABCC6 deficiency and patients with PXE. The results of this study are shown in the graphs below. We believe these data support the use of INZ-701 in patients who carry mutations in the gene for ABCC6 and have soft tissue calcification due to low PPi levels.

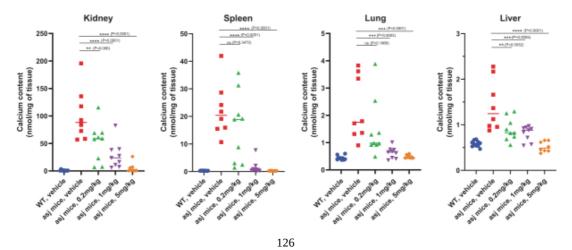


The above findings in ABCC6-deficient mice were also observed in another study, as shown in the graph below, where doses of mENPP1-Fc, a research version of INZ-701 containing a mouse Fc domain, ranging from 2 mg/kg to 8 mg/kg increased plasma PPi levels to wild-type levels. We believe that the data from these two studies in ABCC6-deficient mice suggest the potential of ENPP1-Fc fusion proteins to increase plasma PPi levels and thereby reduce abnormal tissue calcification.

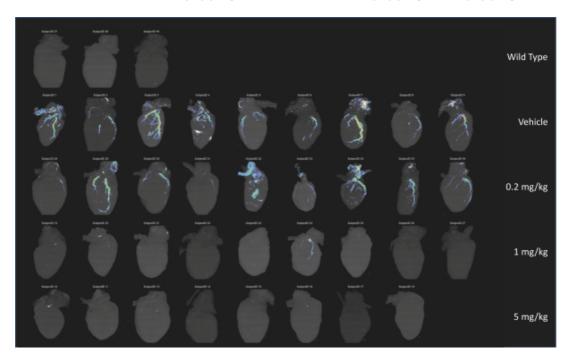


# Reduction of Calcification

Asj mice fed a diet rich in phosphorous and low in magnesium, referred to as an acceleration diet, develop a number of complications due to calcification defects. These defects limit their locomotion, restrict their growth, cause vascular calcium deposits and lead to a shortened lifespan. We dosed mice on the acceleration diet, starting at week two, with both INZ-701 and vehicle control every other day for eight weeks. INZ-701 delivered to asj mice at doses of 0.2 mg/kg, 1 mg/kg and 5 mg/kg significantly reduced ectopic calcification in the kidney, spleen, lung and liver. As shown in the graph below, treatment with as little as 0.2 mg/kg of INZ-701 reduced calcium deposits in all tissues, and mice treated with 5 mg/kg of INZ-701 showed no differences in calcification compared to wild-type controls.

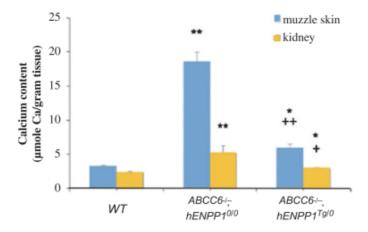


We obtained evidence of changes in vascular calcification in *asj* mice on the acceleration diet by carrying out scans of the heart and aorta using a technique known as high resolution micro computed tomography, or micro CT. All nine *asj* mice dosed with vehicle control showed variable but extensive calcification in the aorta, coronary artery and heart. All nine *asj* mice dosed with 0.2 mg/kg of INZ-701 showed a pattern and intensity of calcification signals similar to that shown when mice were dosed with vehicle control. In almost all cases, increasing the dose of INZ-701 to 1 mg/kg or 5 mg/kg completely prevented calcification in the heart and in the aorta. Only one out of nine mice from the 1 mg/kg group showed some evidence of cardiovascular calcification. Treatment with 5 mg/kg of INZ-701 completely prevented calcification in the heart and aorta in all eight mice dosed in the 5 mg/kg group. The dose response and degree of calcification measured by micro CT of the heart and aorta for each mouse in this study are illustrated below in increasing shades of blue and green. We believe these results suggest that INZ-701 may have the ability to significantly reduce the extent of ectopic calcification due to ENPP1 deficiency. In the study represented by the illustration below, the p-value for the degree of calcification for *asj* mice dosed with INZ-701 compared to *asj* mice dosed with vehicle control was 0.5341 for the 0.2 mg/kg group and 0.0004 for both the 1 mg/kg group and 5 mg/kg group.



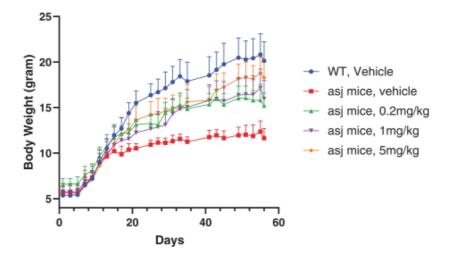
To investigate whether increasing plasma PPi levels would prevent ectopic calcification in ABCC6-deficient mice, ABCC6-deficient mice were crossed with a transgenic mouse with ubiquitous overexpression of human ENPP1 (the ABCC6 -/- hENPP1tg/0 group in the graph below) and the results were compared to mice without overexpression of ENPP1 (the ABCC6-/- hENPP10/0 group in the graph below) and wild-type mice. At 12 weeks of age, all of the mice were euthanized and the mineralization and blood biochemistry was measured. In this study, ABCC6 deficiency in either the ENPP1 overexpression group or the group without ENPP1 overexpression caused significantly increased muzzle skin and kidney calcification. However, ENPP1 overexpression in an ABCC6-deficient mouse caused a significant reduction in the extent of calcification noted in the muzzle skin and kidney compared to control animals in which ENPP1 was not overexpressed. In addition, levels of plasma PPi in the ENPP1 overexpression ABCC6-deficient mice compared to wild-type mice and were significantly elevated compared to the ABCC6 mice without overexpression of ENPP1. This increase in plasma PPi levels in the ABCC6-deficient mice with ENPP1 overexpressed contributed to the reduction in pathological tissue calcification. We believe these data support our findings in the ABCC6-deficient mouse showing increases

in plasma PPi levels described above. In particular, we believe that these data suggest that ABCC6 deficiency contributes to increased ectopic calcification and that ENPP1, through PPi, may be able to reduce the extent of calcification. In this graph, the symbol \*\* represents a p-value of less than 0.01 from wild-type, the symbol \* represents a p-value of less than 0.01 from the ABCC6-/- hENPP10/0 group and the symbol + represents a p-value of less than 0.01.



Overall Health and Survival

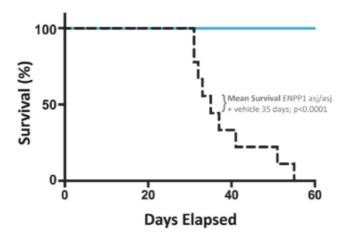
In addition to the measured changes in calcium deposition, treatment of *asj* mice with 0.2 mg/kg, 1 mg/kg or 5 mg/kg of INZ-701 and vehicle control every other day also led to improvements in overall health. Mice treated with INZ-701 had a dose-dependent increase in body weight compared to mice treated with vehicle control, whose average weight at 27 to 56 days was only 60% that of wild-type mice. Compared to *asj* mice treated with vehicle control, mice treated with INZ-701 at 1 mg/kg and 5 mg/kg showed significant increases in body weight. The results of this study are shown in the graph below.



In addition to body weight, treatment of *asj* mice with INZ-701 at 1 mg/kg and 5 mg/kg every other day led to improvement in a number of clinical signs associated with ENPP1 deficiency in mice, including pinned

ear, hunched back, stilted and stiff legs, dehydration and rough hair coat. Treatment with INZ-701 also prevented *asj* mice from early mortality associated with becoming moribund.

In another experiment, we treated mice with either 1 mg/kg of mENPP1-Fc, a research version of INZ-701 containing a mouse Fc domain, or vehicle control starting on the fourteenth day of life and until day 55. In this experiment, all eight mice treated with mENPP1-Fc survived the full 55 days of the trial (represented by the blue line in the graph below), while the median lifespan of the untreated mice decreased from 58 days to 35 days (represented by the black hatched line in the graph below).

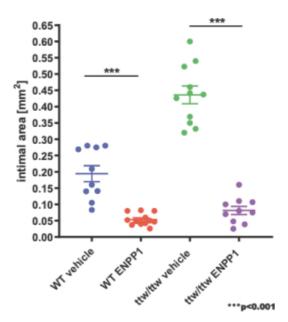


In another experiment, we treated *asj* mice with 0.2 mg/kg, 1 mg/kg or 5 mg/kg of INZ-701 and vehicle control for 56 days to analyze by micro CT the femora and tibiae bones and measure both trabecular number and cortical thickness, which are two important contributors of a bone's strength. The strength of a bone and its ability to resist fracture is dependent upon these two parameters. Treatment of *asj* mice with INZ-701 corrected bone defects, leading to a dose-dependent increase in bone length, trabecular number and cortical thickness as compared to *asj* mice treated with vehicle control.

## Neointimal Proliferation

Neointimal proliferation resulting from ENPP1 deficiency was also replicated in corresponding animal models. In animal models, neointimal proliferation is accelerated during conditions of injury including ligation of the artery. The exact mechanism linking ENPP1 to neointimal proliferation is under investigation, but is believed to directly involve the adenosine pathway.

The increase in neointimal proliferation can be observed in a strain of ENPP1-deficient mice known as *ttw/ttw* mice in a carotid artery ligation model. These mice have a single base pair change in the ENPP1 gene producing ENPP1 deficiency. Following carotid injury where the carotid artery was ligated, the *ttw/ttw* mice were treated with 10 mg/kg of INZ-701 or vehicle control every other day for seven days pre-ligation surgery and for 14 days post-surgery. Vehicle control-treated *ttw/ttw* mice showed a significant increase in neointimal proliferation in the area of the artery at the sites of ligation. We believe these data, shown in the graph below, confirm that the INZ-701 treatment aligns with the earlier published findings indicating that ENPP1 treatment in mice inhibited ligation-induced neointimal proliferation in wild-type mice without ENPP1 deficiency. These important findings in wild-type mice suggest that increasing levels of ENPP1 above normal may be useful in diseases in which vascular neointimal proliferation is increased. We plan to conduct studies in large animal models designed to confirm these findings regarding neointimal proliferation.



To further evaluate INZ-701's effects on neointimal proliferation, we conducted a pilot study in a swine model. In this study, three pigs underwent surgery in which stents were inserted into the coronary, profunda and femoral arteries. At day 14, the stents were re-injured with balloon dilation to initiate additional neointimal proliferation at the stented arterial sites. The sites were then evaluated with angiography and optimal coherence tomography, or OCT. We dosed the pigs with vehicle control and 10 mg/kg of INZ-701 every four days, with the first dose administered on day 10. At day 42, the pigs again underwent angiography and OCT, and quantification of neointimal proliferation was performed in the OCT images and compared to the day 14 OCT evaluation.

In this study, INZ-701 significantly (p<0.05) inhibited stenosis or neointimal proliferation in the profunda artery over 28 days. These results in a large animal model of neointimal proliferation support the results from the studies in the mouse model of neointimal proliferation. We plan to conduct additional studies in a swine model with larger sample sizes to further evaluate the potential effects of INZ-701 at inhibiting neointimal proliferation due to arterial injury.

Safety and Toxicology

We have evaluated INZ-701 in toxicology studies in rats, mice and non-human primates. In rats and non-human primates, we evaluated INZ-701 in a single ascending dose study designed to evaluate a maximum

tolerated dose of INZ-701 of 180 mg/kg and in a multiple ascending dose study at 100 mg/kg of INZ-701. In these studies, no systemic adverse effects or pathological effects were noted with INZ-701. We subsequently evaluated INZ-701 in two 28 days studies in non-human primates with doses of INZ-701 of 30 mg/kg given every other day. In these studies, there were no adverse events and the histology and clinical pathology were normal. Because both non-human primates and mice are relevant species, based on gene sequence homology and biologic activity, we conducted 28-day IND-enabling studies in both species. In these studies, there were no adverse events and we observed normal histopathology and clinical pathology. In addition, we conducted a central nervous system and respiratory risk study in mice. In this study, there were no adverse effects up to the highest dose tested of 30 mg/kg of INZ-701. Overall, in our nonclinical toxicology studies, INZ-701 exhibited a good safety profile and an acceptable therapeutic index.

# Clinical Development Plans for ENPP1 Deficiency

We plan to file an IND with the FDA and a CTA with regulatory authorities in Europe for INZ-701 in the second half of 2020 to allow us to initiate clinical development for the treatment of ENPP1 deficiency. Subject to our IND and CTA becoming effective, we plan to conduct a Phase 1/2 clinical trial of INZ-701 designed as an open-label, dose-escalation trial in adult patients with ENPP1 deficiency in the United States and in Europe. We expect to enroll nine patients in this trial for dosing over a period of seven weeks. The Phase 1/2 clinical trial will primarily investigate the safety and tolerability of INZ-701 and characterize its pharmacokinetic and pharmacodynamic profile, including plasma PPi levels, to establish a recommended dosing regimen. Secondary endpoints will include assessment of immunogenicity and other biochemical and physiological biomarkers associated with ENPP1 deficiency. We plan to collect data from patients that will help characterize physiological and clinical outcomes relevant to patients in a given stage of disease.

If a safe dose is identified for further development, we plan to conduct Phase 2/3 clinical trials of INZ-701 in adult, infant and pediatric patient populations with ENPP1 deficiency. We intend to design these Phase 2/3 clinical trials as pivotal trials for registrational purposes. Many companies pursuing marketing approval for enzyme replacement therapies in rare diseases have followed a similar clinical development strategy.

Prior to initiating these Phase 2/3 clinical trials, we plan to engage with the regulatory authorities in the United States, Europe and other jurisdictions to determine appropriate primary efficacy endpoints and other requirements for potential marketing approval. In particular if we propose new or novel endpoints or methodologies for our clinical trials, regulatory authorities will ultimately need to conclude that the endpoints of our clinical trials have provided clinically meaningful results before we are able to obtain potential marketing approval. We anticipate that data from our Phase 1/2 clinical trial will provide background information useful in the design of our planned Phase 2/3 clinical trials. If successful, the Phase 1/2 clinical trial would allow us to obtain evidence of the mechanism of action of INZ-701 through restoration of plasma PPi levels. Our clinical strategy, subject to ongoing discussions with the regulatory authorities in the United States, Europe and other jurisdictions, is to pursue registration of INZ-701 for ENPP1 deficiency by linking the restoration of plasma PPi levels to measures of physiological and clinical efficacy in this patient population.

The FDA and EMA have granted orphan drug designation to INZ-701 for the treatment of ENPP1 deficiency.

## Clinical Development Plans for ABCC6 Deficiency

We plan to file a CTA with the regulatory authorities in Europe for INZ-701 in the second half of 2020 to allow us to initiate clinical development for the treatment of ABCC6 deficiency. Subject to our CTA becoming effective, we plan to conduct a Phase 1/2 clinical trial of INZ-701 designed as an open-label, dose-escalation trial in adult patients with ABCC6 deficiency in Europe. We expect to enroll nine patients in this trial for dosing over a period of seven weeks. The Phase 1/2 clinical trial will primarily investigate the safety and tolerability of INZ-701 and characterize its pharmacokinetic and pharmacodynamic profile, including plasma PPi levels, to

establish a recommended dosing regimen. Secondary endpoints will include assessment of immunogenicity and other biochemical and physiological biomarkers associated with ABCC6 deficiency.

If a safe dose is identified for further development, we plan to conduct a Phase 2/3 clinical trial of INZ-701 in adults with ABCC6 deficiency. We intend to design this Phase 2/3 clinical trial as a pivotal trial for registrational purposes. Prior to initiating this Phase 2/3 clinical trial, we plan to engage with the regulatory authorities in the United States, Europe and other jurisdictions to determine appropriate primary efficacy endpoints and other requirements for potential marketing approval. In particular if we propose new or novel endpoints or methodologies for our clinical trials, regulatory authorities will ultimately need to conclude that the endpoints of our clinical trials have provided clinically meaningful results before we are able to obtain potential marketing approval. We anticipate that data from our Phase 1/2 clinical trial will provide background information useful in the design of our planned Phase 2/3 clinical trial. If successful, the Phase 1/2 clinical trial would allow us to obtain evidence of the restoration of plasma PPi levels. Our clinical strategy, subject to ongoing discussions with the regulatory authorities in the United States, Europe and other jurisdictions, is to pursue registration of INZ-701 for ABCC6 deficiency by linking the restoration of plasma PPi levels to measures of physiological and clinical efficacy in this patient population.

### Other Potential Indications for INZ-701

Based on its mechanism of action, we believe that INZ-701 has the potential to normalize plasma PPi levels and provide therapeutic benefit to patients beyond those with monogenic defects in the ENPP1 or ABCC6 gene.

We intend to explore the potential of INZ-701 as a therapy in other, non-genetic diseases of abnormal mineralization associated with low levels of PPi. Calciphylaxis, a manifestation of chronic kidney disease, is a non-genetic condition associated with vascular calcification and low PPi levels with a reported one-year survival rate of approximately 50%. The estimated incidence of calciphylaxis is at least 1,800 new patients per year in the United States. There are currently no approved therapies for calciphylaxis, although use of sodium thiosulfate, a chelating agent intended to lower calcium content in the blood, reportedly ameliorates symptoms. Patients are often also advised to maintain a low phosphate diet. We are collaborating with a major academic institution to confirm that PPi levels are low in patients with calciphylaxis and to investigate associated manifestations that may be treated with INZ-701.

Diseases of neointimal proliferation include diseases without a clear genetic basis. In preclinical studies, INZ-701 prevented neointimal proliferation in both wild-type and ENPP1-deficient mice, which we believe is attributable to increased levels of adenosine. We plan to continue to explore the potential of INZ-701 in non-genetic diseases in which arteries have been damaged or disrupted by insertion of a stent, bypass graft occlusion, transplant vasculopathy or inflammation known as arteritis.

### **ENPP1 Gene Therapy**

We plan to continue to develop new and innovative therapies to treat ENPP1 and ABCC6 deficiencies. We believe we are well-positioned to do so because of our in depth knowledge of the biological pathways involved in mineralization and of diseases of abnormal mineralization. For example, we have identified gene therapy constructs in our enzyme replacement therapy program that have shown restoration and sustained enzyme activity leading to normalization of plasma PPi levels in preclinical experiments without adverse effects. Our results to date encourage us to continue to optimize our gene therapy constructs as a potential new modality to treat diseases of abnormal mineralization impacting the vasculature, soft tissue and skeleton, in furtherance of our mission to become leaders in the treatment of such diseases.

## **Manufacturing and Supply**

While we have personnel with substantial manufacturing experience, we do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on

third parties for the manufacture of both drug substance and finished drug product for INZ-701 and any future product candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates receive marketing approval. We also rely on these third parties for packaging, labeling, sterilization, storage, distribution and other production logistics. We have only limited supply agreements in place with respect to our product candidates, and these arrangements do not extend to commercial supply. We obtain supplies of drug substance and finished drug product for INZ-701 on a purchase order basis. We do not have long term committed arrangements with respect to any of our product candidates or other materials.

Manufacturing biologics is complex, especially in large quantities. Biologic products must be made consistently and in compliance with a clearly defined manufacturing process. We have obtained from our third-party manufacturers a supply of INZ-701 that we believe is sufficient for our currently planned clinical trials of INZ-701 for ENPP1 and ABCC6 deficiencies. However, we are continuing the process of scaling up our manufacturing processes and capabilities with our third-party manufacturers to support longer term clinical development. In addition, if we receive marketing approval for any of our product candidates, we will need to establish an agreement for commercial manufacture with a third party. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If any of our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement or be unable to reach agreement with an alternative manufacturer.

### Commercialization

We hold development and commercialization rights to our pipeline and programs, including INZ-701, on a worldwide basis. At this stage, we have not yet established our own commercial organization or distribution capabilities because our product candidates are still in preclinical development. We believe that we will be able to commercialize INZ-701, if approved, for ENPP1 or ABCC6 deficiency with a small, targeted, internal sales and commercial organization in the United States and other major markets. We may explore the use of a variety of types of collaboration, co-promotion, distribution and other marketing arrangements with one or more third parties to commercialize our product candidates in smaller markets outside the United States or for other situations in which a larger sales and marketing organization is required.

We intend to continue to engage with patient advocacy groups, medical centers of excellence and medical specialists in an effort to expeditiously bring our therapy to patients.

# Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, expertise, scientific knowledge and intellectual property provide us with competitive advantages, we face and will continue to face competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Moreover, our industry is characterized by the existence of large numbers of patents and frequent allegations of patent infringement.

The key competitive factors affecting the success of our product candidates, if approved, are likely to be their efficacy, safety, convenience and price, the level of competition and the availability of coverage and adequate reimbursement from third-party payors. If any of our product candidates are approved and successfully commercialized, it is likely that we will face increased competition as a result of other companies pursuing development of products to address similar diseases.

There are currently no approved therapies for the treatment of either ENPP1 or ABCC6 deficiency. Currently available treatments are only palliative, seeking to minimize the symptoms of these diseases. Although a number of companies generally are pursuing development of different enzyme replacement therapies or treatments for vascular calcification disorders and many other companies are focused on rare disease markets, we are not aware of any product candidate currently in clinical development for either ENPP1 or ABCC6 deficiency. SNF472, a calcification inhibitor, is currently in Phase 3 clinical development for calciphylaxis by Sanifit, and Inositec has product candidates in preclinical development for calcification inhibitors.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We may pursue the in-license or acquisition of rights to complementary technologies and product candidates on an opportunistic basis. The acquisition and licensing of technologies and product candidates is a competitive area, and a number of more established companies also have similar strategies to in-license or acquire technologies and product candidates that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to in-license or acquire the relevant technology or product candidate on terms that would allow us to make an appropriate return on our investment.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. Because of our primary focus on rare diseases, if our product candidates achieve marketing approval, we expect to seek premium pricing.

### **Yale University License Agreement**

In January 2017, we entered into a license agreement with Yale, which was amended in May 2020 and July 2020, pursuant to which Yale granted us (1) an exclusive, worldwide license, with specified rights to sublicense, under Yale's interest in specified intellectual property rights and materials for specified therapeutic and prophylactic products, (2) a nonexclusive, worldwide license under Yale's interest in the same intellectual property rights and materials for specified diagnostic products, and (3) a nonexclusive, worldwide license under Yale's interest in specified know-how for specified products, in each case that use any ectonucleotide pyrophosphatase/phosphodiesterase enzymes, or ENPPs, or an agonist or antagonist of ENPP, its receptors, substrates, or ENPP enzymatic products, subject to certain exceptions. These licensed intellectual property rights, materials and know-how arose, and may in the future continue to arise, primarily from research conducted by Dr. Demetrios Braddock and members of his laboratory at Yale. During the period in which Professor Braddock serves as a member of our scientific advisory board or has another arrangement with us pursuant to which he

provides regular advice to us or has an active consulting arrangement with us, and so long as he is an employee or faculty member (including emeritus faculty member) at Yale, Yale is restricted from granting any third party any rights for any therapeutic or prophylactic uses for any ENPP technology made, created, developed, discovered, conceived or first reduced to practice by or on behalf of Professor Braddock or his laboratory. Under the license agreement, we are obligated to use commercially reasonable efforts to pursue development and commercialization of specified ENPP products and licensed methods.

Pursuant to the license agreement, as partial upfront consideration, we paid to Yale approximately \$60,000, which amount reflected unreimbursed patent expenses incurred by Yale prior to the date of the license agreement. We are responsible for paying Yale an annual license maintenance fee in varying amounts throughout the term ranging from the low tens of thousands of dollars to the high tens of thousands of dollars. As of March 31, 2020, we have incurred a total of \$42,500 in license maintenance fees to Yale. We are required to pay Yale \$3.0 million, based on the achievement of a specified net product sales milestone or specified development and commercialization milestones, for each therapeutic and prophylactic licensed product developed. We are required to pay Yale an amount in the several hundreds of thousands of dollars, based on the achievement of a specified net product sales milestone or specified development and commercialization milestones, for each diagnostic licensed product developed. While the agreement remains in effect, we are required to pay Yale low single-digit percentage royalties on aggregate worldwide net sales of certain licensed products, which may be subject to reductions. Yale is guaranteed a minimum royalty payment amount (ranging in dollar amounts from the mid six figures to low seven figures) for each year after the first sale of a therapeutic or prophylactic licensed product that results in net sales. Yale is guaranteed a minimum royalty payment amount (ranging from the low tens of thousands of dollars to the mid tens of thousands of dollars) for each year after the first sale of a diagnostic licensed product that results in net sales. Such minimum royalty payment amounts are summed for each year after the first sale of both a therapeutic or prophylactic licensed product and a diagnostic licensed product has occurred. We must also pay Yale a percentage in the twenties of certain types of income we receive from sublicensees. We are also responsible for costs relating to the prosecution and maintenance of the licensed patents. Finally, subject to certain conditions, all payments due by us to Yale will be tripled following any patent challenge or challenge to a claim by Yale that a product is a licensed product under the agreement made by us against Yale if Yale prevails in such challenge.

We have also agreed to pay for ENPP research support from Yale pursuant to a sponsored research agreement that we entered into with Yale in January 2017 and amended in February 2019. Under the sponsored research agreement, as amended, we agreed to pay Yale an aggregate of \$2.4 million over five years, ending in the fourth quarter of 2021, and as of March 31, 2020, we had paid Yale an aggregate of approximately \$1.7 million. The research is performed by and under the supervision and direction of Professor Braddock for so long as he is employed by Yale.

The license agreement remains in effect until the latest of, on a country-by-country basis, (a) the date on which the last claim of the licensed patents in such country expires; (b) 10 years after the last licensed know-how, licensed materials or licensed methods have been provided to us by Yale; and (c) 10 years after the first sale of a specified ENPP product; but in no event later than the date that is 30 years after the effective date of the agreement. We may terminate the agreement for Yale's uncured material breach of the agreement, we may terminate the agreement for convenience upon six months' prior notice, and Yale may terminate the agreement for our uncured material breach of certain provisions or if we fail to make a payment when due, fail to obtain or maintain adequate insurance coverage or fail to engage in specified development and regulatory activities. For example, Yale would have the right to terminate the license agreement if we do not file an IND for INZ-701 with the FDA on or before December 31, 2020. The agreement will automatically terminate if we become insolvent or the subject of a bankruptcy event. Upon termination for any reason other than Yale's breach of the agreement, in certain circumstances, Yale is permitted to use all regulatory approvals of, or clinical trials or other studies conducted by or on behalf of us on, and all filings made by or on behalf of us with regulatory agencies with respect to, certain licensed technology.

## **Alexion Intellectual Property Asset Acquisition**

In July 2020, we entered into an intellectual property asset purchase agreement with Alexion pursuant to which Alexion sold and assigned to us Alexion's right, title and interest in and to specified patent rights and other specified assets solely related to ENPP1. We issued 8,294,360 shares of our Series A-2 Convertible Preferred Stock to Alexion in consideration for the sale and assignment to us of such assets. Under the intellectual property asset purchase agreement, we also granted a non-exclusive license to Alexion and its affiliates to continue to use the assets we acquired for Alexion's and its affiliates' internal, non-clinical research purposes. In addition, subject to certain specified qualifications set forth in the intellectual property assets purchase agreement, Alexion is obligated to assign to us its rights with respect to any other assets owned by it that are solely related to ENPP1.

# **Intellectual Property**

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to the development of our business, including by seeking, maintaining and defending patent rights, whether developed internally or licensed from third parties. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain our proprietary position in our field. Additionally, we intend to rely on regulatory protection afforded through rare drug designations, data exclusivity and market exclusivity as well as patent term extensions, where available.

Our future commercial success depends, in part, on our ability to: obtain, maintain and enforce patent and other proprietary protection in the United States and other countries for commercially important technology, inventions and know-how related to our business; defend and enforce in our intellectual property rights, in particular our patents rights; preserve the confidentiality of our trade secrets; and operate without infringing, misappropriating or violating the valid and enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell or importing our products may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patent positions of pharmaceutical and biotechnology companies like ours are generally uncertain and can involve complex legal, scientific and factual issues. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. We also cannot ensure that patents will issue with respect to any patent applications that we or our licensors may file in the future, nor can we ensure that any of our owned or licensed patents or future patents will be commercially useful in protecting our product candidates and methods of manufacturing the same. In addition, the coverage claimed in a patent application may be significantly reduced before a patent is issued, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that any of our products will be protected or remain protectable by enforceable patents. Moreover, any patents that we hold may be challenged, circumvented or invalidated by third parties. See "Risk Factors—Risks Related to Our Intellectual Property" for a more comprehensive description of risks related to our intellectual property.

We generally file patent applications directed to our key programs in an effort to secure our intellectual property positions with respect to these programs. As of July 17, 2020, we owned or possessed exclusive rights to approximately 15 issued U.S. patents, six pending U.S. provisional patent applications, 10 pending U.S. non-provisional patent applications, nine issued foreign patents (including 2 issued European patents), 35 pending foreign patent applications, and three pending Patent Cooperation Treaty applications. As of July 17, 2020, we co-own with a third party three of the aforementioned pending patent applications and have an exclusive option to acquire a worldwide royalty-bearing license of all of such party's rights in one of the aforementioned pending U.S. provisional patent applications. In addition, as of July 17, 2020, we owned approximately two pending U.S. trademark applications, one pending foreign trademark application and one foreign registered trademark application.

#### INZ-701

The intellectual property portfolio for INZ-701, our most advanced program, as of July 17, 2020, is summarized below. Prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the U.S. Patent and Trademark Office may be significantly narrowed before issuance, if issued at all. We expect this may be the case with respect to some of our pending patent applications referred to below.

Currently, our patent protection includes patents and patent applications that we have exclusively licensed under our license agreement with Yale. This licensed patent portfolio includes:

- A patent family that includes five issued U.S. patents and one allowed U.S. application relating to: (1) reducing and/or preventing progression of pathological calcification, (2) reducing or preventing ectopic calcification of soft tissue, (3) reducing or preventing pathological ossification, (4) treating, reversing or preventing progression of ossification of the posterior longitudinal ligament, (5) treating aging-related hardening of arteries; and (6) reducing or preventing progression of chronic kidney disease, end-stage renal disease, calcific uremic arteriolopathy, and calciphylaxis, and a pending patent application relating to ameliorating vascular calcification in a human subject having a genetic defect that affects the function, activity and/or expression of the ENPP1 polypeptide. All such methods of treatment involve administration of soluble ENPP1 that lacks a bone targeting domain. These U.S. patents and pending applications that mature to patents are expected to expire in 2034, absent any term adjustments or extensions. Corresponding foreign applications have been filed and are pending in Europe, Japan, and Hong Kong.
- A patent family that includes an issued U.S. patent covering certain compositions that contain ENPP1, including INZ-701. This U.S. patent is expected to expire in 2036, absent any term adjustments or extensions. Corresponding foreign applications have been filed and are pending in Europe, Japan, Australia, Canada, Brazil, India, Hong Kong, South Korea, Mexico, New Zealand, and Russia.

#### Other

Through our acquisition of intellectual property assets from Alexion, we have acquired, among other assets:

- A patent family that includes one issued European patent relating to polypeptides comprising ENPP1 and the therapeutic use of such
  polypeptides, such as in the treatment of generalized arterial calcification of infancy. This European patent is expected to expire in 2031,
  absent any term adjustments or extensions.
- A patent family that includes two issued U.S. patents relating to compositions and fusion proteins comprising ENPP1 and a targeting
  moiety. These U.S. patents are expected to expire in 2031, absent any term adjustments or extensions.
- A patent family that includes one issued U.S. patent relating to methods for reducing vascular calcification in a subject with below normal
  plasma pyrophosphate or above normal serum phosphate by administering to the subject soluble ENPP1. This patent is expected to expire
  in 2035, absent any term adjustments or extensions.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application.

In the United States, the term of a patent covering an FDA-approved drug may, in certain cases, be eligible for a patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 as compensation for the loss of patent term during the FDA regulatory review process. The period of extension may be up to five years, but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and in certain other jurisdictions to extend the term of a patent that covers an approved drug. It is possible that issued U.S. patents covering the use of INZ-701 and products from our intellectual property may be entitled to patent term extensions. If our use of product candidates or the product candidate itself receive FDA approval, we intend to apply for patent term extensions, if available, to extend the term of patents that cover the approved use or product candidate. We also intend to seek patent term extensions in any jurisdictions where available, however, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

In addition to patent protection, we rely upon unpatented trade secrets and confidential know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and confidential know-how are difficult to protect. We seek to protect our proprietary information, in part, using confidentiality agreements with any collaborators, scientific advisors, employees and consultants and invention assignment agreements with our employees. We also have agreements requiring assignment of inventions with selected consultants, scientific advisors and collaborators. These agreements may not provide meaningful protection. These agreements may also be breached, and we may not have an adequate remedy for any such breach. In addition, our trade secrets and confidential know-how may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain or use information that we regard as proprietary. Although we take steps to protect our proprietary information, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information. See "Risk Factors—Risks Related to our Intellectual Property" for a more comprehensive description of risks related to our intellectual property.

## **Government Regulation**

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, pricing, reimbursement, sales, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products, including biological products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

### Licensure and Regulation of Biologics in the United States

In the United States, our product candidates would be regulated as biological products, or biologics, under the Public Health Service Act, or PHSA, and the Federal Food, Drug and Cosmetic Act, or FDCA, and its implementing regulations and guidances. The failure to comply with the applicable U.S. requirements at any time during the product development process, including preclinical testing, clinical testing, the approval process, or post-approval process, may subject an applicant to delays in the conduct of the study, regulatory review, and approval, and/or administrative or judicial sanctions. These sanctions may include, but are not limited to, the FDA's refusal to allow an applicant to proceed with clinical testing, refusal to approve pending applications, license suspension, or revocation, withdrawal of an approval, warning letters, adverse publicity, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, and civil or criminal

investigations, and penalties brought by the FDA or the Department of Justice, or DOJ, and other governmental entities, including state agencies.

An applicant seeking approval to market and distribute a new biologic in the United States generally must satisfactorily complete each of the following steps:

- preclinical laboratory tests, animal studies, and formulation studies all performed in accordance with the FDA's Good Laboratory Practices, or GLP, regulations;
- completion of the manufacture, under current Good Manufacturing Practices, or cGMP, conditions, of the drug substance and drug product that the sponsor intends to use in human clinical trials along with required analytical and stability testing;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin;
- · approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, potency, and purity of the product candidate for
  each proposed indication, in accordance with current Good Clinical Practices, or GCP;
- preparation and submission to the FDA of a biologics license application, or BLA, for a biologic product requesting marketing for one or
  more proposed indications, including submission of detailed information on the manufacture and composition of the product in clinical
  development and proposed labelling;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with cGMP requirements and to assure that the facilities, methods, and controls are adequate to preserve the product's identity, strength, quality, and purity;
- satisfactory completion of any FDA audits of the preclinical studies and clinical trial sites to assure compliance with GLP, as applicable, and GCP, and the integrity of clinical data in support of the BLA;
- payment of user Prescription Drug User Free Act, or PDUFA, securing FDA approval of the BLA and licensure of the new biologic product; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and any post-approval studies or other post-marketing commitments required by the FDA.

Preclinical Studies and Investigational New Drug Application

Before testing any biologic product candidate in humans, the product candidate must undergo preclinical testing. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate the potential for efficacy and toxicity in animal studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application.

An IND is an exemption from the FDCA that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer such investigational product to humans. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product or conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trials can begin or recommence.

As a result, submission of the IND may result in the FDA not allowing the trials to commence or allowing the trial to commence on the terms originally specified by the sponsor in the IND. If the FDA raises concerns or questions either during this initial 30-day period, or at any time during the IND process, it may choose to impose a partial or complete clinical hold. Clinical holds are imposed by the FDA whenever there is concern for patient safety and may be a result of new data, findings, or developments in clinical, preclinical, and/or chemistry, manufacturing, and controls. This order issued by the FDA would delay either a proposed clinical trial or cause suspension of an ongoing trial, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigations may proceed. This could cause significant delays or difficulties in completing our planned clinical trial or future clinical trials in a timely manner.

Expanded Access to an Investigational Drug for Treatment Use

Expanded access, sometimes called "compassionate use," is the use of investigational products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. The rules and regulations related to expanded access are intended to improve access to investigational products for patients who may benefit from investigational therapies. FDA regulations allow access to investigational products under an IND by the company or the treating physician for treatment purposes on a case-by-case basis for: individual patients (single-patient IND applications for treatment in emergency settings and non-emergency settings); intermediate-size patient populations; and larger populations for use of the investigational product under a treatment protocol or treatment IND application.

When considering an IND application for expanded access to an investigational product with the purpose of treating a patient or a group of patients, the sponsor and treating physicians or investigators will determine suitability when all of the following criteria apply: patient(s) have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; the potential patient benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context or condition to be treated; and the expanded use of the investigational drug for the requested treatment will not interfere initiation, conduct, or completion of clinical investigations that could support marketing approval of the product or otherwise compromise the potential development of the product.

There is no obligation for a sponsor to make its drug products available for expanded access; however, as required by the 21st Century Cures Act, or Cures Act, passed in 2016, if a sponsor has a policy regarding how it responds to expanded access requests, it must make that policy publicly available. Although these requirements were rolled out over time, they have now come into full effect. This provision requires drug and biologic companies to make publicly available their policies for expanded access for individual patient access to products intended for serious diseases. Sponsors are required to make such policies publicly available upon the earlier of initiation of a Phase 2 or Phase 3 trial; or 15 days after the investigational drug or biologic receives designation as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy.

In addition, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances,

eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a manufacturer to make its investigational products available to eligible patients as a result of the Right to Try Act.

Human Clinical Trials in Support of a BLA

Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease or condition to be treated under the supervision of a qualified principal investigator in accordance with GCP requirements. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, inclusion and exclusion criteria, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. When a foreign clinical trial is conducted under an IND, all FDA IND requirements must be met unless waived. When a foreign clinical trial is not conducted under an IND, the sponsor must ensure that the trial complies with certain regulatory requirements of the FDA in order to use the trial as support for an IND or application for marketing approval. Specifically, the FDA requires that such trials be conducted in accordance with GCP, including review and approval by an independent ethics committee and informed consent from participants. The GCP requirements encompass both ethical and data integrity standards for clinical trials. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical trials, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign trials are conducted in a manner comparable to that required for clinical trials in the United States.

Further, each clinical trial must be reviewed and approved by an IRB either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors, the safety of human subjects, and the possible liability of the institution. An IRB must operate in compliance with FDA regulations. The FDA, IRB, or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements or that the participants are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP rules and the requirements for informed consent.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board, or DSMB. This group may recommend continuation of the trial as planned, changes in trial conduct, or cessation of the trial at designated check points based on certain available data from the trial to which only the DSMB has access. Finally, research activities involving infectious agents, hazardous chemicals, recombinant DNA, and genetically altered organisms and agents may be subject to review and approval of an Institutional Biosafety Committee, or IBC, in accordance with NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may be required after approval.

- *Phase 1* clinical trials are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion, and pharmacodynamics in healthy humans or, on occasion, in patients, such as cancer patients.
- Phase 2 clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate
  the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2
  clinical trials may

be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trials.

• *Phase 3* clinical trials proceed if the Phase 2 clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population to further evaluate dosage, provide substantial evidence of clinical efficacy, and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites. A well-controlled, statistically robust Phase 3 trial may be designed to deliver the data that regulatory authorities will use to decide whether or not to approve, and, if approved, how to appropriately label a biologic; such Phase 3 studies are referred to as "pivotal."

In some cases, the FDA may approve a BLA for a product but require the sponsor to conduct additional clinical trials to further assess the product's safety and effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 clinical trials. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of biologics approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement or to request a change in the product labeling. The failure to exercise due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval for products.

Under the Pediatric Research Equity Act of 2003, a BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

For products intended to treat a serious or life-threatening disease or condition, the FDA must, upon the request of an applicant, meet to discuss preparation of the initial pediatric study plan or to discuss deferral or waiver of pediatric assessments. In addition, FDA will meet early in the development process to discuss pediatric study plans with sponsors and FDA must meet with sponsors by no later than the end-of-phase 1 meeting for serious or life-threatening diseases and by no later than 90 days after FDA's receipt of the study plan.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in the Food and Drug Administration Safety and Innovation Act, or the FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Information about applicable clinical trials must be submitted within specific timeframes to the NIH for public dissemination on its ClinicalTrials.gov website.

Compliance with cGMP Requirements

Before approving a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes

and facilities are in full compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The PHSA emphasizes the importance of manufacturing control for products like biologics whose attributes cannot be precisely defined.

Manufacturers and others involved in the manufacture and distribution of products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Any product manufactured by or imported from a facility that has not registered, whether foreign or domestic, is deemed misbranded under the FDCA. Establishments may be subject to periodic unannounced inspections by government authorities to ensure compliance with cGMPs and other laws. Inspections must follow a "risk-based schedule" that may result in certain establishments being inspected more frequently. Manufacturers may also have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

## Review and Approval of a BLA

The results of product candidate development, preclinical testing, and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of a BLA requesting license to market the product. The BLA must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling as well as payment of a user fee. Under federal law, the submission of most BLAs is subject to an application user fee, which for federal fiscal year 2020 is \$2,942,965 for an application requiring clinical data. The sponsor of a licensed BLA is also subject to an annual program fee, which for fiscal year 2020 is \$325,424. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for certain small businesses.

The FDA has 60 days after submission of the application to conduct an initial review to determine whether it is sufficient to accept for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under the PDUFA, the FDA has ten months in which to complete its initial review of a standard application and respond to the applicant, and six months for a priority review of the application. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs. The review process may often be significantly extended by FDA requests for additional information or clarification. The review process and the PDUFA goal date may be extended by three months if the FDA requests or if the applicant otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure, and potent, and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure, and potent. On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA audits of preclinical and clinical trial sites to assure compliance with GCPs, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. If the application is not approved, the FDA will issue a complete response letter, which will contain the conditions that must be met in order to secure final approval of the application, and when possible will outline recommended actions the sponsor might take to obtain approval of the application. Sponsors that receive a complete response letter may submit to the FDA information that represents a complete response to the issues identified by the FDA. Such resubmissions are classified under PDUFA as either Class 1 or Class 2. The classification of a resubmission is based on the information submitted by an applicant in response to an action letter. Under the goals and policies agreed to by the FDA under PDUFA,

the FDA has two months to review a Class 1 resubmission and six months to review a Class 2 resubmission. The FDA will not approve an application until issues identified in the complete response letter have been addressed.

The FDA may also refer the application to an advisory committee for review, evaluation, and recommendation as to whether the application should be approved. In particular, the FDA may refer applications for novel biologic products or biologic products that present difficult questions of safety or efficacy to an advisory committee. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates, and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

If the FDA approves a new product, it may limit the approved indication(s) for use of the product. It may also require that contraindications, warnings, or precautions be included in the product labeling. In addition, the FDA may call for post-approval studies, including Phase 4 clinical trials, to further assess the product's efficacy and/or safety after approval. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing only under certain circumstances, special monitoring, and the use of patent registries. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track, Breakthrough Therapy, Priority Review and Regenerative Medicine Advanced Therapy Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are referred to as fast track designation, breakthrough therapy designation, priority review designation, and regenerative medicine advanced therapy designation.

Specifically, the FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the application is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, in 2012, Congress enacted the FDASIA. This law established a new regulatory scheme allowing for expedited review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development

process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner. This designation also holds the potential for priority review of the investigational product.

Third, the FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

With passage of the Cures Act in December 2016, Congress authorized the FDA to accelerate review and approval of products designated as regenerative medicine advanced therapies. A product is eligible for this designation if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product has the potential to address unmet medical needs for such disease or condition. In a recent guidance on expedited programs for regenerative medicine therapies for serious conditions, FDA specified that its interpretation of the definition of regenerative medicine advanced therapy products includes gene therapies that lead to a sustained effect on cells or tissues, such as *in vivo* AAV vectors delivered to non-dividing cells. The benefits of a regenerative medicine advanced therapy designation include early interactions with FDA to expedite development and review, benefits available to breakthrough therapies, potential eligibility for priority review, and accelerated approval based on surrogate or intermediate endpoints.

# Accelerated Approval Pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used

extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

### Post-Approval Regulation

If regulatory approval for marketing of a product or new indication for an existing product is obtained, the sponsor will be required to comply with all regular post-approval regulatory requirements as well as any post-approval requirements that the FDA have imposed as part of the approval process. The sponsor will be required to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling requirements. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP regulations, which impose certain procedural and documentation requirements upon manufacturers. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with cGMP regulations and other regulatory requirements.

A product may also be subject to official lot release, meaning that the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official lot release, the manufacturer must submit samples of each lot, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot, to the FDA. The FDA may in addition perform certain confirmatory tests on lots of some products before releasing the lots for distribution. Finally, the FDA will conduct laboratory research related to the safety, purity, potency, and effectiveness of pharmaceutical products.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- · restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

Pharmaceutical products may be promoted only for the approved indications and in accordance with the provisions of the approved label. Although healthcare providers may prescribe products for off-label uses in their professional judgment, drug manufacturers are prohibited from soliciting, encouraging or promoting unapproved uses of a product. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

The FDA strictly regulates the marketing, labeling, advertising, and promotion of prescription drug products placed on the market. This regulation includes, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet and social media. Promotional claims about a drug's safety or effectiveness are prohibited before the drug is approved. After approval, a drug product generally may not be promoted for uses that are not approved by the FDA, as reflected in the product's prescribing information. In the United States, healthcare professionals are generally permitted to prescribe drugs for such uses not described in the drug's labeling, known as off-label uses, because the FDA does not regulate the practice of medicine. However, FDA regulations impose rigorous restrictions on manufacturers' communications, prohibiting the promotion of off-label uses. It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in nonpromotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information.

If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the DOJ, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

## Orphan Drug Designation

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the biologic for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation qualifies a company for tax credits and market exclusivity for seven years following the date of the product's marketing approval if granted by the FDA. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. A product becomes an orphan when it receives orphan drug designation from the Office of Orphan Products Development at the FDA based on acceptable confidential requests made under the regulatory provisions. The product must then go through the review and approval process like any other product.

A sponsor may request orphan drug designation of a previously unapproved product or new orphan indication for an already marketed product. In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first drug. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

If a product with orphan designation receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve another sponsor's marketing application for the same product for the same indication for seven years, except in certain limited circumstances. If a product designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second application for the same product for a different use or a second application for a clinically superior version of the product for the same use. The FDA cannot, however, approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor or the sponsor is unable to provide sufficient quantities.

The FDA and EMA have granted orphan drug designation to INZ-701 for the treatment of ENPP1 deficiency. Although we have applied for orphan drug designation from the FDA for INZ-701 for ABCC6 deficiency, our initial application was not granted, though we have received an extension of time to submit an amendment to our application.

## Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity that cover the product are extended by six months.

## Biosimilars and Exclusivity

The 2010 Patient Protection and Affordable Care Act, which was signed into law in March 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA. The BPCIA established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. A biosimilar is a biological product that is highly similar to an existing FDA-licensed "reference product." As of January 1, 2020, the FDA has approved 26 biosimilar products for use in the United States. No interchangeable biosimilars, however, have been approved. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Additional guidances are expected to be finalized by the FDA in the near term.

Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity, and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law. Since the passage of the BPCIA, many states have passed laws or amendments to laws, including laws governing pharmacy practices, which are state-regulated, to regulate the use of biosimilars.

Federal and State Data Privacy and Security Laws

Under the federal Health Insurance Portability and Accountability Act of 1966, or HIPAA, the U.S. Department of Health and Human Services has issued regulations to protect the privacy and security of protected health information used or disclosed by covered entities including certain healthcare providers, health plans, and healthcare clearinghouses. HIPAA also regulates standardization of data content, codes, and formats used in healthcare transactions and standardization of identifiers for health plans and providers. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their regulations, including the omnibus final rule published on January 25, 2013, also imposes certain obligations on the business associates of covered entities that obtain protected health information in providing services to or on behalf of covered entities. In addition to federal privacy regulations, there are a number of state laws governing confidentiality and security of health information that are applicable to our business. In addition to possible federal civil and criminal penalties for HIPAA violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. Accordingly, state attorneys general (along with private plaintiffs) have brought civil actions seeking injunctions and damages resulting from alleged violations of HIPAA's privacy and security rules. New laws and regulations governing privacy and security may be adopted in the future as well.

Additionally, California recently enacted legislation that has been dubbed the first "GDPR-like" law in the United States. Known as the California Consumer Privacy Act, or CCPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA went into effect on January 1, 2020 and requires covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. The CCPA could impact our business activities depending on how it is interpreted and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data and protected health information.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our current or future business activities, including certain clinical research, sales, and marketing practices and the provision of certain items and services to our customers, could be subject to challenge under one or more of such privacy and data security laws. The heightening compliance environment and the need to build and maintain robust and secure systems to comply with different privacy compliance and/or reporting requirements in multiple jurisdictions could increase the possibility that a healthcare company may fail to comply fully with one or more of these requirements. If our operations are found to be in violation of any of the privacy or data security laws or regulations described above that are applicable to us, or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal, civil, and administrative penalties, damages, fines, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements, and/or oversight if we become subject to a consent decree or similar agreement to resolve allegations of non-compliance with these

laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our product candidates, once approved, are sold in a foreign country, we may be subject to similar foreign laws.

### Patent Term Restoration and Extension

In the United States, a patent claiming a new biologic product, its method of use or its method of manufacture may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent extension of up to five years for patent term lost during product development and FDA regulatory review. Assuming grant of the patent for which the extension is sought, the restoration period for a patent covering a product is typically one-half the time between the effective date of the investigational new drug application, or IND, involving human beings and the submission date of the BLA, plus the time between the submission date of the BLA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date in the United States. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension in consultation with the FDA.

# FDA Approval of Companion Diagnostics

In August 2014, the FDA issued final guidance clarifying the requirements that will apply to approval of therapeutic products and *in vitro* companion diagnostics. According to the guidance, for novel drugs, a companion diagnostic device and its corresponding therapeutic should be approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product's labeling. Approval or clearance of the companion diagnostic device will ensure that the device has been adequately evaluated and has adequate performance characteristics in the intended population. In July 2016, the FDA issued a draft guidance intended to assist sponsors of the drug therapeutic and in vitro companion diagnostic device on issues related to co-development of the products.

Under the FDCA, *in vitro* diagnostics, including companion diagnostics, are regulated as medical devices. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution.

The FDA previously has required *in vitro* companion diagnostics intended to select the patients who will respond to the product candidate to obtain pre-market approval, or PMA, simultaneously with approval of the therapeutic product candidate. The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to an application fee. For federal fiscal year 2020, the standard fee is \$340,995 and the small business fee is \$85,249.

## Regulation and Procedures Governing Approval of Medicinal Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety, and efficacy, and governing, among other things, clinical trials, marketing authorization, commercial sales, and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain

the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of preclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication. It also requires the submission to the relevant competent authorities of a marketing authorization application, or MAA, and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union.

## Clinical Trial Approval

Pursuant to the currently applicable Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted, or in multiple member states if the clinical trial is to be conducted in a number of member states. Furthermore, the applicant may only start a clinical trial at a specific site after the competent ethics committee has issued a favorable opinion. The clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the member states and further detailed in applicable guidance documents.

In April 2014, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, but it has not yet become effective. It will overhaul the current system of approvals for clinical trials in the European Union. Specifically, the new legislation, which will be directly applicable in all member states, aims at simplifying and streamlining the approval of clinical trials in the European Union. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure via a single-entry point and strictly defined deadlines for the assessment of clinical trial applications. As of January 1, 2020, the website of the European Commission reported that the implementation of the new Clinical Trials Regulation was dependent on the development of a fully functional clinical trials portal and database, which would be confirmed by an independent audit, and that the new legislation would come into effect six months after the European Commission publishes a notice of this confirmation. The website indicated that the audit was expected to commence in December 2020.

Parties conducting certain clinical trials must, as in the United States, post clinical trial information in the European Union at the EudraCT website: https://eudract.ema.europa.eu.

### PRIME Designation in the EU

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRIority MEdicines, or PRIME, scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated marketing authorization application assessment once a dossier has been submitted. Importantly, a dedicated EMA contact and rapporteur from the Committee for Human Medicinal Products, or CHMP, or Committee for Advanced Therapies are appointed early in the PRIME scheme facilitating increased understanding of the product at the EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

### Marketing Authorization

To obtain a marketing authorization for a product under the European Union regulatory system, an applicant must submit an MAA, either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in European Union Member States (decentralized procedure, national procedure, or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the European Union. Regulation (EC) No 1901/2006 provides that prior to obtaining a marketing authorization in the European Union, an applicant must demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver, or a deferral for one or more of the measures included in the PIP.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all EU member states. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional. Manufacturers must demonstrate the quality, safety, and efficacy of their products to the EMA, which provides an opinion regarding the MAA. The European Commission grants or refuses marketing authorization in light of the opinion delivered by the EMA.

Specifically, the grant of marketing authorization in the European Union for products containing viable human tissues or cells such as gene therapy medicinal products is governed by Regulation 1394/2007/EC on advanced therapy medicinal products, read in combination with Directive 2001/83/EC of the European Parliament and of the Council, commonly known as the Community code on medicinal products. Regulation 1394/2007/EC lays down specific rules concerning the authorization, supervision, and pharmacovigilance of gene therapy medicinal products, somatic cell therapy medicinal products, and tissue engineered products. Manufacturers of advanced therapy medicinal products must demonstrate the quality, safety, and efficacy of their products to EMA which provides an opinion regarding the application for marketing authorization. The European Commission grants or refuses marketing authorization in light of the opinion delivered by EMA.

Under the centralized procedure, the CHMP established at the EMA is responsible for conducting an initial assessment of a product. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

### Regulatory Data Protection in the European Union

In the European Union, new chemical entities approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity pursuant to Regulation (EC) No 726/2004, as amended, and Directive 2001/83/EC, as amended. Data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic (abbreviated) application for a period of eight years. During the additional two-year period of market exclusivity, a generic MAA can be submitted, and the innovator's data may be

referenced, but no generic medicinal product can be marketed until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity so that the innovator gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Patent Term Extensions in the European Union and Other Jurisdictions

The European Union also provides for patent term extension through Supplementary Protection Certificates, or SPCs. The rules and requirements for obtaining a SPC are similar to those in the United States. An SPC may extend the term of a patent for up to five years after its originally scheduled expiration date and can provide up to a maximum of fifteen years of marketing exclusivity for a drug. In certain circumstances, these periods may be extended for six additional months if pediatric exclusivity is obtained, which is described in detail below. Although SPCs are available throughout the European Union, sponsors must apply on a country-by-country basis. Similar patent term extension rights exist in certain other foreign jurisdictions outside the European Union.

## Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a reevaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the drug on the EU market (in the case of the centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid.

## Regulatory Requirements after Marketing Authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include compliance with the European Union's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. In addition, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's good manufacturing practice requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities, and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union under Directive 2001/83EC, as amended.

## Orphan Drug Designation and Exclusivity

Regulation (EC) No 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (1) a life-threatening or chronically debilitating condition

affecting not more than five in 10,000 persons in the European Union when the application is made, or (2) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention, or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the drug will be of significant benefit to those affected by that condition.

An orphan drug designation provides a number of benefits, including fee reductions, regulatory assistance, and the possibility to apply for a centralized European Union marketing authorization. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. During this market exclusivity period, neither the EMA nor the European Commission or the member states can accept an application or grant a marketing authorization for a "similar medicinal product." A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation because, for example, the product is sufficiently profitable not to justify market exclusivity.

Brexit and the Regulatory Framework in the United Kingdom

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. Following protracted negotiations, the United Kingdom left the European Union on January 31, 2020. Under the withdrawal agreement, there is a transitional period until December 31, 2020, which is extendable up to two years. Discussions between the United Kingdom and the European Union have so far mainly focused on finalizing withdrawal issues and transition agreements but have been extremely difficult to date. To date, only an outline of a trade agreement has been reached. Much remains open but the Prime Minister has indicated that the United Kingdom will not seek to extend the transitional period beyond the end of 2020. If no trade agreement has been reached before the end of the transitional period, there may be significant market and economic disruption. The Prime Minister has also indicated that the UK will not accept high regulatory alignment with the European Union.

Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime that applies to products and the approval of product candidates in the United Kingdom. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business.

Furthermore, while the Data Protection Act of 2018 in the United Kingdom that "implements" and complements the EU General Data Protection Regulation, or GDPR, has achieved Royal Assent on May 23, 2018 and is now effective in the United Kingdom, it is still unclear whether transfer of data from the EEA to the United Kingdom will remain lawful under GDPR. During the period of "transition" (i.e., until December 31, 2020), EU law will continue to apply in the UK, including the GDPR, after which the GDPR will be converted into UK law. Beginning in 2021, the UK will be a "third country" under the GDPR. We may, however, incur liabilities, expenses, costs, and other operational losses under GDPR and applicable EU Member States and the United Kingdom privacy laws in connection with any measures we take to comply with them.

## General Data Protection Regulation

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the GDPR, which became effective on May 25, 2018. The

GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR will be a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance.

## Coverage, Pricing, and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may seek regulatory approval by the FDA or other government authorities. In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use any product candidates we may develop unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such product candidates. Even if any product candidates we may develop are approved, sales of such product candidates will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers, and managed care organizations, provide coverage, and establish adequate reimbursement levels for, such product candidates. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover any product candidates we may develop could reduce physician utilization of such product candidates once approved and have a material adverse effect on our sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Third-party reimbursement and coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. In addition, any companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to any companion diagnostics.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of pharmaceuticals have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and

adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Outside the United States, ensuring adequate coverage and payment for any product candidates we may develop will face challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of any product candidates we may develop to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization efforts.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic, and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states, and parallel trade (arbitrage between low-priced and high-priced member states), can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceut

## Healthcare Law and Regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of pharmaceutical products that are granted marketing approval. Arrangements with providers, consultants, third-party payors, and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, reporting of payments to physicians and teaching physicians and patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit
  individuals or entities from, among other things,

knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious, or fraudulent or knowingly making, using, or causing to made or used a false record or statement to avoid, decrease, or conceal an obligation to pay money to the federal government;

- the federal civil monetary penalty and false statement laws and regulations relating to pricing and submission of pricing information for government programs, including penalties for knowingly and intentionally overcharging 340b eligible entities and the submission of false or fraudulent pricing information to government entities;
- HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting
  to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by HITECH, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, on certain covered healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that perform services for them, that involve the use, or disclosure of, individually identifiable health information, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information;
- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the Foreign Corrupt Practices Act, which prohibits companies and their intermediaries from making, or offering or promising to make improper payments to non-U.S. officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, or ACA, as amended by the Health Care Education Reconciliation Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the U.S. Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians, as defined by such law, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring pharmaceutical manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures. In addition, certain state and local laws require drug manufacturers to register pharmaceutical sales representatives. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages,

fines, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations.

### Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States.

By way of example, the United States and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. In March 2010, the United States Congress enacted the ACA, which, among other things, includes changes to the coverage and payment for products under government healthcare programs. Among the provisions of the ACA of importance to our potential product candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents,
   apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain
  individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate
  liability;
- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded
  and generic drugs and revising the definition of "average manufacturer price" for calculating and reporting Medicaid drug rebates on
  outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans;
- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for
  products that are inhaled, infused, instilled, implanted or injected;
- expanded the types of entities eligible for the 340B drug discount program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount off
  the negotiated price of applicable products to eligible beneficiaries during their coverage gap period as a condition for the manufacturers'
  outpatient products to be covered under Medicare Part D;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- the Independent Payment Advisory Board, or IPAB, which has authority to recommend certain changes to the Medicare program to reduce
  expenditures by the program that could result in reduced payments for prescription products. However, the IPAB implementation has been
  not been clearly defined. The ACA provided that under certain circumstances, IPAB recommendations will become law unless Congress
  enacts legislation that will achieve the same or greater Medicare cost savings; and
- established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription product spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation from 2011 to 2019.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2012 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2029 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, which was enacted in January 2013, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers, and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Since enactment of the ACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017, or the TCJA, which was signed by President Trump on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, will become effective in 2019. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. Further, the Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." The Congress may consider other legislation to replace elements of the ACA during the next Congressional session.

The current presidential administration has also taken executive actions to undermine or delay implementation of the ACA. Since January 2017, the president has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than \$12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. This decision is under review by the U.S. Supreme Court during its current term. The full effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

In addition, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. The current presidential administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the same judge issued an order staying the judgment pending appeal. The current presidential administration recently represented to the Court of Appeals considering this judgment that it does not oppose the lower court's ruling. On July 10, 2019, the Court of Appeals for the Fifth Circuit heard oral argument in this case. On December 18, 2019, that court affirmed the lower court's ruling that the individual mandate portion of the ACA is unconstitutional and it remanded the case to the district court for reconsideration of the severability question and additional analysis of the provisions of the ACA. On March 2, 2020, the U.S. Supreme

Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

Further, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. For example, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, Congress and the current presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. For example, on May 11, 2018, the Administration issued a plan to lower drug prices. Under this blueprint for action, the Administration indicated that the Department of Health and Human Services will take steps to end the gaming of regulatory and patent processes by drug makers to unfairly protect monopolies; advance biosimilars and generics to boost price competition; evaluate the inclusion of prices in drug makers' ads to enhance price competition; speed access to and lower the cost of new drugs by clarifying policies for sharing information between insurers and drug makers; avoid excessive pricing by relying more on value-based pricing by expanding outcome-based payments in Medicare and Medicaid; work to give Part D plan sponsors more negotiation power with drug makers; examine which Medicare Part B drugs could be negotiated for a lower price by Part D plans, and improving the design of the Part B Competitive Acquisition Program; update Medicare's drugpricing dashboard to increase transparency; prohibit Part D contracts that include "gag rules" that prevent pharmacists from informing patients when they could pay less out-of-pocket by not using insurance; and require that Part D plan members be provided with an annual statement of plan payments, out-of-pocket spending, and drug price increases. On March 10, 2020, the current presidential administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. In addition, on December 23, 2019, the current presidential administration published a proposed rulemaking that, if finalized, would allow states or certain other non-federal government entities to submit importation program proposals to FDA for review and approval. Applicants would be required to demonstrate their importation plans pose no additional risk to public health and safety and will result in significant cost savings for consumers. At the same time, FDA issued draft guidance that would allow manufacturers to import their own FDA-approved drugs that are authorized for sale in other countries (multi-market approved products).

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

There have been, and likely will continue to be, additional legislative and regulatory proposals at the foreign, federal, and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. Such reforms could have an adverse effect on anticipated revenues from product

candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop product candidates.

## **Employees**

As of July 17, 2020, we had 24 full-time employees, including a total of six employees with M.D. or Ph.D. degrees. Of these full-time employees, 16 are engaged in research and development activities. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

## **Facilities**

Our principal facilities consist of office and laboratory space in Boston, Massachusetts. We occupy approximately 8,499 square feet of office space under a lease that is expected to expire in the second half of 2025 and approximately 3,560 square feet of laboratory space under a lease that expires in August 2020. Beginning in late 2020, we expect to occupy approximately 6,244 square feet of laboratory space under a lease that expires in late 2025. We believe that our facilities are sufficient to meet our current needs.

## **Legal Proceedings**

We are currently not a party to any material legal proceedings.

#### MANAGEMENT

#### **Executive Officers and Directors**

The following table sets forth the name, age as of July 17, 2020 and position of each of our executive officers and directors.

<u>Name</u>	<u>Age</u>	Position Position
Axel Bolte	48	President and Chief Executive Officer, Director
Stephen Basso	54	Senior Vice President, Finance
Henric Bjarke	53	Senior Vice President, Chief Operating Officer
Pedro Huertas	66	Senior Vice President, Chief Medical Officer
Steven Jungles	55	Senior Vice President, Chief Technical Operations Officer
Douglas Treco(3)	62	Chairman
Sarah Bhagat(1)	34	Director
Reinaldo Diaz(2)	66	Director
Martin Edwards(1)(3)	64	Director
Robert Hopfner(2)	48	Director
Edward Mathers(2)(3)	60	Director
Lynne Sullivan(1)	54	Director

- (1) Member of the Audit Committee.
- (2) Member of the Compensation Committee.
- (3) Member of the Nominating and Corporate Governance Committee.

## **Executive Officers**

Axel Bolte has served as our president and chief executive officer and as a member of our board of directors since September 2015, when he co-founded our company. Since March 2017, Mr. Bolte also has served as a managing member of Healthcare Advisors GmbH, a private healthcare advisory company. Mr. Bolte served as a venture partner at HBM Partners AG, a provider of investment advisor services in the life sciences industry, from February 2017 to September 2019 and as an investment advisor to HBM Partners AG from March 2003 to January 2017. Mr. Bolte currently serves on the board of directors of IVERIC bio, Inc. (formerly known as Ophthotech Corporation), or IVERIC, and previously served on the board of directors of Allena Pharmaceuticals, Inc., Nabriva Therapeutics plc and PTC Therapeutics, Inc., all of which are publicly traded biotechnology or pharmaceutical companies. Mr. Bolte received a degree in biochemistry from the Swiss Federal Institute of Technology, Zurich, Switzerland and an M.B.A. from the University of St. Gallen, Switzerland. We believe Mr. Bolte's extensive experience as a venture capital investor in the life sciences industry and his extensive knowledge of our company based on his current role as our chief executive officer qualify him to serve on our board of directors.

Stephen Basso has served as our senior vice president, finance since January 2020. Mr. Basso served as our vice president, finance from October 2017 to January 2020. Prior to joining our company, Mr. Basso held a variety of positions at Alexion Pharmaceuticals, Inc., or Alexion, a pharmaceutical company, including vice president, North America commercial and global general and administrative finance from May 2016 to May 2017, vice president, corporate financial planning and analysis from February 2014 to May 2016, executive director, finance from July 2011 to February 2014 and senior director, finance and planning from January 2009 to July 2011. Prior to joining Alexion, Mr. Basso served in various finance roles at Pfizer Inc., or Pfizer, a pharmaceutical company. Mr. Basso received a B.S. in business from Providence College and an M.B.A. from Boston College.

*Henric Bjarke* has served as our senior vice president and chief operating officer since July 2017. Prior to joining our company, Mr. Bjarke served as senior vice president, chief commercial officer of IVERIC from

September 2015 to April 2017. Mr. Bjarke served as vice president, global metabolic disorders franchise of Alexion from November 2012 to August 2015 and as vice president, North America commercial operations of Alexion from September 2010 to November 2012. Prior to joining Alexion, Mr. Bjarke served in various commercial roles at Watson Pharmaceuticals, Eyetech Pharmaceuticals, Inc. and Pharmacia Corporation. Mr. Bjarke received a B.A. Sc. in business administration and economics from Uppsala University in Sweden.

**Pedro Huertas, M.D., Ph.D.** has served as our senior vice president and chief medical officer since September 2019. Since 2005, Dr. Huertas has also served as managing director of Mirror Neuron Systems, LLC, a consulting company focusing on the biopharmaceutical industry. Prior to joining our company, Dr. Huertas served as chief medical officer of Sentien Biotechnologies, Inc., a biotechnology company, from September 2018 to September 2019 and as chief medical officer of Eloxx Pharmaceuticals, Inc., a pharmaceutical company, from May 2015 to September 2018. Dr. Huertas served as precision medicine clinical lead at Pfizer from March 2014 to May 2015 and as a global medical lead from January 2012 to March 2014. Prior to joining Pfizer, Dr. Huertas served as global medical lead at Shire Human Genetic Therapies, a biopharmaceutical company. Dr. Huertas also served in senior roles at Amicus Therapeutics, Inc., Advanced Cell Technologies, Novazyme Pharmaceuticals and Genzyme Corp. Dr. Huertas received an M.S. in biochemistry from Stanford University, an M.S. in management from the Sloan School of Management at the Massachusetts Institute of Technology, an M.D. from Harvard Medical School and a Ph.D. in cell and developmental biology from Harvard University.

Steven Jungles has served as our senior vice president and chief technical operations officer since May 2017. Mr. Jungles has also served as a consultant to SJJ BioConsulting LLC, a biopharmaceutical consulting company, since April 2015. Mr. Jungles served as senior vice president of technical operations at Ultragenyx Pharmaceutical Inc., a pharmaceutical company, from July 2011 to April 2015, and in various roles at BioMarin Pharmaceutical, Inc., a pharmaceutical company, from 1999 to July 2011. Mr. Jungles received a B.S. in biology from the University of Iowa.

## Non-Employee Directors

**Douglas Treco, Ph.D.** has served as the chairman of our board of directors since May 2020. Dr. Treco co-founded RA Pharmaceuticals, Inc., or RA Pharma, a pharmaceutical company, in 2008, which was acquired by UCB S.A. in April 2020. He has served as the president and chief executive officer of Ra Pharma since June 2008. Dr. Treco served as an entrepreneur-in-residence with Morgenthaler Ventures, a venture capital firm, from January 2008 to May 2014. Dr. Treco served as a visiting scientist in the Department of Molecular Biology at Massachusetts General Hospital and as a lecturer in genetics at Harvard Medical School from 2004 to 2007. Dr. Treco currently serves on the board of directors of CRISPR Therapeutics AG and served on the board of directors of Ra Pharma from June 2008 to April 2020. Dr. Treco received a B.A. in Biology from the University of Delaware and a Ph.D. in biochemistry and molecular biology from the State University of New York, Stony Brook, and performed post-doctoral research at the Salk Institute for Biological Studies and Massachusetts General Hospital. We believe Dr. Treco's extensive and broad range of experience in business and in the biopharmaceutical industry qualifies him to serve on our board of directors.

Sarah Bhagat, Ph.D. has served on our board of directors since March 2019. Dr. Bhagat has served as a partner at Sofinnova Investments, Inc., or Sofinnova, a venture capital firm, since March 2020. She served as principal at Sofinnova from January 2019 to December 2019 and as an associate from May 2017 to December 2018. Dr. Bhagat was a postdoctoral fellow at Stanford University from April 2016 to May 2017. Dr. Bhagat served as a venture fellow at Canaan Partners, a venture capital firm, from February 2015 to February 2016. Dr. Bhagat also served as a research assistant at The Rockefeller University from May 2008 to May 2010 and a clinical research coordinator at Massachusetts General Hospital from June 2007 to May 2008. Dr. Bhagat received a B.A. in biological psychology from Franklin & Marshall College and a Ph.D. in neuroscience from Yale University. We believe Dr. Bhagat's extensive industry experience and her scientific background qualifies her to serve on our board of directors.

Reinaldo M. Diaz has served on our board of directors since January 2017. Mr. Diaz has served as venture partner at Longitude Capital Management Co., LLC, a venture capital firm focusing on healthcare companies, since November 2015. Mr. Diaz has served as the managing member and managing director of DA Advisors, LLC, a financial and strategic consulting company focusing on biopharmaceutical companies, since 2005. Mr. Diaz served as a managing director at Auven Therapeutics, a private equity firm focusing on life sciences from 2008 to 2018. Mr. Diaz served as managing member and co-founder of Diaz & Altschul Capital Management, LLC, an asset management firm focusing on healthcare companies, from 1996 to 2005. Mr. Diaz served as managing director and head of the healthcare group at Schroder Wertheim & Co., Inc. from 1993 to 1996. Mr. Diaz served in various roles at PaineWebber Development Corporation from 1985 to 1993, including as president from 1990 to 1993. Mr. Diaz received a B.A. in general studies from Harvard University and an M.B.A. from Harvard Business School. We believe Mr. Diaz's extensive experience as a venture capital investor in the life sciences industry qualifies him to serve on our board of directors.

*Martin Edwards, M.D.* has served on our board of directors since September 2017. Dr. Edwards is employed on a part-time basis as a senior partner at Novo Holdings A/S, a Danish limited liability company that manages investments and financial assets. He has been employed as a partner or more recently senior partner by Novo Ventures or Novo Holdings A/S since 2003. Dr. Edwards is expected to retire from Novo Holdings A/S in the fall of 2020. Earlier in his career, Dr. Edwards served as chief executive officer of ReNeuron Ltd., a stem cell research company based in the United Kingdom, and as global head of drug development for Novo Nordisk A/S, where he led preclinical and clinical drug development. Dr. Edwards currently serves on the board of directors of KalVista Pharmaceuticals, Inc. and Verona Pharma plc, both publicly traded pharmaceutical companies, and previously served on the board of directors of CoLucid Pharmaceuticals, Inc., a publicly traded pharmaceutical company, from January 2015 to March 2017. Dr. Edwards received an M.B.A. from the University of Warwick in England and an M.D. from the University of Manchester in England. We believe Dr. Edwards is qualified to serve on our board of directors based on his medical background and extensive experience as an investor and executive in the pharmaceutical industry.

Robert Hopfner, Ph.D. has served on our board of directors since November 2018. Dr. Hopfner has served as managing partner of Pivotal bioVenture Partners, a venture capital firm focused on life sciences, since October 2017. Dr. Hopfner served in various roles at Bay City Capital, a venture capital firm focused on life sciences, from August 2002 to October 2017, including as a principal from June 2007 to October 2009 and as managing director and investment partner from October 2009 to October 2017. Dr. Hopfner currently serves on the board of directors of Vaxcyte, Inc., a publicly traded vaccine company. Dr. Hopfner received a B.S. in pharmacy from the University of Saskatchewan, an M.B.A. from the University of Chicago Booth School of Business and a Ph.D. in pharmacology from the University of Saskatchewan. We believe Dr. Hopfner's experience as a venture capital investor in the life sciences industry and his scientific background qualifies him to serve on our board of directors.

Edward Mathers has served on our board of directors since January 2017. Mr. Mathers has served as a general partner at New Enterprise Associates, Inc., or NEA, a private venture capital firm focusing on technology and healthcare investments, since November 2019. He served as partner at NEA from August 2008 to October 2019. Prior to joining NEA, Mr. Mathers served as executive vice president, corporate development and venture at MedImmune, Inc., or MedImmune, a biopharmaceutical company, and led its venture capital subsidiary, MedImmune Ventures, Inc. Mr. Mathers currently serves on the board of directors of Akouos, Inc., ObsEva SA, Rhythm Pharmaceuticals, Inc., Synlogic, Inc. (formerly known as Mirna Therapeutics, Inc.), Trevi Therapeutics, Inc. and Mirum Pharmaceuticals, Inc., all publicly traded pharmaceutical companies, and he previously served on the board of directors of Liquidia Technologies, Inc., a publicly traded life sciences company, from April 2009 to May 2019 and Ra Pharma, a publicly-traded pharmaceutical company, from February 2010 to April 2020. Mr. Mathers received a B.S. in chemistry from North Carolina State University. We believe Mr. Mathers is qualified to serve on our board of directors based on his experience advising pharmaceutical companies as well as his experience as a director of public and private companies in the life sciences industry.

Lynne Sullivan has served on our board of directors since May 2020. Ms. Sullivan expects to join UNITY Biotechnology, Inc., a biotechnology company, as the interim chief financial officer in August 2020. Ms. Sullivan served as chief financial officer of Compass Therapeutics, LLC, a biotechnology company, from December 2018 to August 2019. Ms. Sullivan served in various roles at Biogen Inc., a biotechnology company, including vice president of tax from April 2008 to February 2015, vice president of tax and corporate finance from February 2015 to March 2016 and senior vice president of finance from March 2016 to December 2018. Ms. Sullivan currently serves on the board of directors of Solid Biosciences Inc., a publicly traded biotechnology company, resTORbio, Inc., a publicly traded biopharmaceutical company, and BiomX Inc., a publicly traded biopharmaceutical company. Ms. Sullivan was a certified public accountant for over 20 years. Ms. Sullivan received a B.S.B.A. in Accounting from Suffolk University and an M.S. in Taxation from Bentley University. We believe Ms. Sullivan's extensive financial expertise and her experience working in the healthcare sector qualifies her to serve on our board of directors.

# **Board Composition and Election of Directors**

## **Board Composition**

Our board of directors is currently authorized to have nine members and currently consists of eight members. Our directors hold office until their successors have been elected and qualified or until the earlier of their death, resignation or removal.

Our certificate of incorporation and bylaws that will become effective upon the closing of this offering provide that the authorized number of directors may be changed only by resolution of our board of directors. Our certificate of incorporation and bylaws will also provide that our directors may be removed only for cause by the affirmative vote of the holders of 75% of our shares of capital stock present in person or by proxy and entitled to vote, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

In accordance with the terms of our certificate of incorporation and bylaws that will become effective upon the closing of this offering, our board of directors will be divided into three classes, class I, class II and class III, with members of each class serving staggered three-year terms. Upon the closing of this offering, the members of the classes will be divided as follows:

- the class I directors will be Axel Bolte, Robert Hopfner and Edward Mathers, and their term will expire at the annual meeting of stockholders to be held in 2021;
- the class II directors will be Sarah Bhagat and Reinaldo Diaz, and their term will expire at the annual meeting of stockholders to be held in 2022; and
- the class III directors will be Martin Edwards, Lynne Sullivan and Douglas Treco, and their term will expire at the annual meeting of stockholders to be held in 2023.

Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires.

The classification of our board of directors may have the effect of delaying or preventing changes in our control or management. See the "Description of Capital Stock—Delaware Anti-Takeover Law and Certain Charter and Bylaw Provisions" section of this prospectus for additional information.

# Director Independence

Applicable Nasdaq rules require a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, Nasdaq rules require that, subject to specified

exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under applicable Nasdaq rules, a director will only qualify as an "independent director" if, in the opinion of the listed company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board of directors must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (1) the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director; and (2) whether the director is affiliated with the company or any of its subsidiaries or affiliates.

In June 2020, our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that each of our directors, with the exception of Mr. Bolte, is an "independent director" as defined under applicable Nasdaq rules, including, in the case of all the members of our audit committee, the independence criteria set forth in Rule 10A-3 under the Exchange Act, and in the case of all the members of our compensation committee, the independence criteria set forth in Rule 10C-1 under the Exchange Act. In making such determination, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director. Mr. Bolte is not an independent director under these rules because he is our president and chief executive officer.

There are no family relationships among any of our directors or executive officers.

### **Board Committees**

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which operates under a charter that has been approved by our board of directors.

### **Audit Committee**

The members of our audit committee are Lynne Sullivan, Sarah Bhagat and Martin Edwards. Lynne Sullivan is the chair of the audit committee. Effective upon the effectiveness of the registration statement of which this prospectus is a part, our audit committee's responsibilities will include:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from that firm;

- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- monitoring our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- overseeing our risk assessment and risk management policies;
- establishing procedures for the receipt and retention of accounting related complaints and concerns;
- · meeting independently with our internal auditing staff, if any, our independent registered public accounting firm and management;
- · reviewing and approving or ratifying any related person transactions; and
- preparing the audit committee report required SEC rules.

All audit and non-audit services, other than *de minimis* non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

Our board of directors has determined that Lynne Sullivan is an "audit committee financial expert" as defined in applicable SEC rules and that each of the members of our audit committee possesses the financial sophistication required for audit committee members under Nasdaq rules. We believe that the composition of our audit committee will meet the requirements for independence under current Nasdaq and SEC rules and regulations.

### **Compensation Committee**

The members of our compensation committee are Reinaldo Diaz, Robert Hopfner and Edward Mathers. Reinaldo Diaz is the chair of the compensation committee. Effective upon the effectiveness of the registration statement of which this prospectus is a part, our compensation committee's responsibilities will include:

- reviewing and approving, or making recommendations to our board of directors with respect to, the compensation of our chief executive officer and our other executive officers;
- overseeing an evaluation of our senior executives;
- · overseeing and administering our cash and equity incentive plans;
- reviewing and making recommendations to our board of directors with respect to director compensation;
- reviewing and discussing annually with management our "Compensation Discussion and Analysis" disclosure if and to the extent then
  required by SEC rules; and
- preparing the compensation committee report if and to the extent then required by SEC rules.

We believe that the composition of our compensation committee will meet the requirements for independence under current Nasdaq and SEC rules and regulations.

## Nominating and Corporate Governance Committee

The members of our nominating and corporate governance committee are Douglas Treco, Martin Edwards and Edward Mathers. Douglas Treco is the chair of the nominating and corporate governance

committee. Effective upon the effectiveness of the registration statement of which the prospectus is a part, our nominating and corporate governance committee's responsibilities will include:

- recommending to our board of directors the persons to be nominated for election as directors and to each of our board's committees;
- reviewing and making recommendations to our board of directors with respect to our board leadership structure;
- reviewing and making recommendations to our board of directors with respect to management succession planning;
- · developing and recommending to our board of directors corporate governance guidelines; and
- overseeing a periodic evaluation of our board of directors.

We believe that the composition of our nominating and corporate governance committee will meet the requirements for independence under current Nasdaq and SEC rules and regulations.

### **Compensation Committee Interlocks and Insider Participation**

None of our executive officers serves, or in the past year has served, as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or our compensation committee. None of the members of our compensation committee is, or has ever been, an officer or employee of our company.

## **Code of Ethics and Code of Conduct**

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We intend to post a current copy of the code on our website, www.inozyme.com. In addition, we intend to post on our website all disclosures that are required by law or Nasdaq listing standards concerning any amendments to, or waivers from, any provision of the code. The information contained on, or that can be accessed through, our website is not a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

### **EXECUTIVE COMPENSATION**

The following discussion relates to the compensation of our president and chief executive officer, Axel Bolte, our senior vice president and chief operating officer, Henric Bjarke, and our senior vice president and chief technical operations officer, Steven Jungles, for fiscal year 2019. Mr. Bolte, Mr. Bjarke and Mr. Jungles are collectively referred to in this prospectus as our named executive officers.

In preparing to become a public company, we have conducted a thorough review of all elements of our executive compensation program, including the function and design of our equity incentive programs. As part of this review, we have evaluated the need for revisions to our executive compensation program to ensure that our program is competitive with the companies with which we compete for executive talent and is appropriate for a public company.

As we are an emerging growth company, we have elected to comply with the reduced compensation disclosure requirements available to emerging growth companies under the Jumpstart Our Business Startups Act of 2012.

## **Summary Compensation Table**

The following table sets forth information regarding compensation awarded to, earned by or paid to each of our named executive officers for the year ended December 31, 2019.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)(1)	Option awards (\$)(2)	All other compensation (\$)	Total _(\$)
Axel Bolte President and Chief Executive Officer	2019	378,000(3)	179,313	353,470	60,000(4)	970,783
Henric Bjarke Senior Vice President and Chief Operating Officer	2019	350,200	99,201	141,388	_	590,789
Steven Jungles Senior Vice President and Chief Technical Operations Officer	2019	283,250	80,236	121,172	_	484,658

- (1) The amounts reported in the "Bonus" column reflect discretionary annual cash bonuses paid to our executive officers for their performance in 2019.
- The amounts reported in the "Option awards" column reflect the grant date fair value of stock options awarded during the year computed in accordance with the provisions of Financial Accounting Standard Board, or FASB, Accounting Standards Codification, or ASC, Topic 718. See Note 8 to our consolidated financial statements appearing at the end of this prospectus regarding assumptions underlying the valuation of equity awards. These amounts reflect the accounting cost for these stock options and do not reflect the actual economic value that may be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options or the sale of the common stock underlying such stock options.
- (3) Represents base compensation paid by us under our consulting agreement with Healthcare Advisors GmbH, of which Mr. Bolte is the manager. Under the consulting agreement with Healthcare Advisors GmbH, Mr. Bolte has provided services to us as our president and chief executive officer.
- (4) Represents amounts paid to Mr. Bolte for the purchase of health insurance, disability insurance and other benefits in Switzerland that are similar to a 401(k) plan.

### **Narrative to Summary Compensation Table**

*Base Compensation*. In 2019, we paid Mr. Bolte annual base compensation of \$378,000. In March 2020, our board of directors set Mr. Bolte's 2020 monthly base compensation at \$32,445 for an aggregate annual

amount of \$389,340. In 2019, we paid Mr. Bjarke and Mr. Jungles an annualized base salary of \$350,200 and \$283,250, respectively. In March 2020, our board of directors set Mr. Bjarke's and Mr. Jungles' 2020 annual base salary at \$360,706 and \$386,164, respectively. Effective upon the effectiveness of the registration statement of which this prospectus is a part, the annual base salary of Mr. Bolte, Mr. Bjarke and Mr. Jungles will be increased to \$525,000, \$430,200 and \$386,200, respectively.

We use base compensation or salaries to recognize the experience, skills, knowledge and responsibilities required of our executive officers. None of our executive officers is currently party to an employment agreement or other agreement or arrangement that provides for automatic or scheduled increases in base compensation or salary.

Annual Bonus. Our board of directors may, in its discretion, award bonuses to our executive officers from time to time. Our executive officers are eligible for annual performance-based bonuses up to a specified percentage of their base compensation or salary, subject to approval by our board of directors. Performance-based bonuses, which are calculated as a percentage of base compensation or salary, are designed to motivate our executive officers to achieve annual goals based on our strategic, financial and operating performance objectives. From time to time, our board of directors has approved discretionary annual cash bonuses to our executive officers with respect to their prior year performance.

With respect to 2019 performance, our board of directors awarded bonuses of \$179,313, \$99,201 and \$80,236 to Mr. Bolte, Mr. Bjarke and Mr. Jungles, respectively.

In March 2020, our board of directors set the 2020 target bonus amount, expressed as a percentage of 2020 base compensation or salary, at 50% for Mr. Bolte and 35% for each of Mr. Bjarke and Mr. Jungles. Effective upon the effectiveness of the registration statement of which this prospectus is a part, the target bonus amount, expressed as a percentage of base salary, will be 55% for Mr. Bolte and 40% for each of Mr. Bjarke and Mr. Jungles.

Equity Incentives. Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers, or any formal equity ownership guidelines applicable to them, we believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. In addition, we believe that equity grants with a time-based vesting feature promote executive retention because this feature incentivizes our executive officers to remain in our employment during the vesting period. Accordingly, our board of directors periodically reviews the equity incentive compensation of our executive officers and from time to time may grant equity incentive awards to them in the form of stock options.

In June 2019, we granted options to purchase 234,176, 93,670 and 60,216 shares of our common stock to Mr. Bolte, Mr. Bjarke and Mr. Jungles, respectively, at an exercise price per share of \$2.02. These options were merit-based awards, and such options vest in equal monthly installments over a term of four years from the vesting commencement date, subject to continued service. In December 2019, we granted options to purchase 20,072 shares of our common stock to Mr. Jungles at an exercise price per share of \$2.02 in connection with his promotion to full-time employment. These options vest as to 25% of the shares underlying the option on the first anniversary of the vesting commencement date and as to an additional 2.0833% of the original number of shares underlying the option monthly thereafter, subject to continued service.

In April 2020, we granted options to purchase 159,187, 51,105 and 44,315 shares of our common stock to Mr. Bolte, Mr. Bjarke and Mr. Jungles, respectively, at an exercise price per share of \$2.77. These options were merit-based awards, and such options vest in equal monthly installments over a term of four years from the vesting commencement date, with vesting contingent upon the acceptance by the FDA of our IND for INZ-701 on or prior to the first anniversary of the vesting commencement date, subject to continued service.

We also granted options to purchase 354,494 and 32,905 shares of our common stock to Mr. Bolte and Mr. Bjarke, respectively, effective upon the effectiveness of the registration statement of which this prospectus is a part, at an exercise price per share equal to the initial public offering price per share of our common stock in this offering. The grants to Mr. Bolte consist of an option to purchase 287,706 shares of our common stock, which vests in equal monthly installments over a term of four years, and an option to purchase 66,788 shares of our common stock, which vests in equal monthly installments over a term of four years, with vesting contingent upon the acceptance by the FDA of our IND for INZ-701 on or prior to the first anniversary of the vesting commencement date. The grant made to Mr. Bjarke vests in equal monthly installments over a term of four years.

Prior to this offering, our executives were eligible to participate in our Amended and Restated 2017 Equity Incentive Plan, as amended to date, or the 2017 Plan. During 2017, 2018, 2019 and 2020 (and through the effectiveness of the registration statement of which this prospectus is a part), all stock options were granted pursuant to the 2017 Plan, other than the stock option grants that are effective upon the effectiveness of the registration statement of which this prospectus is a part, which were granted pursuant to our 2020 Stock Incentive Plan, or 2020 Plan. Following the closing of this offering, our employees and executives will be eligible to receive stock options and other stock-based awards pursuant to our 2020 Plan. For a description of our 2017 Plan and our 2020 Plan, see "—Stock Option and Other Compensation Plans" below.

We use stock options to compensate our executive officers in the form of initial grants in connection with the commencement of employment and also at various times, often but not necessarily annually, if we or they have performed as expected or better than expected. Prior to this offering, awards of stock options to our executive officers have been made by our board of directors. None of our executive officers is currently party to an employment agreement that provides for the automatic award of stock options. We have granted option awards to our executive officers with time-based vesting and performance-based vesting. The option awards that we have granted to our executive officers in connection with commencement of employment typically become exercisable as to 25% of the shares underlying the option on the first anniversary of the vesting commencement date and as to an additional 2.0833% of the original number of shares underlying the option monthly thereafter. The option awards that we have granted to our executive officers at times other than in connection with employment typically become exercisable in equal monthly installments over a term of four years from the applicable vesting commencement date. Vesting rights cease upon termination of employment and exercise rights for previously vested stock options cease shortly after termination, though exercisability is extended in the case of death or disability. Mr. Bolte received an option to purchase 56,750 shares in 2017 that provides for acceleration of vesting in event we undergo a change of control or Mr. Bolte ceases to provide services to due his death or disability. Prior to the exercise of an option, the holder has no rights as a stockholder with respect to the shares subject to such option, including no voting rights and no right to receive dividends or dividend equivalents.

We have historically granted stock options with exercise prices that are equal to the fair market value of our common stock on the date of grant as determined by our board of directors, based on a number of objective and subjective factors. The exercise price of all stock options granted after the closing of this offering will be equal to the fair market value of shares of our common stock on the date of grant, which will be determined by reference to the closing market price of our common stock on the date of grant.

### Outstanding Equity Awards at December 31, 2019

The following table sets forth information regarding all outstanding stock options held by each of our named executive officers as of December 31, 2019.

Name	Number of securities underlying unexercised options (#) exercisable	Option Av Number of securities underlying unexercised options (#) unexercisable	Option exercise price (\$)	Option expiration date
Axel Bolte	121,966	45,302(1)	\$ 0.98	6/27/2027
	41,380	15,370(2)	\$ 0.98	6/27/2027
	29,272	204,904(3)	\$ 2.02	6/19/2029
Henric Bjarke	80,846	52,969(4)	\$ 0.98	9/6/2027
	11,709	81,961(5)	\$ 2.02	6/19/2029
Steven Jungles	83,912	31,168(6)	\$ 0.98	6/27/2027
	7,527	52,689(7)	\$ 2.02	6/19/2029
	_	20,072(8)	\$ 2.02	12/11/2029

- (1) This option to purchase 167,268 shares of our common stock vests over four years, with 25% of the shares vested on January 17, 2018 and 2.0833% of the original number of shares vesting thereafter in equal monthly installments through January 17, 2021, subject to continued service.
- (2) This option to purchase 56,750 shares of our common stock vests over four years, with 25% of the shares vested on January 17, 2018 and 2.0833% of the original number of shares vesting thereafter in equal monthly installments through January 17, 2021, subject to continued service.
- This option to purchase 234,176 shares of our common stock vests over four years, in equal monthly installments through June 20, 2023, subject to continued service.
- (4) This option to purchase 133,815 shares of our common stock vests over four years, with 25% of the shares vested on July 10, 2018 and 2.0833% of the original number of shares vesting thereafter in equal monthly installments through July 10, 2021, subject to continued service.
- (5) This option to purchase 93,670 shares of our common stock vests over four years, in equal monthly installments through June 20, 2023, subject to continued service.
- 6) This option to purchase 115,080 shares of our common stock vests over four years, with 25% of the shares vested on January 17, 2018 and 2.0833% of the original number of shares vesting thereafter in equal monthly installments through January 17, 2021, subject to continued service.
- (7) This option to purchase 60,216 shares of our common stock vests over four years, in equal monthly installments through June 20, 2023, subject to continued service.
- (8) This option to purchase 20,072 shares of our common stock vests over four years, with 25% of the shares vested on January 1, 2021 and 2.0833% of the original number of shares vesting thereafter in equal monthly installments through January 1, 2024, subject to continued service.

# **Employment Agreements**

We have entered into written employment agreements with each of our executive officers. These agreements set forth the terms of the executive officer's compensation, including base salary, annual discretionary bonus eligibility and severance benefits, among other matters. The employment agreements with our named executive officers are summarized below.

### Agreement with Axel Bolte

In July 2020, we entered into an agreement with Mr. Bolte in connection with his employment as our chief executive officer, which agreement becomes effective on the effectiveness of the registration statement of

which this prospectus is a part and which we refer to as the Bolte employment agreement. The Bolte employment agreement supersedes and replaces a consulting agreement for Mr. Bolte's services that we previously entered into in June 2017, as it was subsequently amended. Under the Bolte employment agreement, Mr. Bolte is an at-will employee, and his employment with us can be terminated by Mr. Bolte or us at any time and for any reason. Pursuant to the Bolte employment agreement, Mr. Bolte's annualized base salary is \$525,000, and he is eligible to receive an annual discretionary bonus of up to 55% of his gross base salary for the applicable calendar year. For a period of up to 24 months following the effectiveness of the registration statement of which this prospectus is a part, we will reimburse Mr. Bolte for his travel expenses between his home and our Boston area headquarters.

Under the Bolte employment agreement, and in connection with our initial public offering, we agreed to grant Mr. Bolte options to purchase an aggregate of 354,494 shares of our common stock at a price per share equal to the initial public offering price of our common stock in this offering. The options have been granted under the 2020 Plan effective upon the effectiveness of the registration statement of which this prospectus is a part.

Under the Bolte employment agreement, Mr. Bolte is entitled, subject to his execution and nonrevocation of a release of claims in our favor and his continued compliance with certain restrictive covenants, in the event of the termination of his employment by us without cause or by him for good reason, each as defined in the Bolte employment agreement, to (1) continued payment of his then-current annual base salary for a period of 12 months following the date his release of claims becomes effective, (2) continued payment by us of our share of the COBRA premiums for health benefit coverage for a period of up to 12 months following the date that his employment with us is terminated, and (3) payment of a pro-rated portion of his annual target discretionary bonus that he would otherwise have received based on individual and company performance in a lump sum on the date the first installment of severance pay is paid.

In the event that Mr. Bolte's employment is terminated by us without cause or by Mr. Bolte with good reason during the 60-day period prior to a change in control, as defined in the Bolte employment agreement, or during the 12-month period following a change in control, Mr. Bolte will be entitled, subject to his execution and nonrevocation of a release of claims in our favor and his continued compliance with certain restrictive covenants, to (1) continued payment of his then-current annual base salary for a period of 18 months following the date his release of claims becomes effective, (2) continued payment by us of our share of the COBRA premiums for health benefit coverage for a period of up to 18 months following the date that his employment with us is terminated, and (3) payment of 150% of his annual target discretionary bonus amount for the year in which the termination occurs in a lump sum on the date the first installment of severance pay is paid. In addition, Mr. Bolte will be entitled to full acceleration of vesting of all outstanding and unvested stock options and other equity awards that vest solely based on continued service. However, if Mr. Bolte's termination date is within 60 days prior to the closing of a change in control, then such accelerated vesting will not occur unless and until the closing of a change in control within 60 days of his termination date. Under the Bolte employment agreement, if payments and benefits payable to Mr. Bolte that are contingent on a change in ownership or control, as defined the Bolte employment agreement, are subject to Section 4999 of the Internal Revenue Code of 1986, then such payments and benefits will either be paid in full or be reduced so that the Section 4999 excise tax does not apply, whichever results in the better after-tax result for Mr. Bolte.

### Agreement with Henric Bjarke

In connection with our initial hiring of Mr. Bjarke as our senior vice president and chief operating officer, we entered into an agreement with him in June 2017. We entered into an amended and restated agreement with Mr. Bjarke in July 2020, which agreement will become effective upon the effectiveness of the registration statement of which this prospectus is a part and which we refer to as the Bjarke employment agreement. Under the Bjarke employment agreement, Mr. Bjarke is an at-will employee, and his employment with us can be terminated by Mr. Bjarke or us at any time and for any reason. Pursuant to the Bjarke employment agreement, Mr. Bjarke's annualized base salary is \$430,200, and he is eligible to receive an annual discretionary

bonus of up to 40% of his gross base salary for the applicable calendar year. For a period of up to 24 months following the effectiveness of the registration statement of which this prospectus is a part, we will reimburse Mr. Bjarke for his travel expenses between his home and our Boston area headquarters on a grossed-up basis.

Under the Bjarke employment agreement, and in connection with our initial public offering, we agreed to grant Mr. Bjarke an option to purchase 32,905 shares of our common stock at a price per share equal to the initial public offering price of our common stock in this offering. The option has been granted under the 2020 Plan effective upon the effectiveness of the registration statement of which this prospectus is a part.

Under the Bjarke employment agreement, Mr. Bjarke is entitled, subject to his execution and nonrevocation of a release of claims in our favor and his continued compliance with certain restrictive covenants, in the event of the termination of his employment by us without cause or by him for good reason, each as defined in the Bjarke employment agreement, to (1) continued payment of his then-current annual base salary for a period of nine months following the date his release of claims becomes effective, and (2) continued payment by us of our share of the COBRA premiums for health benefit coverage for a period of up to nine months following the date that his employment with us is terminated.

In the event that Mr. Bjarke's employment is terminated by us without cause or by Mr. Bjarke with good reason during the 12-month period following a change in control, as defined in the Bjarke employment agreement, Mr. Bjarke will be entitled, subject to his execution and nonrevocation of a release of claims in our favor and his continued compliance with certain restrictive covenants, to (1) continued payment of his then-current annual base salary for a period of 12 months following the date his release of claims becomes effective, (2) continued payment by us of our share of the COBRA premiums for health benefit coverage for a period of up to 12 months following the date that his employment with us is terminated, and (3) payment of 100% of his annual target discretionary bonus amount for the year in which the termination occurs in a lump sum on the date the first installment of severance pay is paid. In addition, Mr. Bjarke will be entitled to full acceleration of vesting of all outstanding and unvested stock options and other equity awards that vest solely based on continued service. Under the Bjarke employment agreement, if payments and benefits payable to Mr. Bjarke that are contingent on a change in ownership or control, as defined the Bjarke employment agreement, are subject to Section 4999 of the Internal Revenue Code of 1986, then such payments and benefits will either be paid in full or be reduced so that the Section 4999 excise tax does not apply, whichever results in the better after-tax result for Mr. Bjarke.

# Agreement with Steven Jungles

In connection with our initial hiring of Mr. Jungles as our senior vice president and chief technical operations officer, we entered into an agreement with him in April 2017. We entered into an amended and restated agreement with Mr. Jungles in July 2020, which agreement will become effective upon the effectiveness of the registration statement of which this prospectus is a part and which we refer to as the Jungles employment agreement. Under the Jungles employment agreement, Mr. Jungles is an at-will employee, and his employment with us can be terminated by Mr. Jungles or us at any time and for any reason. Pursuant to the Jungles employment agreement, Mr. Jungles' annualized base salary is \$386,200, and he is eligible to receive an annual discretionary bonus of up to 40% of his gross base salary for the applicable calendar year. For a period of up to 24 months following the effectiveness of the registration statement of which this prospectus is a part, we will reimburse Mr. Jungles for his travel expenses between his home and our Boston area headquarters.

Under the Jungles employment agreement, Mr. Jungles is entitled, subject to his execution and nonrevocation of a release of claims in our favor and his continued compliance with certain restrictive covenants, in the event of the termination of his employment by us without cause or by him for good reason, each as defined in the Jungles employment agreement, to (1) continued payment of his then-current annual base salary for a period of nine months following the date his release of claims becomes effective, and (2) continued payment by

us of our share of the COBRA premiums for health benefit coverage for a period of up to nine months following the date that his employment with us is terminated.

In the event that Mr. Jungles' employment is terminated by us without cause or by Mr. Jungles with good reason during the 12-month period following a change in control, as defined in the Jungles employment agreement, Mr. Jungles will be entitled, subject to his execution and nonrevocation of a release of claims in our favor and his continued compliance with certain restrictive covenants, to (1) continued payment of his then-current annual base salary for a period of 12 months following the date his release of claims becomes effective, (2) continued payment by us of our share of the COBRA premiums for health benefit coverage for a period of up to 12 months following the date that his employment with us is terminated, and (3) payment of 100% of his annual target discretionary bonus amount for the year in which the termination occurs in a lump sum on the date the first installment of severance pay is paid. In addition, Mr. Jungles will be entitled to full acceleration of vesting of all outstanding and unvested stock options and other equity awards that vest solely based on continued service. Under the Jungles employment agreement, if payments and benefits payable to Mr. Jungles that are contingent on a change in ownership or control, as defined the Jungles employment agreement, are subject to Section 4999 of the Internal Revenue Code of 1986, then such payments and benefits will either be paid in full or be reduced so that the Section 4999 excise tax does not apply, whichever results in the better after-tax result for Mr. Jungles.

### Employee Proprietary Rights, Non-Disclosure, Developments, Non-Competition, and Non-Solicitation Agreements

Each of our executive officers has entered into a standard form of agreement with respect to proprietary and confidential information, developments, non-competition, and non-solicitation. Under this agreement, each executive officer has agreed to protect our confidential and proprietary information during and after the executive officer's employment with us, not to compete with us during his employment and for a period generally lasting for one year after the termination of his employment, and not to solicit our employees, consultants, clients or customers during his employment and for a period generally lasting for one year after the termination of his employment. In addition, under this agreement, each executive officer has agreed that we own all developments and inventions that are developed by such executive officer within the scope of and during the period of his employment with us that are related to our business or research and development conducted or planned to be conducted by us at the time such development is created. Each executive officer also agreed to provide us with a non-exclusive, royalty-free, perpetual license to use any prior inventions that such executive officer incorporates into inventions assigned to us under this agreement.

## **Stock Option and Other Compensation Plans**

In this section we describe our 2017 Plan, our 2020 Plan and our 2020 Employee Stock Purchase Plan, or the 2020 ESPP. Prior to this offering, we granted awards to eligible participants under the 2017 Plan. Upon and following the effectiveness of the 2020 Plan, we will grant awards to eligible participants from time to time only under the 2020 Plan.

## Amended and Restated 2017 Equity Incentive Plan

The 2017 Equity Incentive Plan was initially approved by our board of directors and our stockholders in January 2017 and was subsequently amended and restated in June 2017. The Amended and Restated 2017 Equity Incentive Plan, which we refer to herein as the 2017 Plan, was further amended in January 2018, November 2018 and March 2019, in each case to increase the total number of shares reserved for issuance under the 2017 Plan. The 2017 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, awards of restricted stock, restricted stock units and other stock-based awards. Our employees, officers, directors, consultants and advisors are eligible to receive awards under the 2017 Plan; however, incentive stock options may only be granted to our employees. The type of award granted under the 2017 Plan and the terms of

such award are set forth in the applicable award agreement. Pursuant to the terms of the 2017 Plan, our board of directors (or a committee delegated by our board of directors) administers the plan and, subject to any limitations in the plan, selects the recipients of awards and determines:

- the number of shares of our common stock covered by options and the dates upon which the options become exercisable;
- the type of options to be granted;
- the duration of options, which may not be in excess of ten years;
- · the exercise price of options, which must be at least equal to the fair market value of our common stock on the date of grant; and
- the number of shares of our common stock subject to and the terms of any stock appreciation rights, restricted stock awards, restricted stock units or other stock-based awards and the terms and conditions of such awards, including conditions for repurchase or cancellation, measurement price, issue price and repurchase price (though the measurement price of stock appreciation rights must be at least equal to the fair market value of our common stock on the date of grant and the duration of such awards may not be in excess of ten years).

If our board of directors delegates authority to one or more of our officers to grant awards under the 2017 Plan, the officers will have the power to make awards to all of our employees, except executive officers (as such terms are defined in the 2017 Plan). Our board of directors will fix the terms of the awards to be granted by any such officer, the maximum number of shares subject to awards that such officer may grant, and the time period in which such awards may be granted.

The maximum number of shares of our common stock authorized for issuance under the 2017 Plan is 2,730,496 shares. Our board of directors may amend, suspend or terminate the 2017 Plan at any time, except that stockholder approval may be required to comply with applicable law or provisions under the 2017 Plan.

Effect of Certain Changes in Capitalization

Upon the occurrence of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of our common stock other than an ordinary cash dividend, under the terms of the 2017 Plan, we are required to equitably adjust (or make substitute awards, if applicable), in the manner determined by our board of directors:

- the number and class of securities available under the 2017 Plan;
- · the number and class of securities and exercise price per share of each outstanding option;
- · the share and per-share provisions and the measurement price of each outstanding stock appreciation right;
- the number of shares subject to and the repurchase price per share subject to each outstanding restricted stock award or restricted stock unit award; and
- · the share and per-share-related provisions and the purchase price, if any, of each outstanding other stock-based award.

### Effect of Certain Corporate Transactions

Upon the occurrence of a merger or other reorganization event (as defined in the 2017 Plan), our board of directors may, on such terms as our board of directors determines (except to the extent specifically provided otherwise in an applicable award agreement or other agreement between the participant and us), take any one or more of the following actions pursuant to the 2017 Plan as to all or any (or any portion of) outstanding awards, other than awards of restricted stock:

- provide that outstanding awards will be assumed, or substantially equivalent awards will be substituted, by the acquiring or succeeding corporation (or an affiliate thereof):
- upon written notice to a participant, provide that all of the participant's unexercised awards will terminate immediately prior to the consummation of the reorganization event unless exercised by the participant (to the extent then exercisable) within a specified period following the date of the notice;
- provide that outstanding awards will become exercisable, realizable or deliverable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon such reorganization event;
- in the event of a reorganization event pursuant to which holders of shares of our common stock will receive a cash payment for each share surrendered in the reorganization event, make or provide for a cash payment to participants with respect to each award held by a participant equal to (1) the number of shares of our common stock subject to the vested portion of the award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to the reorganization event) multiplied by (2) the excess, if any, of the cash payment for each share surrendered in the reorganization event over the exercise, measurement or purchase price of such award and any applicable tax withholdings, in exchange for the termination of the award;
- provide that, in connection with our liquidation or dissolution, awards will convert into the right to receive liquidation proceeds (if applicable, net of the exercise measurement or purchase price thereof and any applicable tax withholdings); or
- · any combination of the foregoing.

Our board of directors is not obligated under the 2017 Plan to treat all awards, all awards held by a participant, or all awards of the same type, identically.

In the case of certain restricted stock units, no assumption or substitution is permitted, and the restricted stock units will instead be settled in accordance with the terms of the applicable restricted stock unit agreement.

Upon the occurrence of a reorganization event other than our liquidation or dissolution, the repurchase and other rights with respect to outstanding restricted stock awards will continue for the benefit of the succeeding company and will, unless our board of directors determines otherwise, apply to the cash, securities, or other property which our common stock was converted into or exchanged for in the reorganization event in the same manner and to the same extent as they applied to the common stock subject to the restricted stock award. However, the board may provide for the termination or deemed satisfaction of such repurchase or other rights under the restricted stock award agreement or any other agreement between a participant and us, either initially or by amendment. Upon our liquidation or dissolution, except to the extent specifically provided to the contrary in the restricted stock award agreement or any other agreement between the plan participant and us, all restrictions and conditions on all restricted stock awards then outstanding will automatically be deemed terminated or satisfied.

Our board of directors may at any time provide that any award under the 2017 Plan will become immediately exercisable in whole or in part, free of some or all restrictions or conditions, or otherwise realizable in whole or in part, as the case may be.

As of July 17, 2020, there were options to purchase 2,078,405 shares of our common stock outstanding under the 2017 Plan at a weighted average exercise price of \$1.99 per share and 426,065 shares of our common stock were available for future issuance under the 2017 Plan. No further awards will be made under the 2017 Plan on or after the effective date of the 2020 Plan described below; however, awards outstanding under the 2017 Plan will continue to be governed by their existing terms.

#### 2020 Stock Incentive Plan

Our board of directors has adopted, and our stockholders have approved, the 2020 Plan, which will become effective immediately prior to the effectiveness of the registration statement of which this prospectus is a part. The 2020 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. Upon effectiveness of the 2020 Plan, the number of shares of our common stock that will be reserved for issuance under the 2020 Plan will be the sum of: (1) 1,588,315; plus (2) the number of shares (up to 2,613,638 shares) equal to the sum of (x) the number of shares of our common stock reserved for issuance under the 2017 Plan that remain available for grant under the 2017 Plan immediately prior to the effectiveness of the registration statement of which this prospectus is a part and (y) the number of shares of our common stock subject to outstanding awards under the 2017 Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right; plus (3) an annual increase, to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2021 and continuing until, and including, the fiscal year ending December 31, 2030, equal to the lower of (i) 4% of the number of shares of our common stock outstanding on the first day of such fiscal year and (ii) an amount determined by our board of directors. No more than 1,588,315 shares of our common stock may be granted subject to incentive stock options under the 2020 Plan.

Our employees, officers, directors, consultants and advisors will be eligible to receive awards under the 2020 Plan. Incentive stock options, however, may only be granted to our employees. Our board of directors has granted under the 2020 Plan options to purchase 768,380 shares of our common stock to certain of our employees and non-employee directors effective upon the effectiveness of the registration statement of which this prospectus is a part.

Pursuant to the terms of the 2020 Plan, our board of directors (or a committee delegated by our board of directors) will administer the plan and, subject to any limitations in the plan, will select the recipients of awards and determine:

- the number of shares of our common stock covered by options and the dates upon which the options become exercisable;
- the type of options to be granted;
- the duration of options, which may not be in excess of ten years;
- · the exercise price of options, which must be at least equal to the fair market value of our common stock on the date of grant; and
- the number of shares of our common stock subject to and the terms of any stock appreciation rights, restricted stock awards, restricted stock units or other stock-based awards and the terms and conditions of such awards, including conditions for repurchase, issue price and repurchase price

(though the measurement price of stock appreciation rights must be at least equal to the fair market value of our common stock on the date of grant and the duration of such awards may not be in excess of ten years).

If our board of directors delegates authority to one or more of our officers to grant awards under the 2020 Plan, the officers will have the power to make awards to all of our employees, except executive officers. Our board of directors will fix the terms of the awards to be granted by any such officer, the maximum number of shares subject to awards that such officer may make, and the time period in which such awards may be granted. Pursuant to the 2020 Plan, the maximum amount of cash and equity compensation (calculated based on grant date fair value for financial reporting purposes) granted in any calendar year to any individual non-employee director in his or her capacity as a non-employee director shall not exceed \$750,000 in the case of an incumbent director or \$1,000,000 in the case of a new director during his or her first year of service, in each case, subject to the terms and limitations set forth in the 2020 Plan.

#### Effect of Certain Changes in Capitalization

Upon the occurrence of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of our common stock other than an ordinary cash dividend, under the terms of the 2020 Plan, we are required to equitably adjust (or make substitute awards, if applicable), in the manner determined by our board of directors:

- the number and class of securities available under the 2020 Plan;
- the share counting rules under the 2020 Plan;
- · the number and class of securities and exercise price per share of each outstanding option;
- the share and per-share provisions and the measurement price of each outstanding stock appreciation right;
- the number of shares subject to, and the repurchase price per share subject to, each outstanding award of restricted stock; and
- the share and per-share related provisions and the purchase price, if any, of each restricted stock unit award and each other stock-based award.

# Effect of Certain Corporate Transactions

Upon the occurrence of a merger or other reorganization event (as defined in the 2020 Plan), our board of directors may, on such terms as our board determines (except to the extent specifically provided otherwise in an applicable award agreement or other agreement between the participant and us), take any one or more of the following actions pursuant to the 2020 Plan as to all or any (or any portion of) outstanding awards, other than awards of restricted stock:

- provide that outstanding awards will be assumed, or substantially equivalent awards will be substituted, by the acquiring or succeeding corporation (or an affiliate thereof);
- upon written notice to a participant, provide that all of the participant's unvested awards will be forfeited, and/or vested but unexercised awards will terminate, immediately prior to the consummation of the reorganization event unless exercised by the participant (to the extent then exercisable) within a specified period following the date of the notice;

- provide that outstanding awards will become exercisable, realizable or deliverable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon such reorganization event;
- in the event of a reorganization event pursuant to which holders of shares of our common stock will receive a cash payment for each share surrendered in the reorganization event, make or provide for a cash payment to participants with respect to each award held by a participant equal to (1) the number of shares of our common stock subject to the vested portion of the award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such reorganization event) multiplied by (2) the excess, if any, of the cash payment for each share surrendered in the reorganization event over the exercise, measurement or purchase price of such award and any applicable tax withholdings, in exchange for the termination of such award; and/or
- provide that, in connection with our liquidation or dissolution, awards will convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings).

Our board of directors is not obligated under the 2020 Plan to treat all awards, all awards held by a participant, or all awards of the same type, identically.

In the case of certain restricted stock units, no assumption or substitution is permitted, and the restricted stock units will instead be settled in accordance with the terms of the applicable restricted stock unit agreement.

Upon the occurrence of a reorganization event other than our liquidation or dissolution, our repurchase and other rights with respect to outstanding awards of restricted stock will continue for the benefit of the succeeding company and will, unless our board of directors determines otherwise, apply to the cash, securities, or other property which our common stock was converted into or exchanged for pursuant to the reorganization event in the same manner and to the same extent as they applied to the common stock subject to the restricted stock award. However, the board may provide for the termination or deemed satisfaction of such repurchase or other rights under the restricted stock award agreement or in any other agreement between a participant and us, either initially or by amendment. Upon our liquidation or dissolution, except to the extent specifically provided to the contrary in the restricted stock award agreement or any other agreement between the participant and us, all restrictions and conditions on all restricted stock awards then outstanding will automatically be deemed terminated or satisfied.

At any time, our board of directors may provide that any award under the 2020 Plan will become immediately exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in whole or in part, as the case may be.

No award may be granted under the 2020 Plan on or after the date that is ten years following the effectiveness of the registration statement of which this prospectus is a part. Our board of directors may amend, suspend or terminate the 2020 Plan at any time, except that stockholder approval may be required to comply with applicable law or stock market requirements.

# 2020 Employee Stock Purchase Plan

Our board of directors has adopted, and our stockholders have approved, the 2020 ESPP, which will become effective immediately prior to the effectiveness of the registration statement of which this prospectus is a part. The 2020 ESPP will be administered by our board of directors or by a committee appointed by our board of directors. The 2020 ESPP initially provides participating employees with the opportunity to purchase up to an aggregate of 198,539 shares of our common stock. The number of shares of our common stock reserved for issuance under the 2020 ESPP will automatically increase on the first day of each fiscal year, beginning with the fiscal year commencing on January 1, 2021 and continuing until, and including, the fiscal

year commencing on January 1, 2031, in an amount equal to the lowest of (1) 397,079 shares of our common stock, (2) 1% of the number of shares of our common stock outstanding on the first day of such fiscal year and (3) an amount determined by our board of directors.

All of our employees and employees of any designated subsidiary, as defined in the 2020 ESPP, are eligible to participate in the 2020 ESPP, provided that:

- such person is customarily employed by us or a designated subsidiary for more than 20 hours a week and for more than five months in a calendar year;
- · such person has been employed by us or by a designated subsidiary for at least three months prior to enrolling in the 2020 ESPP; and
- such person was our employee or an employee of a designated subsidiary on the first day of the applicable offering period under the 2020 FSPP

We retain the discretion to determine which eligible employees may participate in an offering under applicable regulations.

We expect to make one or more offerings to our eligible employees to purchase stock under the 2020 ESPP beginning at such time and on such dates as our board of directors may determine, or on the first business day thereafter. Each offering will consist of a six-month offering period during which payroll deductions will be made and held for the purchase of our common stock at the end of the offering period. Our board of directors or a committee designated by the board of directors may, at its discretion, choose a different period of not more than 12 months for offerings.

On each offering commencement date, each participant will be granted the right to purchase, on the last business day of the offering period, up to a number of shares of our common stock determined by multiplying \$2,083 by the number of full months in the offering period and dividing that product by the closing price of our common stock on the first day of the offering period. No employee may be granted an option under the 2020 ESPP that permits the employee's rights to purchase shares under the 2020 ESPP and any other employee stock purchase plan of ours or of any of our subsidiaries to accrue at a rate that exceeds \$25,000 of the fair market value of our common stock (determined as of the first day of each offering period) for each calendar year in which the option is outstanding. In addition, no employee may purchase shares of our common stock under the 2020 ESPP that would result in the employee owning 5% or more of the total combined voting power or value of our stock or the stock of any of our subsidiaries.

On the commencement date of each offering period, each eligible employee may authorize up to a maximum of 15% of his or her compensation to be deducted by us during the offering period. Our board of directors or the committee designated by the board of directors may designate a lower maximum deduction rate in its discretion. Each employee who continues to be a participant in the 2020 ESPP on the last business day of the offering period will be deemed to have exercised an option to purchase from us the number of whole shares of our common stock that his or her accumulated payroll deductions on such date will pay for, not in excess of the maximum numbers set forth above. Under the terms of the 2020 ESPP, the purchase price will be determined by our board of directors or the committee designated by the board of directors for each offering period and will be at least 85% of the applicable closing price of our common stock. If our board of directors or the committee does not make a determination of the purchase price, the purchase price will be 85% of the lesser of the closing price of our common stock on the first business day of the offering period or on the last business day of the offering period.

An employee may at any time prior to the close of business on the fifteenth business day prior to the end of an offering period, and for any reason, permanently withdraw from participating in an offering prior to the end

of an offering period and permanently withdraw the balance accumulated in the employee's account. If an employee elects to discontinue his or her payroll deductions during an offering period but does not elect to withdraw his or her funds, funds previously deducted will be applied to the purchase of common stock at the end of the offering period. If a participating employee's employment ends before the last business day of an offering period, no additional payroll deductions will be taken and the balance in the employee's account will be paid to the employee.

We will be required to make equitable adjustments to the extent determined by our board of directors or a committee thereof to the number and class of securities available under the 2020 ESPP, the share limitations under the 2020 ESPP, and the purchase price for an offering period under the 2020 ESPP to reflect stock splits, reverse stock splits, stock dividends, recapitalizations, combinations of shares, reclassifications of shares, spin-offs and other similar changes in capitalization or events or any dividends or distributions to holders of our common stock other than ordinary cash dividends.

In connection with a merger or other reorganization event, as defined in the 2020 ESPP, our board of directors or a committee of our board of directors may take any one or more of the following actions as to outstanding options to purchase shares of our common stock under the 2020 ESPP on such terms as our board of directors or committee thereof determines:

- provide that options will be assumed, or substantially equivalent options will be substituted, by the acquiring or succeeding corporation (or an affiliate thereof);
- upon written notice to employees, provide that all outstanding options will be terminated immediately prior to the consummation of such reorganization event and that all such outstanding options will become exercisable to the extent of accumulated payroll deductions as of a date specified by our board of directors or a committee thereof in such notice, which date will not be less than ten days preceding the effective date of the reorganization event;
- upon written notice to employees, provide that all outstanding options will be cancelled as of a date prior to the effective date of the reorganization event and that all accumulated payroll deductions will be returned to participating employees on such date;
- in the event of a reorganization event under the terms of which holders of our common stock will receive upon consummation thereof a cash payment for each share surrendered in the reorganization event, change the last day of the offering period to be the date of the consummation of the reorganization event and make or provide for a cash payment to each employee equal to (1) the cash payment for each share surrendered in the reorganization event times the number of shares of our common stock that the employee's accumulated payroll deductions as of immediately prior to the reorganization event could purchase at the applicable purchase price, where the cash payment for each share surrendered in the reorganization event is treated as the fair market value of our common stock on the last day of the applicable offering period for purposes of determining the purchase price and where the number of shares that could be purchased is subject to the applicable limitations under the 2020 ESPP minus (2) the result of multiplying such number of shares by the purchase price; and/or
- provide that, in connection with our liquidation or dissolution, options will convert into the right to receive liquidation proceeds (net of the purchase price thereof).

Our board of directors may at any time, and from time to time, amend or suspend the 2020 ESPP or any portion of the 2020 ESPP. We will obtain stockholder approval for any amendment if such approval is required by Section 423 of the Internal Revenue Code of 1986. Further, our board of directors may not make any amendment that would cause the 2020 ESPP to fail to comply with Section 423 of the Internal Revenue Code of

1986. The 2020 ESPP may be terminated at any time by our board of directors. Upon termination, we will refund all amounts in the accounts of participating employees.

#### 401(k) Plan

We maintain a defined contribution employee retirement plan for our employees, including our executive officers. The plan is intended to qualify as a tax-qualified 401(k) plan so that contributions to the 401(k) plan, and income earned on such contributions, are not taxable to participants until withdrawn or distributed from the 401(k) plan (except in the case of contributions under the 401(k) plan designated as Roth contributions). Under the 401(k) plan, each employee is fully vested in his or her deferred salary contributions and our discretionary match. Employee contributions are held and invested by the plan's trustee as directed by participants. The 401(k) plan provides us with the discretion to match employee contributions, but to date we have not provided any employer matching contributions.

# **Limitation of Liability and Indemnification**

Our certificate of incorporation, which will become effective upon the closing of this offering, limits the personal liability of directors for breach of fiduciary duty to the maximum extent permitted by the Delaware General Corporation Law, or the DGCL, and provides that no director will have personal liability to us or to our stockholders for monetary damages for breach of fiduciary duty as a director. However, these provisions do not eliminate or limit the liability of any of our directors:

- for any breach of the director's duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- · for voting for or assenting to unlawful payments of dividends, stock repurchases or other distributions; or
- for any transaction from which the director derived an improper personal benefit.

Any amendment to or repeal of these provisions will not eliminate or reduce the effect of these provisions in respect of any act, omission or claim that occurred or arose prior to such amendment or repeal. If the DGCL is amended to provide for further limitations on the personal liability of directors of corporations, then the personal liability of our directors will be further limited to the greatest extent permitted by the DGCL.

In addition, our certificate of incorporation, which will become effective upon the closing of this offering, provides that we must indemnify our directors and officers and we must advance expenses, including attorneys' fees, to our directors and officers in connection with legal proceedings, subject to very limited exceptions.

We maintain a general liability insurance policy that covers specified liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers. In addition, we intend to enter into indemnification agreements with all of our executive officers and directors prior to the completion of this offering. These indemnification agreements may require us, among other things, to indemnify each such executive officer or director for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by him or her in any action or proceeding arising out of his or her service as one of our executive officers or directors.

Some of our non-employee directors may, through their relationships with their employers, be insured or indemnified against specified liabilities incurred in their capacities as members of our board of directors.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, or the Securities Act, may be permitted to directors, executive officers or persons controlling us, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

#### Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from the director or officer. It also is possible that the director or officer could amend or terminate the plan when not in possession of material, nonpublic information. In addition, our directors and executive officers may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

#### **Director Compensation**

The table below shows all compensation to our non-employee directors during the year ended December 31, 2019.

<u>Name</u>	Fees earned or paid in cash (\$)	Option awards (\$)(1)(2)	All other compensation (\$)	Total _(\$)_
Joseph Schlessinger(3)	_	100,992(4)	135,000(5)	235,992
Sarah Bhagat	_	_	_	_
Reinaldo Diaz	_	_	_	
Martin Edwards	_	_	_	_
Robert Hopfner	_	_	_	_
Edward Mathers	_	_	_	_
Lynne Sullivan(6)	_	_	_	_
Douglas Treco(7)		_	_	

- (1) The amount reported in the "Option awards" column reflects the aggregate grant date fair value of stock options awarded during the year computed in accordance with the provisions of ASC 718. See Note 8 to our consolidated financial statements appearing at the end of this prospectus regarding assumptions underlying the valuation of equity awards. This amount reflects the accounting cost for this stock option and does not reflect the actual economic value that may be realized by the director upon the vesting of the stock option, the exercise of the stock option or the sale of the common stock underlying such stock option.
- (2) As of December 31, 2019, the aggregate number of shares of our common stock subject to outstanding option awards for each non-employee director was as follows: Dr. Schlessinger, 76,943 shares; Dr. Bhagat, 0 shares; Mr. Diaz, 0 shares; Dr. Edwards, 0 shares; Dr. Hopfner, 0 shares, Mr. Mathers, 0 shares, Ms. Sullivan, 0 shares and Dr. Treco, 0 shares.
- (3) Dr. Schlessinger resigned from our board of directors in May 2020.
- (4) Represents an option to purchase 66,907 shares of our common stock granted on June 20, 2019, in respect of Dr. Schlessinger's consulting services for the year ended December 31, 2019. See the "Transactions with Related Persons" section of this prospectus for further information about our consulting agreement with Dr. Schlessinger.
- (5) Represents consulting fees paid to Dr. Schlessinger in respect of his consulting services for the year ended December 31, 2019. See the "Transactions with Related Persons" section of this prospectus for further information about our consulting agreement with Dr. Schlessinger.
- (6) Ms. Sullivan joined our board of directors in May 2020.
- (7) Dr. Treco joined our board of directors in May 2020.

In May 2020, we granted options to purchase 86,979 and 28,368 shares of our common stock to Dr. Treco and Ms. Sullivan, respectively, each at an exercise price of \$2.77 per share, and such options vest in equal monthly installments over a term of four years from the grant date.

Effective upon the effectiveness of the registration statement of which this prospectus is a part, we granted options to purchase 9,367 shares of our common stock to each of our non-employee directors, at an exercise price per share equal to the initial public offering price per share of our common stock in this offering. Such options vest with respect to all of the shares underlying the options on the first anniversary of the date of effectiveness of the registration statement of which this prospectus is a part or, if earlier, immediately prior to the first annual meeting of stockholders occurring after the date of effectiveness of the registration statement of which this prospectus is a part.

Prior to this offering, we did not have a formal non-employee director compensation policy. We have historically reimbursed our non-employee directors for reasonable travel and out-of-pocket expenses incurred in connection with attending board of director and committee meetings.

Mr. Bolte, one of our directors who also serves as our president and chief executive officer, does not receive any additional compensation for his service as a director. Mr. Bolte is one of our named executive officers and, accordingly, the compensation that we pay to Mr. Bolte is discussed above under "—Summary Compensation Table" and "—Narrative to Summary Compensation Table."

In June, 2020, our board of directors approved a director compensation program that will become effective on the effective date of the registration statement of which this prospectus is a part. Under this director compensation program, we will pay our non-employee directors a cash retainer for service on the board of directors and for service on each committee on which the director is a member. The chair of the board and of each committee will receive higher retainers for such service. These fees are payable in arrears in four equal quarterly installments on the last day of each quarter, provided that the amount of such payment will be prorated for any portion of such quarter that the director is not serving on our board of directors or on such committee, no fee will be payable in respect of any period prior to the completion of this offering and the first payment under the director compensation program after the closing will be prorated. The fees paid to non-employee directors for service on the board of directors and for service on each committee of the board of directors on which the director is a member are as follows:

	Memb	er Annual Fee	ncremental nual Fee
Board of Directors	\$	35,000	\$ 30,000
Audit Committee	\$	7,500	\$ 7,500
Compensation Committee	\$	5,000	\$ 5,000
Nominating and Corporate Governance Committee	\$	4,000	\$ 4,000

We also will continue to reimburse our non-employee directors for reasonable travel and other expenses incurred in connection with attending meetings of our board of directors and any committee of our board of directors on which he or she serves.

In addition, under our director compensation program to be effective on the effective date of the registration statement of which this prospectus is a part, each non-employee director will receive, upon his or her initial election or appointment to our board of directors, an option to purchase 18,734 shares of our common stock under the 2020 Plan. Each of these options will vest as to 2.7778% of the shares of our common stock underlying such option at the end of each successive one-month period following the date of grant until the third anniversary of the date of grant, subject to the non-employee director's continued service as a director. Further, on the date of the first board meeting held after each annual meeting of stockholders, each non-employee director that has served on our board of directors for at least six months will receive, under the 2020 Plan, an option to purchase 9,367 shares of our common stock under the 2020 Plan. Each of these options will vest with respect to all of the shares underlying the option on the first anniversary of the date of grant or, if earlier, immediately prior to the first annual meeting of stockholders occurring after the grant date, subject to the non-employee director's continued service as a director. All options issued to our non-employee directors under our director compensation program will be issued at exercise prices equal to the fair market value of our common stock on the date of grant and will become exercisable in full upon specified change in control events.

#### TRANSACTIONS WITH RELATED PERSONS

Since January 1, 2017, we have engaged in the following transactions in which the amounts involved exceeded \$120,000 and any of our directors, executive officers or holders of more than 5% of our voting securities, or any member of the immediate family of, or person sharing the household with, the foregoing persons, had or will have a direct or indirect material interest. We believe that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

#### **Series A Convertible Preferred Stock Financing**

From January 12, 2017 through May 26, 2017, we issued and sold an aggregate of 27,183,333 shares of our Series A Convertible Preferred Stock, of which (1) 27,083,333 shares of Series A Convertible Preferred Stock were sold at a price per share of \$1.00 in cash, for an aggregate purchase price of \$27,083,333 and (2) 100,000 shares of Series A Convertible Preferred Stock were issued upon conversion of 100,000 shares of Series A-1 Convertible Preferred Stock of Inozyme Pharma, LLC in connection with our conversion into a corporation in 2017.

The following table sets forth the aggregate number of shares of our Series A Convertible Preferred Stock that we issued and sold to our directors, executive officers and holders of more than 5% of our voting securities and their affiliates in this transaction and the aggregate amount of consideration for such shares:

		Shares of Series A Convertible	Ag	gregate Cash Purchase
Purchaser(1)	<u>Date</u>	Preferred Stock		Price
Longitude Venture Partners III, L.P.	1/17/2017	8,333,333	\$	8,333,333
Entities affiliated with New Enterprise Associates (2)	1/17/2017	8,333,333	\$	8,333,333
Novo Holdings A/S	1/17/2017	8,333,333	\$	8,333,333
Joseph Schlessinger (3)	1/12/2017	50,000(5)		— (5)
	4/20/2017	27,778	\$	27,778
Steven Jungles Trust Dated Nov. 12, 2014 (4)	1/12/2017	50,000(5)		— (5)
	4/27/2017	27,778	\$	27,778

<sup>(1)</sup> See the "Principal Stockholders" section of this prospectus for additional information about shares held by these entities and individuals.

<sup>(2)</sup> Consists of (i) 8,283,333 shares held by New Enterprise Associates 15, L.P. and (ii) 50,000 shares held by NEA Ventures 2016, L.P.

<sup>(3)</sup> Joseph Schlessinger was a member of our board of directors from September 2015 to May 2020.

<sup>(4)</sup> Steven Jungles, our chief technical operations officer, is the trustee of the Steven Jungles Trust Dated Nov. 12, 2014.

<sup>(5)</sup> Represents 50,000 shares of Series A Convertible Preferred Stock acquired upon conversion of 50,000 shares of Series A-1 Convertible Preferred Stock, which shares of Series A-1 Convertible Preferred Stock were purchased for \$50,000.

On November 8, 2018, we issued and sold an aggregate of 21,666,667 additional shares of our Series A Convertible Preferred Stock at a price per share of \$1.00 in cash, for an aggregate purchase price of \$21,666,667. The following table sets forth the aggregate number of shares of our Series A Convertible Preferred Stock that we issued and sold to our directors, executive officers and holders of more than 5% of our voting securities and their affiliates in this transaction and the aggregate amount of consideration for such shares:

	Shares of Series A Convertible	gregate Cash Purchase
Purchaser(1)	Preferred Stock	 Price
Longitude Venture Partners III, L.P.	6,666,667	\$ 6,666,667
New Enterprise Associates 15, L.P.	6,666,667	\$ 6,666,667
Novo Holdings A/S	6,666,667	\$ 6,666,667
Aventis Inc.(2)	1,333,334	\$ 1,333,334
Joseph Schlessinger(3)	22,222	\$ 22,222
Steven Jungles Trust Dated Nov. 12, 2014(4)	22,222	\$ 22,222

- (1) See the "Principal Stockholders" section of this prospectus for additional information about shares held by these entities and individuals, other than Aventis Inc., which stockholder is no longer a holder of more than 5% of our voting securities.
- (2) Aventis was a holder of more than 5% of our voting securities during this transaction, but is no longer a current holder of more than 5% of our voting securities.
- (3) Joseph Schlessinger was a member of our board of directors from September 2015 to May 2020.
- (4) Steven Jungles, our chief technical operations officer, is the trustee of the Steven Jungles Trust Dated Nov. 12, 2014.

# **Series A-2 Convertible Preferred Stock Financing**

On November 9, 2018, we issued and sold an aggregate of 7,482,515 shares of our Series A-2 Convertible Preferred Stock at a price per share of \$1.43 in cash, for an aggregate purchase price of \$10,699,996. The following table sets forth the aggregate number of shares of our Series A-2 Convertible Preferred Stock that we issued and sold to holders of more than 5% of our voting securities and their affiliates in this transaction and the aggregate amount of consideration for such shares:

Purchaser(1)	Shares of Series A-2 Convertible <u>Preferred Stock</u>	Aggregate Purchase <u>Price</u>
Longitude Venture Partners III, L.P.	699,300	\$ 999,999
New Enterprise Associates 15, L.P.	699,300	\$ 999,999
Novo Holdings A/S	699,300	\$ 999,999
Pivotal bioVenture Partners Fund I, L.P.	5,244,755	\$7,500,000

1) See the "Principal Stockholders" section of this prospectus for additional information about shares held by these entities.

On March 22, 2019, we issued and sold an aggregate of 16,083,916 additional shares of our Series A-2 Convertible Preferred Stock at a price per share of \$1.43 in cash, for an aggregate purchase price of \$23,000,000. The following table sets forth the aggregate number of shares of our Series A-2 Convertible Preferred Stock that we issued and sold to holders of more than 5% of our voting securities and their affiliates in this transaction and the aggregate purchase price for such shares:

Purchaser(1)	Shares of Series A-2 Convertible Preferred Stock	Aggregate Purchase Price
Sofinnova Venture Partners X, L.P.	5,944,056	\$8,500,000
Entities affiliated with RA Capital Management, L.P.(2)	5,244,755	\$7,500,000

- (1) See the "Principal Stockholders" section of this prospectus for additional information about shares held by these entities.
- (2) Consists of (i) 4,448,601 shares held by RA Capital Healthcare Fund, L.P. and (ii) 796,154 shares held by Blackwell Partners LLC—Series A.

On June 5, 2020, we issued and sold an aggregate of 23,566,431 additional shares of our Series A-2 Convertible Preferred Stock at a price per share of \$1.43, for an aggregate purchase price of \$33,699,996. The following table sets forth the aggregate number of shares of our Series A-2 Convertible Preferred Stock that we issued and sold to holders of more than 5% of our voting securities and their affiliates in this transaction and the aggregate purchase price for such shares:

Shares of Series A-2 Convertible Preferred Stock	Aggregate Purchase Price
699,300	\$ 999,999
699,300	\$ 999,999
699,300	\$ 999,999
5,944,056	\$8,500,000
5,244,755	\$7,500,000
5,244,755	\$7,500,000
3,146,853	\$4,500,000
	A-2 Convertible Preferred Stock 699,300 699,300 699,300 5,944,056 5,244,755 5,244,755

- 1) See "Principal Stockholders" for additional information about shares held by these entities.
- (2) Consists of (i) 3,336,451 shares held by RA Capital Healthcare Fund, L.P., (ii) 597,115 shares held by Blackwell Partners LLC—Series A and (iii) 1,311,189 shares held by RA Capital Nexus Fund, L.P.
- (3) Consists of (i) 2,930,010 shares held by Cowen Healthcare Investments II LP and (ii) 216,843 shares held by CHI EF II LP.

#### **Director Affiliations**

Some of our directors are affiliated or associated with and, prior to the closing of this offering, have served on our board of directors as representatives of entities which beneficially own or owned 5% or more of our voting securities, as indicated in the table below:

Directors
Sarah Bhagat
Reinaldo Diaz
Martin Edwards
Robert Hopfner
<b>Edward Mathers</b>

# Principal Stockholder Sofinnova Venture Partners X, L.P. Longitude Venture Partners III, L.P. Novo Holdings A/S Pivotal bioVenture Partners Fund I, L.P. New Enterprise Associates 15, L.P.

#### **Consulting Agreement with Joseph Schlessinger**

In January 2017, we entered into a consulting agreement with Joseph Schlessinger, pursuant to which Dr. Schlessinger serves on our scientific advisory board and provides certain services to us related to planning, organizing and developing our research and development activities, advising on research techniques, assisting in recruiting scientists and attending meetings with investors, collaborators and strategic partners. Dr. Schlessinger was a member of our board of directors from September 2015 to May 2020. The consulting agreement is in effect until January 2021, and will automatically renew for additional successive one-year periods, unless we or Dr. Schlessinger notify the other 30 days prior to the renewal date that the consulting agreement will not be extended. Under the consulting agreement, we have agreed to pay Dr. Schlessinger at a rate of \$135,000 per year and reimburse Dr. Schlessinger for reasonable out-of-pocket expenses incurred in the performance of his

services. As of July 17, 2020, we have paid Dr. Schlessinger an aggregate of \$468,871 for his consulting services. In addition, in connection with his services as a consultant, we granted Dr. Schlessinger an option to purchase 10,036 shares at an exercise price per share of \$0.98 in 2017 and an option to purchase 66,907 shares at an exercise price of \$2.02 per share in 2019.

#### Relationship with Yale University and Demetrios Braddock

In 2017, we entered into a license agreement and a sponsored research agreement with Yale University, or Yale, a then holder of more than 5% of our outstanding voting securities. The license agreement relates to certain intellectual property developed in the course of research conducted under Yale auspices primarily by Demetrios Braddock, an associate professor of pathology at Yale, current member of our scientific advisory board and then holder of more than 5% of our outstanding voting securities. Pursuant to the license agreement, as partial upfront consideration, we paid to Yale approximately \$60,000, which amount reflected unreimbursed patent expenses incurred by Yale prior to the date of the license agreement. In connection with our entry into the license agreement with Yale, we issued to Yale 1,000,000 shares of our Class 1 stock (which shares subsequently converted into 113,501 shares of our common stock upon our conversion into a corporation in 2017). We are responsible for paying Yale an annual license maintenance fee in varying amounts throughout the term ranging from the low tens of thousands of dollars to the high tens of thousands of dollars. As of the date hereof, we have paid an aggregate of \$30,000 in license maintenance fees to Yale. We are also responsible for costs relating to the prosecution and maintenance of the licensed patents. As of the date hereof, we have paid to Yale approximately \$463,000 for costs relating to the prosecution and maintenance of the licensed patents. We must also pay Yale a percentage in the twenties of any consideration we receive from sublicensees. We are also required to pay Yale milestone and royalty payments on net product sales. We have not made any milestone or royalty payments to Yale to date. As the inventor of the patents that we license from Yale, Dr. Braddock is entitled to receive a share of any royalties that we pay to Yale under the agreement with respect to the covered intellectual property, under Yale's policies.

The sponsored research agreement relates to ENPP research support provided to us by and under the supervision of Dr. Braddock for so long as he employed by Yale. Under the sponsored research agreement, as amended, with Yale, we agreed to pay to Yale an aggregate of \$2.4 million over five years, ending in the fourth quarter of 2021, and as of the date hereof, we had paid Yale an aggregate of approximately \$1.8 million. For a further description of our license agreement with Yale, including the payment, royalty and milestone obligations thereunder, and the sponsored research agreement, see "Business—Yale University License Agreement."

In addition, from January 1, 2017 through the date hereof, we made gifts in the aggregate amount of approximately \$1.4 million to Yale, with the wish that Yale use such gifts to provide general support of Dr. Braddock's ENPP research program.

#### **Consulting Agreement with Demetrios Braddock**

In January 2017, we entered into a scientific advisory board consulting agreement with Dr. Braddock, an associate professor of pathology at Yale and then holder of more than 5% of our outstanding voting securities. Pursuant to the consulting agreement, Dr. Braddock serves on our scientific advisory board and provides certain services to us related to planning, organizing and developing our research and development activities, advising on research techniques, assisting in recruiting scientists and attending meetings with investors, collaborators, strategic partners and contract research or manufacturing organizations. The consulting agreement is in effect until January 2021, and will automatically renew for additional successive one-year periods, unless we or Dr. Braddock notify the other 30 days prior to the renewal date that the consulting agreement will not be extended. Pursuant to such consulting agreement, we have agreed to pay Dr. Braddock at a rate of \$100,000 per year and reimburse Dr. Braddock for reasonable out-of-pocket expenses incurred in the performance of his services. If Dr. Braddock provides services under the consulting agreement for more than 35 days in any period of 12 consecutive months, we will pay Dr. Braddock an additional \$2,860 for each such additional day of service.

As of July 17, 2020, we have paid Dr. Braddock an aggregate of \$347,312 for his consulting services. In addition, we granted Dr. Braddock an option to purchase 9,111 shares of our common stock, at an exercise price per share of \$0.98 in 2017 and an option to purchase 13,381 shares of our common stock, at an exercise price per share of \$2.02 in 2019.

#### **Alexion Intellectual Property Asset Acquisition**

In July 2020, we entered into an intellectual property asset purchase agreement with Alexion Pharmaceuticals, Inc., or Alexion, pursuant to which Alexion sold and assigned to us Alexion's right, title and interest in and to specified patent rights and other specified assets solely related to ENPP1. We issued 8,294,360 shares of our Series A-2 Convertible Preferred Stock to Alexion in consideration for the sale and assignment to us of such assets, resulting in Alexion becoming a holder of more than 5% of our outstanding voting securities. For a further description of our intellectual property asset purchase agreement with Alexion, see "Business—Alexion Intellectual Property Asset Acquisition."

# **Registration Rights**

We are a party to an investor rights agreement with the holders of our convertible preferred stock, including our 5% stockholders and their affiliates and entities affiliated with some of our directors. This investor rights agreement provides these holders the right, subject to certain conditions, beginning six months following the completion of this offering, to demand that we file a registration statement or to request that their shares be covered by a registration statement that we are otherwise filing.

We are a party to a registration rights agreement with certain holders of our common stock, including some of our executive officers. The registration rights agreement provides these holders the right, subject to certain conditions, following the completion of the offering, to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing.

See the "Description of Capital Stock—Registration Rights" section for additional information regarding these registration rights.

# **Indemnification Agreements**

Our certificate of incorporation, which will become effective upon the closing of this offering, provides that we will indemnify our directors and officers to the fullest extent permitted by Delaware law. In addition, we intend to enter into indemnification agreements with all of our directors and executive officers prior to the completion of this offering. These indemnification agreements may require us, among other things, to indemnify each such director or executive officer for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by him or her in any action or proceeding arising out of his or her service as one of our directors or executive officers.

#### **Policies and Procedures for Related Person Transactions**

Our board of directors has adopted written policies and procedures, which will be effective upon the effectiveness of the registration statement of which this prospectus is a part, for the review of any transaction, arrangement or relationship in which our company is a participant, the amount involved exceeds \$120,000 and one of our executive officers, directors, director nominees or 5% stockholders, or their immediate family members, each of whom we refer to as a "related person," has a direct or indirect material interest.

If a related person proposes to enter into such a transaction, arrangement or relationship, which we refer to as a "related person transaction," the related person must report the proposed related person transaction to our general counsel, chief operating officer or chief financial officer. The policy calls for the proposed related person transaction to be reviewed and, if deemed appropriate, approved by our audit committee. Whenever practicable, the reporting, review and approval will occur prior to entry into the transaction. If advance review and approval is not

practicable, the audit committee will review, and, in its discretion, may ratify the related person transaction. The policy also permits the chair of the audit committee to review and, if deemed appropriate, approve proposed related person transactions that arise between committee meetings, subject to ratification by the committee at its next meeting. Any related person transactions that are ongoing in nature will be reviewed annually.

A related person transaction reviewed under the policy will be considered approved or ratified if it is authorized by the audit committee after full disclosure of the related person's interest in the transaction. As appropriate for the circumstances, the audit committee will review and consider:

- the related person's interest in the related person transaction;
- · the approximate dollar value of the amount involved in the related person transaction;
- the approximate dollar value of the amount of the related person's interest in the transaction without regard to the amount of any profit or loss:
- whether the transaction was undertaken in the ordinary course of our business;
- whether the terms of the transaction are no less favorable to us than terms that could have been reached with an unrelated third party;
- the purpose of, and the potential benefits to us of, the transaction; and
- any other information regarding the related person transaction or the related person in the context of the proposed transaction that would be material to investors in light of the circumstances of the particular transaction.

Our audit committee may approve or ratify the transaction only if it determines that, under all of the circumstances, the transaction is in, or is not inconsistent with, our best interests. Our audit committee may impose any conditions on the related person transaction that it deems appropriate.

In addition to the transactions that are excluded by the instructions to the SEC's related person transaction disclosure rule, our board of directors has determined that the following transactions do not create a material direct or indirect interest on behalf of related persons and, therefore, are not related person transactions for purposes of this policy:

- interests arising solely from the related person's position as an executive officer of another entity, whether or not the person is also a director of the entity, that is a participant in the transaction where the related person and all other related persons own in the aggregate less than a 10% equity interest in such entity, the related person and his or her immediate family members are not involved in the negotiation of the terms of the transaction and do not receive any special benefits as a result of the transaction and the amount involved in the transaction is less than the greater of \$200,000 or 5% of the annual gross revenues of the company receiving payment under the transaction; and
- a transaction that is specifically contemplated by provisions of our certificate of incorporation or bylaws.

The policy provides that transactions involving compensation of executive officers shall be reviewed and approved by our compensation committee in the manner specified in the compensation committee's charter.

We did not have a written policy regarding the review and approval of related person transactions prior to this offering. Nevertheless, with respect to such transactions, it has been the practice of our board of directors to consider the nature of and business reasons for such transactions, how the terms of such transactions compared to those which might be obtained from unaffiliated third parties and whether such transactions were otherwise fair to and in the best interests of, or not contrary to, our best interests.

#### PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of July 17, 2020 by:

- each of our directors;
- each of our named executive officers;
- all of our directors and executive officers as a group; and
- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock.

The column entitled "Percentage of Shares Beneficially Owned—Before Offering" is based on a total of 15,314,851 shares of our common stock outstanding as of July 17, 2020, after giving effect to the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 13,953,850 shares of our common stock upon the closing of this offering. The column entitled "Percentage of Shares Beneficially Owned—After Offering" is based on 20,314,851 shares of our common stock to be outstanding after this offering, including the 5,000,000 shares of our common stock that we are selling in this offering, but not including any additional shares issuable upon exercise of outstanding options. The table below does not reflect any potential purchases by our existing principal stockholders or their affiliated entities of shares of our common stock in this offering. If any shares of our common stock are purchased in the offering by these persons or entities, the number and percentage of shares of our common stock beneficially owned by them after this offering will differ from the amounts set forth in the below table.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our common stock. Shares of our common stock subject to options that are currently exercisable or exercisable within 60 days after July 17, 2020 are considered outstanding and beneficially owned by the person holding the options for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted, the persons and entities in this table have sole voting and investing power with respect to all of the shares of our common stock beneficially owned by them, subject to community property laws, where applicable. Except as otherwise set forth below, the address of each beneficial owner is c/o Inozyme Pharma, Inc., 321 Summer Street, Suite 400, Boston, Massachusetts 02210.

	Number of	Percentage Beneficial	
Name and Address of Beneficial Owner	Shares Beneficially Owned	Before Offering (%)	After Offering (%)
5% Stockholders			· <u></u>
Longitude Venture Partners III, L.P.(1)	2,194,379	14.3	10.8
Entities affiliated with New Enterprise Associates(2)	2,194,379	14.3	10.8
Novo Holdings A/S(3)	2,194,379	14.3	10.8
Sofinnova Venture Partners X, L.P.(4)	1,590,808	10.4	7.8
Pivotal bioVenture Partners Fund I, L.P.(5)	1,403,654	9.2	6.9
Entities affiliated with RA Capital Management, L.P.(6)	1,403,653	9.2	6.9
Alexion Pharmaceuticals, Inc.(7)	1,109,910	7.2	5.5
Entities affiliated with Cowen Healthcare Investments(8)	842,191	5.5	4.1
Directors and Named Executive Officers			
Axel Bolte(9)	459,810	3.0	2.2
Henric Bjarke(10)	133,257	*	*
Steven Jungles(11)	135,928	*	*
Douglas Treco(12)	5,436	*	*
Sarah Bhagat(13)	_	_	
Reinaldo Diaz(14)	_	_	_
Martin Edwards(15)	_	_	_
Robert Hopfner(16)	1,403,654	9.2	6.9
Edward Mathers(17)	_	_	_
Lynne Sullivan (18)	1,773	*	*
All current executive officers and directors as a group (12 persons)(19)	2,170,872	13.8	10.4

<sup>\*</sup> Less than 1%

<sup>(1)</sup> Consists of 2,194,379 shares of our common stock issuable upon conversion of our preferred stock held by Longitude Venture Partners III, L.P., or LVP III. Longitude Capital Partners, III, LLC, or LCP III, is the general partner of LVP III and may be deemed to have voting and dispositive power over our securities held by LVP III. Patrick G. Enright and Juliet Tammenoms Bakker are managing members of LCP III and may be deemed to share voting and dispositive power with respect to the shares held by LVP III. Each of LCP III, Mr. Enright and Ms. Tammenoms Bakker disclaims beneficial ownership of such shares, except to the extent of their respective pecuniary interests therein. The principal business address of LVP III is 2740 Sand Hill, 2nd Floor, Road, Menlo Park, California 94025.

<sup>(2)</sup> Consists of (i) 2,187,689 shares of our common stock issuable upon conversion of our preferred stock held by New Enterprise Associates 15, L.P., or NEA 15, and (ii) 6,690 shares of our common stock issuable upon conversion of our preferred stock held by NEA Ventures 2016, L.P., or Ven 2016. The shares directly held by NEA 15 are indirectly held by each of (a) NEA Partners 15, L.P., or NEA Partners 15, the sole general partner of NEA 15, (b) NEA 15 GP, LLC, or NEA 15 LLC, the sole general partner of NEA Partners 15 and (c) each of the individual Managers, or the Managers, of NEA 15 LLC. The Managers of NEA 15 LLC are Forest Baskett, Anthony A. Florence, Jr., Mohamad Makhzoumi, Joshua Makower, Scott D. Sandell and Peter Sonsini. The shares directly held by Ven 2016 are indirectly held by Karen P. Welsh, the general partner of Ven 2016. NEA Partners 15, NEA 15 LLC and the Managers share voting and dispositive power with regard to the shares held by NEA 15. Karen P. Welsh shares voting and dispositive

- power with regard to the shares held by in Ven 2016. All indirect holders of the above referenced shares disclaim beneficial ownership of all applicable shares, except to the extent of their actual pecuniary interest therein. The principal business address of NEA 15 and NEA Ventures is 1954 Greenspring Drive, Suite 600, Timonium, MD 21093.
- (3) Consists of 2,194,379 shares of our common stock issuable upon conversion of our preferred stock held by Novo Holdings A/S. Novo Holdings A/S is a Danish limited liability company, which is wholly owned by Novo Nordisk Foundation, or the Foundation. Novo Holdings A/S, through its board of directors, or the Novo Board, has the sole power to vote and dispose of the shares held by Novo Holdings A/S. The Novo Board may exercise shared voting and dispositive control over the shares held by Novo Holdings A/S with approval by a majority of the Novo Board. As such, no individual member of the Novo Board is deemed to hold any beneficial ownership or reportable pecuniary interest in the shares held by Novo Holdings A/S. The principal business address of Novo Holdings A/S is Tuborg Havnevej 19, 2900 Hellerup, Denmark.
- (4) Consists of 1,590,808 shares of our common stock issuable upon conversion of our preferred stock held by Sofinnova Venture Partners X, L.P., or SVP X. Sofinnova Management X, L.L.C., or SM X, the general partner of SVP X, may be deemed to have sole voting power over the shares held by SVP X, and Dr. James I. Healy, Dr. Michael F. Powell and Dr. Maha Katabi, the managing members of SM X, may be deemed to have shared voting and dispositive power with respect to the shares held by SVP X. Such individuals disclaim beneficial ownership of such shares except to the extent of their pecuniary interest therein. The principal address of SVP X is c/o Sofinnova, 3000 Sand Hill Road, Building 4, Suite 250, Menlo Park, California 94025.
- (5) Consists of 1,403,654 shares of our common stock issuable upon conversion of our preferred stock held by Pivotal bioVenture Partners Fund I, L.P. Pivotal bioVenture Partners Fund I G.P., L.P. is the general partner of Pivotal bioVenture Partners Fund I, L.P. and Pivotal bioVenture Partners Fund I U.G.P., Ltd is the general partner of Pivotal bioVenture Partners Fund I G.P., L.P. Richard Coles, Peter Bisgaard and Vincent Sai Sing Cheung are directors of Pivotal bioVenture Partners Fund I U.G.P., Ltd, and may, along with Pivotal bioVenture Partners Fund I U.G.P., Ltd be deemed to have shared voting and investment control and power over the shares owned by Pivotal bioVenture Partners Fund I, L.P. The principal business address of Pivotal bioVenture Partners Fund I, L.P. is 501 Second Street, Suite 200, San Francisco, California 94107.
- (6) Consists of (i) 1,041,757 shares of our common stock issuable upon conversion of our preferred stock held by RA Capital Healthcare Fund, L.P., or RA Capital, (ii) 186,440 shares of our common stock issuable upon conversion of our preferred stock held by Blackwell Partners LLC—Series A, or Blackwell and (iii) 175,456 shares of our common stock issuable upon conversion of our preferred stock held by RA Capital Nexus Fund, L.P., or Nexus Fund. RA Capital Management, L.P. is the investment manager for RA Capital, Blackwell and Nexus Fund. The general partner of RA Capital Management, L.P. is RA Capital Management GP, LLC, of which Peter Kolchinsky and Rajeev Shah are managing members. RA Capital Management, L.P., RA Capital Management GP, LLC, Peter Kolchinsky and Rajeev Shah may be deemed to have voting and investment power over the shares held of record by RA Capital, Blackwell and Nexus Fund. RA Capital Management, L.P., RA Capital Management GP, LLC, Peter Kolchinsky and Rajeev Shah disclaim beneficial ownership of such shares, except to the extent of any pecuniary interest therein. The address of the entities listed above is 200 Berkeley Street, 18th Floor, Boston, Massachusetts 02116.
- (7) Consists of 1,109,910 shares of our common stock issuable upon conversion of our preferred stock held by Alexion Pharmaceuticals, Inc., a publicly traded biopharmaceutical company. The address of Alexion Pharmaceuticals, Inc. is 121 Seaport Boulevard, Boston, Massachusetts 02210.
- (8) Consists of (i) 784,158 shares of our common stock issuable upon conversion of our preferred stock held by Cowen Healthcare Investments II LP, or CHI II, and (ii) 58,033 shares of our common stock issuable upon conversion of our preferred stock held by CHI EF II LP, or CHI EF. CHI II and CHI EF are collectively referred to as the Cowen Entities. CHI Advisors LLC, the Cowen Entities' investment advisor, has voting and investment power with respect to the shares held by each of the Cowen Entities. Investment and voting decisions by each Cowen Entity are made jointly by an investment committee consisting of three or more individuals associated with CHI Advisors LLC. The address of each of the Cowen Entities is CHI Advisors LLC, 599 Lexington Avenue, 19th Floor, New York, NY 10022.

- (9) Consists of (i) 190,825 shares of our common stock held by Mr. Bolte and (ii) 268,985 shares of our common stock underlying options held by Mr. Bolte that are exercisable as of July 17, 2020 or will become exercisable within 60 days after such date. Such number does not include shares of our common stock that may become exercisable within 60 days after July 17, 2020 underlying an option to purchase 287,706 shares of our common stock granted to Mr. Bolte effective upon the effectiveness of the registration statement of which this prospectus is a part. Such option vests in equal monthly installments over a term of four years from the date of effectiveness of the registration statement of which this prospectus is a part.
- (10) Consists of (i) 53,526 shares of our common stock held by Mr. Bjarke and (ii) 79,731 shares of our common stock underlying options held by Mr. Bjarke that are exercisable as of July 17, 2020 or will become exercisable within 60 days after such date. Such number does not include shares of our common stock that may become exercisable within 60 days after July 17, 2020 underlying an option to purchase 32,905 shares of our common stock granted to Mr. Bjarke effective upon the effectiveness of the registration statement of which this prospectus is a part. Such option vests in equal monthly installments over a term of four years from the date of effectiveness of the registration statement of which this prospectus is a part.
- (11) Consists of (i) 42,036 shares of our common stock held by Steven Jungles Trust Dated Nov. 12, 2014, of which Mr. Jungles is trustee, (ii) 13,381 shares of our common stock issuable upon conversion of our preferred stock held by Steven Jungles Trust Dated Nov. 12, 2014, of which Mr. Jungles is trustee and (iii) 80,511 shares of our common stock underlying options held by Mr. Jungles that are exercisable as of July 17, 2020 or will become exercisable within 60 days after such date.
- (12) Consists of 5,436 shares of our common stock underlying options held by Dr. Treco that are exercisable as of July 17, 2020 or will be become exercisable within 60 days after such date.
- (13) Dr. Bhagat is a partner at Sofinnova. Dr. Bhagat does not have voting or dispositive power over any of the shares held directly by SVP X referenced in footnote (4) above.
- (14) Mr. Diaz is a member of LCP III. Mr. Diaz does not have voting or dispositive power with respect to the shares held by LVP III.
- (15) Dr. Edwards is employed as a senior partner at Novo Holdings A/S. Dr. Edwards does not have voting or dispositive power over any of the shares held by Novo Holdings A/S referenced in footnote (3) above.
- (16) Consists of the shares set forth in footnote (5) above. Dr. Hopfner is the managing partner of Pivotal bioVenture Partners Investment Advisor LLC and may be deemed to share voting and investment power over the shares held by Pivotal bioVenture Partners Fund I, L.P. Dr. Hopfner disclaims beneficial ownership of such shares except to the extent of any pecuniary interest therein.
- (17) Mr. Mathers is a general partner at New Enterprise Associates, Inc. Mr. Mathers does not have voting or dispositive power over any of the shares directly held by NEA 15 or Ven 2016 referenced in footnote (2) above.
- (18) Consists of 1,773 shares of our common stock underlying options held by Ms. Sullivan that are exercisable as of July 17, 2020 or will be become exercisable within 60 days after such date.
- (19) Consists of (i) 286,387 shares of our common stock, (ii) 1,417,035 shares of our common stock issuable upon conversion of our preferred stock and (iii) 467,450 shares of our common stock underlying options that are exercisable as of July 17, 2020 or will become exercisable within 60 days after such date. Such number does not include shares of our common stock that may become exercisable within 60 days after July 17, 2020 underlying options to purchase 391,995 shares of our common stock granted to our executive officers effective upon the effectiveness of the registration statement of which this prospectus is a part. Such options vest in equal monthly installments over a term of four years from the date of effectiveness of the registration statement of which this prospectus is a part.

#### DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock and provisions of our certificate of incorporation and bylaws are summaries and are qualified by reference to the certificate of incorporation and the bylaws that will be in effect upon the closing of this offering. We will file copies of these documents with the SEC as exhibits to our registration statement of which this prospectus is a part. The description of the capital stock reflects changes to our capital structure that will occur upon the closing of this offering.

Upon the closing of this offering, our authorized capital stock will consist of 200,000,000 shares of our common stock, par value \$0.0001 per share, and 5,000,000 shares of our preferred stock, par value \$0.0001 per share, all of which preferred stock will be undesignated.

As of July 17, 2020, we had issued and outstanding:

- 1,361,001 shares of our common stock held by 19 stockholders of record;
- 48,850,000 shares of our Series A Convertible Preferred Stock held by 14 stockholders of record, convertible into 6,536,856 shares of our common stock; and
- 55,427,222 shares of our Series A-2 Convertible Preferred Stock held by 13 stockholders of record, convertible into 7,416,994 shares of our common stock.

Upon the closing of this offering, all of the outstanding shares of our preferred stock will automatically convert into an aggregate of 13,953,850 shares of our common stock.

#### Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. Each election of directors by our stockholders will be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of our common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

In the event of our liquidation or dissolution, the holders of our common stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any of our outstanding preferred stock. Holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

# **Preferred Stock**

Under the terms of our certificate of incorporation that will become effective upon the closing of this offering, our board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could

discourage a third party from seeking to acquire, a majority of our outstanding voting stock. Upon the closing of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

#### **Options**

As of July 17, 2020, options to purchase an aggregate of 2,078,405 shares of our common stock, at a weighted average exercise price of \$1.99 per share, were outstanding.

#### Delaware Anti-Takeover Law and Certain Charter and Bylaw Provisions

#### Delaware Law

We are subject to Section 203 of the DGCL. Subject to certain exceptions, Section 203 prevents a publicly held Delaware corporation from engaging in a "business combination" with any "interested stockholder" for three years following the date that the person became an interested stockholder, unless either the interested stockholder attained such status with the approval of our board of directors, the business combination is approved by our board of directors and stockholders in a prescribed manner or the interested stockholder acquired at least 85% of our outstanding voting stock in the transaction in which it became an interested stockholder. A "business combination" includes, among other things, a merger or consolidation involving us and the "interested stockholder" and the sale of more than 10% of our assets. In general, an "interested stockholder" is any entity or person beneficially owning 15% or more of our outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person. The restrictions contained in Section 203 are not applicable to any of our existing stockholders that will own 15% or more of our outstanding voting stock upon the closing of this offering.

## Staggered Board; Removal of Directors

Our certificate of incorporation and our bylaws to be effective upon the closing of this offering divide our board of directors into three classes with staggered three-year terms. In addition, our certificate of incorporation and our bylaws to be effective upon the closing of this offering provide that directors may be removed only for cause and only by the affirmative vote of the holders of 75% of our shares of capital stock present in person or by proxy and entitled to vote. Under our certificate of incorporation and our bylaws to be effective upon the closing of this offering, any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office. Furthermore, our certificate of incorporation to be effective upon the closing of this offering provides that the authorized number of directors may be changed only by the resolution of our board of directors. The classification of our board of directors and the limitations on the ability of our stockholders to remove directors, change the authorized number of directors and fill vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our company.

# Stockholder Action; Special Meeting of Stockholders; Advance Notice Requirements for Stockholder Proposals and Director Nominations

Our certificate of incorporation and our bylaws to be effective upon the closing of this offering provide that any action required or permitted to be taken by our stockholders at an annual meeting or special meeting of stockholders may only be taken if it is properly brought before such meeting and may not be taken by written action in lieu of a meeting. Our certificate of incorporation and our bylaws to be effective upon the closing of this offering also provide that, except as otherwise required by law, special meetings of the stockholders can only be called by our board of directors. In addition, our bylaws to be effective upon the closing of this offering establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of candidates for election to our board of directors. Stockholders at an annual

meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors, or by a stockholder of record on the record date for the meeting who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities. These provisions also could discourage a third party from making a tender offer for our common stock because even if the third party acquired a majority of our outstanding voting stock, it would be able to take action as a stockholder, such as electing new directors or approving a merger, only at a duly called stockholders meeting and not by written consent.

#### Super-Majority Voting

The DGCL provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws unless a corporation's certificate of incorporation or bylaws, as the case may be, requires a greater percentage. Our bylaws to be effective upon the closing of this offering may be amended or repealed by a majority vote of our board of directors or the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in any annual election of directors. In addition, the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in any election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of our certificate of incorporation described above.

#### **Exclusive Forum Selection**

Our certificate of incorporation to be effective upon the closing of this offering provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for (1) any derivative action or proceeding brought on behalf of our company, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, other employees or stockholders to our company or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware or (4) any action asserting a claim arising pursuant to any provision of our certificate of incorporation or bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine. These choice of forum provisions will not apply to claims arising under the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, or any other claim for which federal courts have exclusive jurisdiction. Furthermore, our certificate of incorporation that will become effective upon the closing of this offering provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any claims arising under the Securities Act of 1933, as amended.

These exclusive forum provisions may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find such provisions contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect our business, financial condition and operating results.

# **Registration Rights**

We have entered into a second amended and restated investor rights agreement, dated as of November 9, 2018, as amended, or the investor rights agreement, with holders of our convertible preferred stock and a

registration rights agreement, dated June 1, 2016, or the registration rights agreement, with certain holders of our common stock.

Pursuant to the investor rights agreement, beginning 180 days following the closing of this offering, holders of a total of 13,953,850 shares of our common stock issued upon conversion of our convertible preferred stock will have the right to require us to register these shares under the Securities Act under specified circumstances and to participate in future registrations of securities by us under the circumstances described below. We refer to the shares with these registration rights as registrable securities. After registration pursuant to these rights, the registrable securities will become freely tradable without restriction under the Securities Act.

Pursuant to the registration rights agreement, holders of a total of 1,925,429 shares of our common stock, including shares of our common stock issued upon conversion of our convertible preferred stock and shares of our common stock issued or issuable upon exercise of options, will have the right to, beginning one year after this offering, require us to register these shares under the Securities Act under specified circumstances and to, beginning upon the completion of this offering, participate in future registrations of securities by us under the circumstances described below. We refer to the shares with these registration rights as founder registrable securities. After registration pursuant to these rights, the founder registrable securities will become freely tradable without restriction under the Securities Act.

# Demand and Form S-3 Registration Rights

Investor Rights Agreement

Beginning 180 days after this offering, subject to specified limitations set forth in the investor rights agreement, at any time, the holders of a majority of the outstanding registrable securities, including at least one of Pivotal bioVenture Partners Fund I, L.P., Sofinnova Venture Partners X, L.P. or RA Capital Healthcare Fund, L.P., may demand that we register all or a part of the registrable securities then outstanding under the Securities Act for purposes of a public offering having an aggregate offering price to the public, net of underwriting discounts and commissions, of not less than \$10.0 million. We are not obligated to file a registration statement pursuant to this provision on more than two occasions.

In addition, subject to specified limitations set forth in the investor rights agreement, at any time after we become eligible to file a registration statement on Form S-3, the holders of any of the then outstanding registrable securities may request that we register such securities on a registration statement on Form S-3 so long as the holders propose to sell securities at an aggregate price to the public of at least \$1.0 million. We are not obligated to file a registration statement pursuant to this provision on more than two occasions in any 12-month period.

Registration Rights Agreement

Beginning one year after this offering, subject to specified limitations set forth in the registration rights agreement, at any time, the holders of 30% of the then outstanding founder registrable securities under the registration rights agreement may demand that we register all or a portion of the founder registrable shares then outstanding under the Securities Act. We are not obligated to file a registration statement pursuant to this provision on more than two occasions, and we are not obligated to file a registration statement pursuant to this provision within 180 days of the effective date of any other registration statement that we may file (other than a registration statement on Form S-3).

In addition, subject to specified limitations set forth in the registration rights agreement, at any time after which we become eligible to file a registration statement on Form S-3, the holders of 30% of the then outstanding founder registrable securities may demand that we register all or a portion of their founder registrable securities on Form S-3 so long as the holders propose to sell securities at an aggregate price to the public of at least \$1.0 million.

#### **Incidental Registration Rights**

**Investor Rights Agreement** 

If, at any time after the closing of this offering, we propose to register for our own account any of our securities under the Securities Act, the holders of registrable securities will be entitled to notice of the registration and, subject to specified exceptions, will be afforded an opportunity to register all or a portion of the registrable securities then held by them in that registration.

In the event that any registration in which the holders of registrable securities participate pursuant to our investor rights agreement is an underwritten public offering, we have agreed to enter into an underwriting agreement in usual and customary form and use our reasonable efforts to facilitate such offering.

Registration Rights Agreement

If, at any time after the closing of this offering, we propose to register for our own account any of our securities under the Securities Act, the holders of founder registrable securities will be entitled to notice of the registration and, subject to specified exceptions, have the right to require us to register all or a portion of the founder registrable securities then held by them in that registration.

In the event that any registration in which the holders of founder registrable securities participate pursuant to our registration rights agreement is an underwritten public offering, we have agreed to enter into an underwriting agreement in usual and customary form and use our reasonable efforts to facilitate such offering.

#### **Expenses**

Pursuant to the investor rights agreement, we are required to pay all registration expenses, including all registration, qualification and filing fees, FINRA fees and expenses, printing expenses, fees and disbursements of our counsel, fees and disbursements, not to exceed \$35,000, of one counsel selected by the selling stockholders to represent the selling stockholders, state Blue Sky fees and expenses, and the expense of any regular or special audits incident to or required by any such registration, but excluding underwriting discounts and selling commissions applicable to the sale any registrable securities. Pursuant to the registration rights agreement, we are required to pay all registration expenses, including all registration, qualification and filings fees, printers' and accounting fees and the reasonable fees and disbursements of a single counsel for the selling stockholders requesting registration on Form S-3, but excluding any underwriting discounts and selling commissions applicable to the sale any founder registrable securities.

If a registration is withdrawn at the request of the stockholders initiating the registration under the investor rights agreement or the registration rights agreement, then such stockholders will bear the expenses of the registration, subject to certain specified exceptions.

The investor rights agreement and registration rights agreement contain customary cross-indemnification provisions, pursuant to which we are obligated to indemnify the selling stockholders in the event of material misstatements or omissions in the registration statement attributable to us or any violation or alleged violation whether by action or inaction by us under the Securities Act, the Exchange Act, any state securities or Blue Sky law or any rule or regulation promulgated under the Securities Act, the Exchange Act or any state securities or Blue Sky law in connection with such registration statement or the qualification or compliance of the offering, and they are obligated to indemnify us for material misstatements or omissions in the registration statement attributable to them.

#### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock will be Computershare Trust Company, N.A.

# Nasdaq Global Market

We have applied to have our common stock listed on the Nasdaq Global Market under the symbol "INZY."

#### SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options, or the anticipation of these sales, could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through sales of equity securities.

Upon the closing of this offering, we will have outstanding 20,314,851 shares of our common stock, based on the 1,361,001 shares of our common stock that were outstanding on July 17, 2020, and after giving effect to the issuance of 5,000,000 shares of our common stock in this offering, assuming no exercise by the underwriters of their option to purchase additional shares of our common stock, and the conversion of all outstanding shares of our preferred stock into an aggregate of 13,953,850 shares of our common stock upon the closing of this offering. Of these shares, all shares sold in this offering will be freely tradable without restriction under the Securities Act of 1933, as amended, or the Securities Act, unless purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining 15,314,851 shares of our common stock will be "restricted securities" under Rule 144, and we expect that substantially all of these restricted securities will be subject to the 180-day lock-up period under the lock-up agreements as described below. These restricted securities may be sold in the public market upon release or waiver of any applicable lock-up agreements and only if registered or pursuant to an exemption from registration, such as Rule 144 or Rule 701 under the Securities Act.

#### **Rule 144**

In general, under Rule 144, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, any person who is not our affiliate and has not been our affiliate at any time during the preceding three months and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell those shares without restriction, subject to the availability of current public information about us. In addition, under Rule 144, any such person who has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available.

In general, under Rule 144, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is our affiliate or who was our affiliate at any time during the preceding three months and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 203,149 shares immediately after this
  offering; and
- the average weekly trading volume in our common stock on the Nasdaq Global Market during the four calendar weeks preceding the date of filing of a Notice of Proposed Sale of Securities Pursuant to Rule 144 with respect to the sale.

Sales under Rule 144 by our affiliates are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

Upon waiver or expiration of the 180-day lock-up period described below, approximately 15,314,851 shares of our common stock will be eligible for sale under Rule 144. We cannot estimate the number of shares of our common stock that our existing stockholders will elect to sell under Rule 144.

#### **Rule 701**

In general, under Rule 701 of the Securities Act, any of our employees, directors, officers, consultants or advisors, other than our affiliates, who purchased shares from us in connection with a qualified compensatory stock plan or other written agreement before the effective date of a registration statement under the Securities Act is eligible to resell these shares 90 days after such effective date in reliance on Rule 144, but without compliance with the various restrictions, including the availability of public information about us, holding period and volume limitations, contained in Rule 144. Substantially all Rule 701 shares are subject to lock-up agreements described below and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

#### **Lock-up Agreements**

We, each of our executive officers and directors and the holders of a majority of our outstanding securities have agreed that, without the prior written consent of BofA Securities, Inc., Cowen and Company, LLC and Piper Sandler & Co., on behalf of the underwriters, we and they will not, subject to limited exceptions, during the period ending 180 days after the date of this prospectus:

- offer, pledge, sell, contract to sell, sell any option or contract to purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for shares of our common stock whether now owned or hereafter acquired or with respect to which such holder has or acquires the power of disposition, or the Lock-up Securities;
- enter into any swap or other agreement or transaction that transfers to another, in whole or in part, directly or indirectly, the economic
  consequence of ownership of the Lock-up Securities, whether any such swap or transaction is to be settled by delivery of our common
  stock or such other securities, in cash or otherwise; or
- publicly disclose the intention to do any of the foregoing.

Each of our directors and executive officers and the holders of a majority of our outstanding securities have also agreed during such 180-period not to make any demand for, or exercise any right with respect to, or confidentially submit or cause to be filed or confidentially submitted any registration statement under the Securities Act with respect to, the registration of shares of our common stock or any securities convertible into or exercisable or exchangeable for shares of our common stock, or warrants or other rights to purchase shares of our common stock or any such securities.

These agreements are subject to certain exceptions, as described in the section of this prospectus entitled "Underwriting."

#### **Registration Rights**

Under our investor rights agreement, beginning 180 days after the closing of this offering, the holders of an aggregate of 13,953,850 shares of our common stock will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Under our registration rights agreement, holders of an aggregate of 1,925,429 shares of our common stock, including shares of our common stock issued upon conversion of our preferred stock and shares of our common stock issued or issuable upon exercise of options, will have the right to, beginning one year after this offering, require us to register these shares under the Securities Act under specified circumstances and to, beginning upon the completion of this offering, participate in future registrations of securities by us. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. See the "Description of Capital Stock—Registration for additional information regarding these registration rights.

# **Stock Options and Form S-8 Registration Statement**

As of July 17, 2020, we had outstanding options to purchase an aggregate of 2,078,405 shares of our common stock under the 2017 Plan. Following this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding options and reserved for future options and other awards under the 2017 Plan, the 2020 Plan and the 2020 ESPP. See the "Executive Compensation—Stock Option and Other Compensation Plans" section for additional information regarding these plans. Accordingly, shares of our common stock registered under the registration statements will be available for sale in the open market, subject to Rule 144 volume limitations applicable to affiliates, and subject to any vesting restrictions and lock-up agreements applicable to these shares.

# MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF COMMON STOCK

The following is a discussion of material U.S. federal income and estate tax considerations relating to ownership and disposition of our common stock by a non-U.S. holder. For purposes of this discussion, the term "non-U.S. holder" means a beneficial owner (other than a partnership or other pass-through entity or arrangement) of our common stock that is not, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States:
- a corporation, or other entity treated as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- · an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or if the trust has a valid election in effect to be treated as a U.S. person under applicable U.S. Treasury Regulations.

This discussion is based on current provisions of the Internal Revenue Code of 1986, as amended, or the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings, and judicial decisions, as in effect as of the date of this prospectus and all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus. In addition, there can be no assurance that the IRS will not challenge one or more of the tax consequences described in this prospectus.

This discussion addresses only non-U.S. holders that hold shares of our common stock as a capital asset (generally, property held for investment). This discussion does not address all aspects of U.S. federal income and estate taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address the alternative minimum tax, the Medicare tax on net investment income or any aspects of U.S. state, local, or non-U.S. taxes. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- insurance companies;
- · tax-exempt organizations;
- · financial institutions;
- · brokers or dealers in securities;
- · pension plans;
- controlled foreign corporations;
- passive foreign investment companies;
- owners that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security, or other integrated investment;
   and
- certain U.S. expatriates.

In addition, this discussion does not address the tax treatment of partnerships or persons who hold their common stock through partnerships or other pass-through entities or arrangements for U.S. federal income tax purposes. A partner in such a partnership that will hold our common stock should consult his, her, or its own tax advisor regarding the tax consequences of the purchase, ownership, and disposition of our common stock through a partnership or other pass-through entity, as applicable.

Prospective investors should consult their own tax advisors regarding the U.S. federal, state, local, and non-U.S. income and other tax considerations of acquiring, holding, and disposing of our common stock.

#### **Distributions**

If we pay distributions on our common stock, those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below under the heading "—Gain on Disposition of Common Stock."

Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence. A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) and satisfy applicable certification and other requirements. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS. Non-U.S. holders are urged to consult their own tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. However, such U.S. effectively connected income is taxed on a net income basis at the same U.S. federal income tax rates applicable to United States persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

# Gain on Disposition of Common Stock

A non-U.S. holder generally will not be subject to U.S. federal income tax on gain recognized on a disposition of our common stock unless:

• the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States; in these cases, the non-U.S. holder will be taxed on a net income basis at the same U.S. federal income tax rates applicable to United States persons (as defined in the Code), and if the non-U.S. holder is a foreign corporation, an additional branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty, may also apply;

- the non-U.S. holder is a nonresident alien present in the United States for 183 days or more in the taxable year of the disposition and certain other requirements are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the net gain derived from the disposition, which may be offset by U.S.-source capital losses of the non-U.S. holder, if any, provided the non-U.S. holder timely files U.S. federal income tax returns with respect to such losses; or
- we are, or have been at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter), a "U.S. real property holding corporation," unless our common stock is regularly traded on an established securities market and the non-U.S. holder held no more than 5% of our outstanding common stock, directly or indirectly, during the shorter of the five year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. If we are determined to be a U.S. real property holding corporation and the foregoing exception does not apply, then the non-U.S. holder generally will be taxed on its net gain derived from the disposition at the U.S. federal income tax rates applicable to United States persons (as defined in the Code) and potentially subject to a withholding tax on gross proceeds. Generally, a corporation is a "U.S. real property holding corporation" if the fair market value of its "U.S. real property interests" equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we believe that we are not currently, and we do not anticipate becoming, a "U.S. real property holding corporation" for U.S. federal income tax purposes. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rule described above.

# **Information Reporting and Backup Withholding**

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. Generally, a non-U.S. holder will comply with such procedures if it provides a properly executed IRS Form W-8BEN or W-8BEN-E (or other applicable Form W-8) or otherwise meets documentary evidence requirements for establishing that it is a non-U.S. holder, or otherwise establishes an exemption. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above under the heading "—Distributions," will generally be exempt from U.S. backup withholding.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Rather, any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

#### **FATCA**

Provisions of the Code commonly referred to as the Foreign Account Tax Compliance Act, or FATCA, generally impose a 30% withholding tax on dividends on, and gross proceeds from the sale or other disposition of, our common stock if paid to a foreign entity unless (1) if the foreign entity is a "foreign financial institution," the foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (2) if the foreign entity is not a "foreign financial institution," the foreign entity identifies certain of its U.S. investors, or (3) the foreign entity is otherwise excepted under FATCA.

Withholding under FATCA generally applies to payments of dividends on our common stock. While withholding under FATCA may have applied to payments of gross proceeds from a sale or other disposition of our common stock after December 31, 2018, under recently proposed U.S. Treasury Regulations, withholding on payments of gross proceeds is not required. Although such regulations are not final, applicable withholding agents may rely on the proposed regulations until final regulations are issued.

If withholding under FATCA is required on any payment related to our common stock, investors not otherwise subject to withholding (or that otherwise would be entitled to a reduced rate of withholding) on such payment may be required to seek a refund or credit from the IRS. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this section. Non-U.S. holders should consult their own tax advisors regarding the possible implications of FATCA on their investment in our common stock and the entities through which they hold our common stock.

#### **Federal Estate Tax**

Common stock owned or treated as owned by an individual who is a non-U.S. holder (as specially defined for U.S. federal estate tax purposes) at the time of death will be included in the individual's gross estate for U.S. federal estate tax purposes and, therefore, may be subject to U.S. federal estate tax, unless an applicable estate tax or other treaty provides otherwise.

The preceding discussion of material U.S. federal tax considerations is for prospective investors' information only. It is not tax advice. Prospective investors should consult their own tax advisors regarding the particular U.S. federal, state, local, and non-U.S. tax consequences of purchasing, holding, and disposing of our common stock, including the consequences of any proposed changes in applicable laws.

#### UNDERWRITING

BofA Securities, Inc., Cowen and Company, LLC and Piper Sandler & Co. are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of our common stock set forth opposite its name below.

Underwriter	Number of Shares
BofA Securities, Inc.	
Cowen and Company, LLC	
Piper Sandler & Co.	
Wedbush Securities Inc.	
Total	5,000,000

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

#### **Commissions and Discounts**

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$ per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	Per Share	Without Option	With Option
Public offering price	\$	\$	\$
Underwriting discount	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

The expenses of the offering, not including the underwriting discount, are estimated at \$3.3 million and are payable by us. We have also agreed to reimburse the underwriters for their expenses relating to clearance of this offering with the Financial Industry Regulatory Authority, Inc. in an amount up to \$50,000.

#### **Option to Purchase Additional Shares**

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 750,000 additional shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

#### No Sales of Similar Securities

We, our executive officers and directors and our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of BofA Securities, Inc., Cowen and Company, LLC and Piper Sandler & Co. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, sell or contract to sell any common stock;
- sell any option or contract to purchase any common stock;
- purchase any option or contract to sell any common stock;
- · grant any option, right or warrant to purchase of any common stock;
- · otherwise dispose of or transfer any common stock;
- request or demand that we file or make a confidential submission of a registration statement related to the common stock;
- enter into any swap or other agreement or transaction that transfers, in whole or in part, the economic consequence of ownership of any
  common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise; or
- publicly disclose the intention to do any of the foregoing.

The exceptions permit our executive officers and directors and such security holders, subject to certain further restrictions, to:

- transfer the common stock (1) as a bona fide gift or gifts, including to a trust, educational or other entity established for charitable purposes, (2) to any trust for the direct or indirect benefit of the person or their immediate family, (3) as a distribution to the person's general or limited partners, members, stockholders, or other equity holders or trust beneficiaries, (4) to the person's affiliates or to any investment fund or other entity that, directly or indirectly controls or manages, is controlled or managed by, or is under common control or management with the person, (5) by will or intestacy, or (6) pursuant to a court order or settlement agreement related to the distribution of assets in connection with the dissolution of a marriage or civil union;
- exercise any stock options, warrants, or other rights to acquire shares of our common stock granted under our incentive plans described in this prospectus;
- transfer the common stock to us pursuant to agreements under which we exercise our option to repurchase such shares or exercise a right of first refusal with respect to transfers of such shares upon termination of the person's service to us;

- convert shares of our preferred stock described in this prospectus into shares of our common stock in connection with the closing of this
  offering;
- transfer the common stock to any nominee or custodian of a person or entity to whom a transfer or disposition would be permissible under the above exceptions; or
- transfer the common stock to a bona fide third party pursuant to a merger, tender offer or other similar transaction made to all holders of common stock and involving a Change of Control (as defined below) that has been approved by our board of directors.

For purposes of the above, "Change of Control" shall mean the transfer (whether by tender offer, merger, consolidation, or other similar transaction), in one transaction or a series of related transactions, to a person or group of affiliated persons, of shares of our voting securities if, after such transfer, such person or group of affiliated persons would hold more than 50% of our outstanding voting securities.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

# **Nasdaq Global Market Listing**

We have applied to have our common stock listed on the Nasdaq Global Market under the symbol "INZY."

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are:

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us;
- our financial information;
- · the history of, and the prospects for, our company and the industry in which we compete;
- · an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues;
- · the present state of our development; and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

#### **Price Stabilization, Short Positions and Penalty Bids**

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. "Naked" short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on the Nasdaq Global Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

#### **Electronic Distribution**

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

#### Other Relationships

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions. Affiliates of Cowen and Company, LLC own 6,293,706 shares of our Series A-2 Convertible Preferred Stock, which were acquired on March 22, 2019 and June 5, 2020, which are convertible into 842,191 shares of common stock upon the closing of this offering. 3,146,853 shares of Series A-2 Convertible Preferred Stock were acquired on June 5, 2020, which are convertible into 421,096 shares of common stock upon the closing of this offering. Of the shares acquired on June 5, 2020, 484,931 shares, which are convertible into 64,891 shares of common stock upon the closing of this offering, have been deemed underwriter compensation by FINRA and are subject to a 180-day lock-up pursuant to FINRA Rule 5110(g)(1), commencing on the effective date of the registration statement of which this prospectus is a part. Pursuant to FINRA Rule 5110(g)(1), these shares will not be sold during the offering, or sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging,

short sale, derivative, put or call transaction that would result in the economic disposition of the shares by any person for a period of 180 days immediately following the effective date of the registration statement of which this prospectus is a part or commencement of sales of the public offering, except as provided in FINRA Rule 5110(g)(2).

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

## **European Economic Area and the United Kingdom**

In relation to each Member State of the European Economic Area and the United Kingdom, each a Relevant State, no shares have been offered or will be offered pursuant to the initial offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation), except that offers of shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

- a. to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- b. to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- c. in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require the Issuer or any Manager to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in a Relevant State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with the Company and the Managers that it is a qualified investor within the meaning of the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in a Relevant State to qualified investors, in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

The Company, the underwriters and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

References to the Prospectus Regulation includes, in relation to the UK, the Prospectus Regulation as it forms part of UK domestic law by virtue of the European Union (Withdrawal) Act 2018.

The above selling restriction is in addition to any other selling restrictions set out below.

# Notice to Prospective Investors in the United Kingdom

This document is for distribution only to persons who (i) have professional experience in matters relating to investments and who qualify as investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Financial Promotion Order, (ii) are persons falling within Article 49(2)(a) to (d) ("high net worth companies, unincorporated associations etc.") of the Financial Promotion Order, (iii) are outside the United Kingdom, or (iv) are persons to whom an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000, as amended, or FSMA) in connection with the issue or sale of any securities may otherwise lawfully be communicated or caused to be communicated (all such persons together being referred to as "relevant persons"). This document is directed only at relevant persons and must not be acted on or relied on by persons who are not relevant persons. Any investment or investment activity to which this document relates is available only to relevant persons and will be engaged in only with relevant persons.

#### **Notice to Prospective Investors in Switzerland**

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority, or FINMA, and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

#### Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

#### **Notice to Prospective Investors in Australia**

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, or ASIC, in relation to the offering.

This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or the Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons, or the Exempt Investors, who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters

#### Notice to Prospective Investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

#### **Notice to Prospective Investors in Japan**

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, "Japanese Person" shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

#### **Notice to Prospective Investors in Singapore**

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the shares were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or

purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time, or SFA, pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

- (a) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4) (i)(B) of the SFA;
- (b) where no consideration is or will be given for the transfer;
- (c) where the transfer is by operation of law; or
- (d) as specified in Section 276(7) of the SFA.

#### **Notice to Prospective Investors in Canada**

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

#### **Notice to Prospective Investors in Israel**

In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase shares of common stock under the Israeli Securities Law, 5728—1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728—1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions (the "Addressed Investors"); or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728—1968, subject to certain conditions (the "Qualified Investors"). The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. The company has not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728—1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for our common stock to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728—1968. In particular, we may request, as a condition to be offered common stock, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728—1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728—1968 and the regulations promulgated thereunder in connection with the offer to be issued common stock; (iv) that the shares of common stock that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728—1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728—1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor's name, address and passport number or Israeli identification number.

#### LEGAL MATTERS

The validity of the shares of our common stock offered hereby is being passed upon for us by Wilmer Cutler Pickering Hale and Dorr LLP. Shearman & Sterling LLP is acting as counsel for the underwriters in connection with this offering.

#### **EXPERTS**

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements at December 31, 2018 and 2019, and for each of the two years in the period ended December 31, 2019, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements) appearing elsewhere herein. We have included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

#### WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our common stock we are offering to sell. This prospectus, which constitutes part of the registration statement, does not include all of the information contained in the registration statement and the exhibits, schedules and amendments to the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and to the exhibits and schedules to the registration statement. Statements contained in this prospectus about the contents of any contract, agreement or other document are not necessarily complete, and, in each instance, we refer you to the copy of the contract, agreement or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference to such contract, agreement or document.

The SEC maintains an Internet website, which is located at http://www.sec.gov, that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. You may access the registration statement of which this prospectus is a part at the SEC's Internet website. Upon completion of this offering, we will be subject to the information reporting requirements of the Securities Exchange Act of 1934, as amended, and we will file reports, proxy statements and other information with the SEC. We plan to fulfill our obligations with respect to such requirements by filing periodic reports and other information with the SEC. We intend to furnish our stockholders with annual reports containing financial statements certified by an independent registered public accounting firm. Our website address is www.inozyme.com. The information contained on, or that can be accessed through, our website is not a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

# INOZYME PHARMA, INC.

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#### Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Inozyme Pharma, Inc.

#### **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Inozyme Pharma, Inc. (the Company) as of December 31, 2018 and 2019, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' (deficit) equity and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2019, and the results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

#### The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

#### **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2017.

Boston, Massachusetts May 8, 2020, except for Note 13(d), as to which the date is July 20, 2020

# INOZYME PHARMA, INC. CONSOLIDATED BALANCE SHEETS (amounts in thousands, except share and per share data)

			ember 31, 2019			Pro Forma March 31, 20 (unaudited)		
Assets					(u.	nauditeu)	(411	lauditeu)
Current assets:								
Cash and cash equivalents	\$	35,966	\$	31,605	\$	21,937	\$	55,637
Short-term investments		7,197		15,527		18,903		18,903
Prepaid expenses and other current assets		104		328		423		423
Total current assets		43,267		47,460		41,263		74,963
Property and equipment, net		242		298		374		374
Restricted cash		_		130		130		130
Other assets		34		56		269		269
Total assets	\$	43,543	\$	47,944	\$	42,036	\$	75,736
Liabilities, convertible preferred stock and stockholders' (deficit) equity								
Current liabilities:								
Accounts payable	\$	984	\$	901	\$	1,569	\$	1,569
Accrued expenses		1,405		2,335		3,340		3,340
Total current liabilities		2,389		3,236		4,909		4,909
Commitments (Note 7)								
Series A Convertible Preferred Stock, \$0.0001 par value – 48,850,000 shares authorized; 48,850,000 shares issued and outstanding at December 31, 2018 and 2019 and March 31, 2020 (unaudited); Liquidation preference of \$48.9 million at December 31, 2019 and March 31, 2020 (unaudited); no shares authorized, issued or outstanding, pro forma								
(unaudited)		44,657		44,657		44,657		_
Series A-2 Convertible Preferred Stock, \$0.0001 par value – 28,951,044 shares authorized at December 31, 2018 and 47,132,862 shares authorized at December 31, 2019 and March 31, 2020 (unaudited); 7,482,515 shares issued and outstanding at December 31, 2018, and 23,566,431 shares issued and outstanding at December 31, 2019 and March 31, 2020 (unaudited); Liquidation preference of \$33.7 million at December 31, 2019 and March 31, 2020 (unaudited); no shares authorized, issued or outstanding, pro forma								
(unaudited)		10,372		33,270		33,270		
Stockholders' (deficit) equity:  Preferred Stock, \$0.0001 par value – no shares authorized, issued or outstanding at  December 31, 2018, December 31, 2019 and March 31, 2020 (unaudited); 5,000,000  shares authorized, no shares issued or outstanding, pro forma (unaudited)  Common Stock, \$0.0001 par value – 129,000,000 shares authorized; 1,135,015,		_		_		_		_
1,204,630 and 1,207,307 shares issued and outstanding at December 31, 2018, December 31, 2019 and March 31, 2020 (unaudited), respectively; 200,000,000 shares authorized, 15,161,157 shares issued and outstanding, pro forma (unaudited)		_		_		_		1
Additional paid in-capital		1,055		1,428		1,562		129,837
Accumulated other comprehensive income (loss)		(2)		5		28		28
Accumulated deficit	_	(14,928)		(34,652)	_	(42,390)		(59,039)
Total stockholders' (deficit) equity		(13,875)		(33,219)	_	(40,800)		70,827
Total liabilities, convertible preferred stock and stockholders' (deficit) equity	\$	43,543	\$	47,944	\$	42,036	\$	75,736

The accompanying notes are an integral part of these consolidated financial statements.

# INOZYME PHARMA, INC. CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (amounts in thousands, except share and per share data)

		December 31,		Ended March 31,
	2018	2019	2019 (unaudited)	2020 (unaudited)
Operating expenses:			(unaudited)	(unaudited)
Research and development	\$ 8,099	\$ 16,220	\$ 4,134	\$ 6,406
General and administrative	3,494	4,586	1,030	1,500
Total operating expenses	11,593	20,806	5,164	7,906
Loss from operations	(11,593)	(20,806)	(5,164)	(7,906)
Other income (expense):				
Interest income	284	1,106	210	171
Other expense, net	(29)	(24)	(17)	(3)
Change in fair value of preferred stock tranche liability	4,374	<u></u> _	<u></u>	
Other income (expense), net	4,629	1,082	193	168
Net loss	\$ (6,964)	\$ (19,724)	\$ (4,971)	\$ (7,738)
Other comprehensive income:			<del></del>	
Unrealized gains on available-for-sale securities	16	7	2	23
Total other comprehensive income	16	7	2	23
Comprehensive loss	\$ (6,948)	\$ (19,717)	\$ (4,969)	\$ (7,715)
Net loss attributable to common stockholders—basic and diluted	\$ (6,964)	\$ (19,724)	\$ (4,971)	\$ (7,738)
Net loss per share attributable to common stockholders—basic and diluted	\$ (6.63)	\$ (16.67)	\$ (4.27)	\$ (6.42)
Weighted-average common shares outstanding—basic and diluted	1,050,706	1,183,144	1,164,173	1,205,346
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited) (Note 10)	, ,	\$ (1.30)	, ,	\$ (0.51)
Pro forma weighted-average common shares outstanding—basic and diluted (unaudited) (Note 10)		15,136,994		15,159,196

The accompanying notes are an integral part of these consolidated financial statements.

# INOZYME PHARMA, INC.

# CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' (DEFICIT) EQUITY (amounts in thousands, except share data)

	Series A Cor Preferred		Series A-2 Co Preferred		Common	Stock	Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders' (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balance at December 31, 2017	27,183,333	\$ 22,912	_	\$ —	893,823	\$ —	\$ 611	\$ (18)	\$ (7,964)	\$ (7,371)
Vesting of restricted stock	_		_	_	241,192		_	_	_	_
Issuance of tranche 2 of Series A										
Convertible Preferred Stock, net of										
issuance costs of \$0.1 million	21,666,667	21,573	_	_	_	_	_	_	_	_
Settlement of Series A Convertible		450								
Preferred tranche liability		172	_		_					_
Issuance of Series A-2 Convertible Preferred Stock, net of issuance costs of										
\$0.3 million			7 400 515	10 272						
Stock-based compensation	_	_	7,482,515	10,372	_	_	444	_	_	444
Comprehensive income:	_		_		_		444	_		444
Unrealized gain on investments								16		16
Net loss								10	(6,964)	(6,964)
Balance at December 31, 2018	48,850,000	\$ 44,657	7,482,515	\$ 10,372	1,135,015	\$ _	\$ 1,055	\$ (2)	\$ (14,928)	\$ (13,875)
	40,030,000	\$ 44,037	7,402,515	\$ 10,372	1,133,013	<u>a —</u>	\$ 1,055	3 (2)	\$ (14,920)	\$ (13,073)
Issuance of Series A-2 Convertible										
Preferred Stock, net of issuance costs of										
\$0.1 million	_	_	16,083,916	22,898	_	_		_		_
Stock-based compensation	_	_	_	_		_	301			301
Exercise of stock options	_	_	_	_	69,615	_	72	_	_	72
Comprehensive income:							_	7		7
Unrealized gain on investments	_	_	_	_	_	_	_	/	(10.724)	(10.724)
Net loss									(19,724)	(19,724)
Balance at December 31, 2019	48,850,000	44,657	23,566,431	33,270	1,204,630	_	1,428	5	(34,652)	(33,219)
Stock-based compensation (unaudited)	_		_	_	2.677		129 5	_		129 5
Exercise of stock options (unaudited)	_	_	_	_	2,677	_	5	_	_	5
Comprehensive income: Unrealized gain on investments (unaudited)								23	_	23
Net loss (unaudited)	_	_	_	_	_	_		_	(7,738)	(7,738)
	48.850.000	44,657	23,566,431	33,270	1,207,307		1,562			
Balance at March 31, 2020 (unaudited) Issuance of Series A-2 Convertible	48,850,000	44,657	23,566,431	33,2/0	1,20/,30/	_	1,562	28	(42,390)	(40,800)
Preferred Stock (unaudited)			31,860,791	50,349						
Write-off of acquired in-process research	_		31,000,731	30,349	_	_	_	_		_
and development (unaudited)	_		_	_	_	_		_	(16,649)	(16,649)
Conversion of convertible preferred stock									(10,043)	(10,043)
into common stock (unaudited)	(48,850,000)	(44,657)	(55,427,222)	(83,619)	13,953,850	1	128,275	_	_	128,276
Pro forma balance at March 31, 2020 (unaudited)	(40,050,000)	¢	(55,427,222)	¢	15,161,157	\$ 1	\$ 129,837	\$ 28	\$ (59,039)	\$ 70.827
		ф		<b>D</b>						
Balance at December 31, 2018	48,850,000	\$ 44,657	7,482,515	\$ 10,372	1,135,015	\$ —	\$ 1,055	\$ (2)	\$ (14,928)	\$ (13,875)
Issuance of Series A-2 Convertible										
Preferred Stock, net of issuance costs of			10,000,010	22.000						
\$0.1 million (unaudited)	_	_	16,083,916	22,898	_	_	41	_	_	41
Stock-based compensation (unaudited)					35,460	_	41 34			41 34
Exercise of stock options (unaudited) Comprehensive income:	_	_	_	_	35,460	_	34	_	_	34
Unrealized gain on investments (unaudited)								2		2
Net loss (unaudited)	_	_	_		_	_		2	(4,971)	(4,971)
,	49.950.000	¢ 44 CE7	22 566 421	\$ 33,270	1.170.475	<u> </u>	\$ 1.130	<u> </u>		
Balance at March 31, 2019 (unaudited)	48,850,000	\$ 44,657	23,566,431	\$ 33,270	1,1/0,4/5	<u> э</u>	a 1,130	<b>a</b>	\$ (19,899)	<u>\$ (18,769</u> )

The accompanying notes are an integral part of these consolidated financial statements.

# INOZYME PHARMA, INC. CONSOLIDATED STATEMENTS OF CASH FLOWS (amounts in thousands)

		Year Ended December 31,		Months Iarch 31,
	2018	2019	2019	2020
Operating activities			(unaudited)	(unaudited)
Net loss	\$ (6,964)	\$(19,724)	\$ (4,971)	\$ (7,738)
Adjustments to reconcile net loss to net cash used in operating activities:				, ()
Depreciation and amortization	26	83	19	25
Stock-based compensation expense	444	301	41	129
Accretion on marketable securities	_	(71)	(22)	(46)
Change in fair value of Series A Convertible Preferred Stock tranche liability	(4,374)	_	_	_
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	(55)	(224)	(67)	(95)
Accounts payable	802	(83)	(54)	668
Accrued expenses	718	930	(234)	814
Other assets	(34)	(22)		(22)
Net cash used in operating activities	(9,437)	(18,810)	(5,288)	(6,265)
Investing activities				
Purchases of marketable securities	(13,568)	(24,662)	(3,674)	(13,408)
Maturities of marketable securities	22,833	16,410	5,475	10,101
Purchases of property and equipment	(259)	(139)	(43)	(101)
Net cash provided by (used in) investing activities	9,006	(8,391)	1,758	(3,408)
Financing activities				
Proceeds from issuance of Series A Convertible Preferred Stock and tranche right, net of				
issuance costs	21,573	_	_	_
Proceeds from issuance of Series A-2 Convertible Preferred Stock, net of issuance costs	10,372	22,898	22,898	_
Proceeds from exercise of stock options		72	34	5
Net cash provided by financing activities	31,945	22,970	22,932	5
Net increase (decrease) in cash, cash equivalents and restricted cash	31,514	(4,231)	19,402	(9,668)
Cash, cash equivalents and restricted cash at beginning of period	4,452	35,966	35,966	31,735
Cash, cash equivalents and restricted cash at end of period	\$ 35,966	\$ 31,735	\$ 55,368	\$ 22,067
Supplemental cash flow information:				
Cash and cash equivalents	\$ 35,966	\$ 31,605	\$ 55,368	\$ 21,937
Restricted cash		130		130
Cash, cash equivalents and restricted cash at end of period	\$ 35,966	\$ 31,735	\$ 55,368	\$ 22,067
Deferred offering costs in accrued expenses	<u>\$</u>	<u> </u>	<u> </u>	\$ 191

 $\label{thm:companying} \textit{ notes are an integral part of these consolidated financial statement.}$ 

# INOZYME PHARMA, INC. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Organization and Basis of Presentation

Inozyme Pharma, Inc. (the "Company") is a rare disease biopharmaceutical company developing novel therapeutics for the treatment of diseases of abnormal mineralization impacting the vasculature, soft tissue and skeleton.

The Company is pursuing the development of therapeutics to address the underlying causes of these debilitating diseases. It is well established that two genes, ENPP1 and ABCC6, play key roles in a critical mineralization pathway and that defects in these genes lead to abnormal mineralization. The Company is initially focused on developing a novel therapy to treat rare genetic diseases of ENPP1 and ABCC6 deficiencies.

The Company's lead product candidate, INZ-701, is a soluble, recombinant, or genetically engineered, fusion protein that is designed to correct a defect in the mineralization pathway caused by ENPP1 and ABCC6 deficiencies. This pathway is central to the regulation of calcium deposition throughout the body and is further associated with neointimal proliferation, or the overgrowth of smooth muscle cells inside blood vessels.

#### Liquidity, Capital Resources, and Going Concern

Since the Company's incorporation in 2017 and through March 31, 2020 (unaudited), the Company has devoted substantially all of its efforts to raising capital, building infrastructure, developing intellectual property and conducting research and development. The Company incurred net losses of \$7.7 million in the three months ended March 31, 2020 (unaudited) and \$19.7 million in the year ended December 31, 2019 and had an accumulated deficit of \$42.4 million as of March 31, 2020 (unaudited) and \$34.7 million as of December 31, 2019. The Company had cash and cash equivalents of \$21.9 million and \$31.6 million, and short-term investments of \$18.9 million and \$15.5 million as of March 31, 2020 (unaudited) and December 31, 2019, respectively.

Because of the numerous risks and uncertainties associated with product development, the Company is unable to predict the timing or amount of increased expenses or when or if the Company will be able to achieve or maintain profitability. Even if the Company is able to generate revenue from product sales, the Company may not become profitable. If the Company fails to become profitable or is unable to sustain profitability on a continuing basis, then the Company may be unable to continue its operations at planned levels and be forced to reduce or terminate its operations.

The Company expects to incur substantial operating losses and negative cash flows from operations for the foreseeable future. As a result, there is a significant degree of uncertainty as to how long the Company's existing cash, cash equivalents and short-term investments will be sufficient to fund its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern for a period of at least one year from the date the Company's consolidated financial statements are issued.

Management expects to seek additional funds through equity financings; however, it may be unable to do so and may implement cost reduction strategies, which may include amending, delaying, limiting, reducing, or terminating planned activities related to its product candidate. As a result of these factors, there is substantial doubt about the Company's ability to continue as a going concern within one year after the date these annual and interim consolidated financial statements are issued.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

## 2. Summary of Significant Accounting Policies and Basis of Presentation

#### **Basis of Presentation**

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). All adjustments considered necessary for a fair presentation have been included.

The accompanying consolidated balance sheet as of March 31, 2020, the consolidated statements of operations and comprehensive loss and of cash flows for the three months ended March 31, 2019 and 2020, and the consolidated statement of convertible preferred stock and stockholders' (deficit) equity for the three months ended March 31, 2020 are unaudited. The unaudited interim consolidated financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of March 31, 2020 and the results of its operations and its cash flows for the three months ended March 31, 2019 and 2020. The financial data and other information disclosed in these notes related to the three months ended March 31, 2019 and 2020 are unaudited. The results for the three months ended March 31, 2020 are not necessarily indicative of results to be expected for the year ending December 31, 2020, any other interim periods, or any future year or period.

#### Use of Estimates

The preparation of the Company's financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Estimates and judgments are based on historical information and other market-specific or various relevant assumptions, including in certain circumstances, future projections, that management believes to be reasonable under the circumstances. Actual results could differ materially from estimates. Significant estimates and assumptions are used for, but not limited to the accruals for research and development expenses, stock-based compensation expense, inclusive of the measurement of fair value of equity instruments, and the valuation of the Series A Convertible Preferred Stock tranche liability. The Company utilized various valuation methodologies in accordance with the framework of the 2013 American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its equity awards. The Company evaluates its estimates and assumptions on an ongoing basis. All revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

#### Concentration of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits and limits its exposure to credit risk by placing its cash with high credit quality financial institutions. The Company's short-term investments are comprised of corporate debt securities, U.S. Treasury and agency securities and commercial paper of corporations. The Company mitigates credit risk by maintaining a diversified portfolio and limiting the amount of investment exposure as to institution, maturity and investment type.

The Company has no significant off-balance sheet risk such as foreign exchange contracts, option contracts, or other foreign hedging arrangements.

#### Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents. Cash and cash equivalents include cash in readily available checking accounts, money market accounts and certain marketable securities. Cash is carried at cost, which approximates its fair value. Cash equivalents are carried at fair market value.

#### Restricted Cash

Restricted cash is composed of amounts held on deposit related to the Company's lease arrangements. Restricted cash is classified as either current or non-current based on the terms of the underlying lease arrangement.

#### Short-Term Investments

The Company classifies its investments as available-for-sale and records such assets at estimated fair value on the balance sheet, with unrealized gains and losses on debt securities, if any, reported as a component of accumulated other comprehensive income (loss). Realized gains and losses are calculated based on the specific-identification method and are recorded as interest income. There have been no realized gains and losses for the years ended December 31, 2018 and 2019 or for the three months ended March 31, 2019 and 2020 (unaudited). The Company periodically reviews available-for-sale securities for other-than-temporary declines in fair value below the cost basis whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable.

## **Property and Equipment**

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the related asset. The estimated useful lives of the Company's property and equipment are as follows:

	Estimated Useful Life (In Years)
Laboratory equipment and manufacturing equipment	5
Furniture and fixtures	5
Computer equipment	3
Leasehold improvements	Lesser of asset life or lease term

#### Impairment of Long-lived Assets

As required under the applicable accounting guidance, the Company periodically reevaluates the original assumptions and rationale used in the establishment of the carrying value and estimated lives of all of its long-lived assets, including property and equipment. The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. An impairment loss is recognized when the total of estimated future undiscounted cash flows, expected to result from the use of the asset and its eventual disposition, are less than its carrying amount. Impairment, if any, would be assessed using discounted cash flows or other appropriate measures of fair value. There were no impairments for the years ended December 31, 2018 and 2019 or for the three months ended March 31, 2019 and 2020 (unaudited).

# **Accrued Research and Development Costs**

The Company records accrued liabilities for estimated costs of research and development activities conducted by service providers for sponsored research, preclinical studies and contract manufacturing activities.

The Company records the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and includes these costs in accrued expenses in the accompanying consolidated balance sheets and within research and development expense in the accompanying consolidated statements of operations and comprehensive loss.

The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with service providers. The Company makes significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. The Company has not experienced any material differences between accrued costs and actual costs incurred since its inception.

#### **Research and Development Costs**

Research and development costs are expensed as incurred. Research and development costs consist of direct and indirect internal costs related to specific projects as well as fees paid to other entities that conduct certain research and development activities on the Company's behalf.

#### **Patent Costs**

The Company expenses all costs as incurred in connection with patent applications, including direct application fees, and the legal and consulting expenses related to making such applications, and such costs are included in general and administrative expenses within the Company's consolidated statements of operations and comprehensive loss.

#### Stock-Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of employee and non-employee stock option grants and restricted stock awards recognized over the requisite service period of the awards on a straight-line basis. For service-based awards that are subject to graded vesting, companies have the option to recognize compensation expense either on a straight-line or accelerated basis. The Company has elected to recognize compensation expense for these awards on a straight-line basis.

The Company accounted for stock options to non-employees using the fair value approach through December 31, 2017. On January 1, 2018, the Company early adopted ASU 2018-07, *Compensation – Stock Compensation* ("ASU 2018-07"), and as a result, the fair value of unvested non-employee awards as of December 31, 2017 is no longer remeasured each reporting period. All future expense related to these awards will be recorded based on the fair value measured as of December 31, 2017, the last period prior to the adoption of ASU 2018-07.

The Company's equity incentive plan allows for the issuance of restricted stock awards to employees and non-employees that may be subject to vesting. The unvested shares of any restricted stock awards are held in escrow as the stock award vests or until award holder termination, whichever occurs first. In the event of a termination, the Company has the right of repurchase, at its option, the portion of unvested stock awards from the terminated award holder. For all unvested stock awards whereby the award recipient has transferred cash to the Company at the grant date, a liability is established related to the cash received for the unvested portion of the stock awards, which represents the Company's obligation if all award holders were to be terminated.

#### Convertible Preferred Stock

The Company's convertible preferred stock is classified as temporary equity and excluded from stockholders' (deficit) equity as the potential redemption of such stock is outside the Company's control. The carrying value of the convertible preferred stock is not adjusted to the redemption value until the contingent redemption events are considered to be probable of occurring.

#### **Income Taxes**

Income taxes have been accounted for using the asset and liability method. Under the asset and liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates applicable to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that includes the enactment date. A valuation allowance against deferred tax assets is recorded if, based upon the weight of all available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for income taxes in accordance with authoritative accounting guidance which states the impact of an uncertain income tax position is recognized at the largest amount that is "more likely than not" to be sustained upon audit by the relevant taxing authority. There are no unrecognized tax benefits included in the Company's consolidated balance sheets at December 31, 2018 or 2019 or at March 31, 2020 (unaudited). The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. The Company has not recognized any interest or penalties in its consolidated statements of operations and comprehensive loss since inception.

#### Leases

The Company categorizes leases at their inception as either operating or capital leases. On certain lease arrangements, the Company may receive rent holidays or other incentives. The Company recognizes lease costs on a straight-line basis once control of the space is obtained, without regard to deferred payment terms, such as rent holidays, that defer the commencement date of required payments or escalating payment amounts. The difference between required lease payments and rent expense has been recorded in accrued expenses in the accompanying consolidated balance sheets. Additionally, incentives received are treated as a reduction of costs over the term of the agreement, as they are considered an inseparable part of the lease agreement. At December 31, 2018, December 31, 2019 and March 31, 2020 (unaudited), no capital leases were recorded in the consolidated balance sheets.

#### **Unaudited Pro Forma Information**

Upon the closing of the Company's qualified initial public offering ("IPO"), all of the outstanding shares of convertible preferred stock will automatically convert into shares of common stock. The accompanying unaudited pro forma consolidated balance sheet and consolidated statements of convertible preferred stock and stockholders' (deficit) equity as of March 31, 2020 have been prepared to give effect to 1) the issuance of 23,566,431 shares of Series A-2 Convertible Preferred Stock in June 2020 (refer to Note 13) for net proceeds of \$33.7 million; 2) the issuance in July 2020 of 8,294,360 shares of Series A-2 Convertible Preferred Stock in connection with the purchase of intellectual property assets from Alexion Pharmaceuticals, Inc. ("Alexion") (refer to Note 13); and 3) the automatic conversion of all shares of convertible preferred stock outstanding at March 31, 2020, inclusive of shares of the Series A-2 Convertible Preferred Stock issued in June and July 2020, into 13,953,850 shares of common stock upon the occurrence of a qualified IPO. The conversion of the Company's convertible preferred stock is based on the conversion ratios associated with each series of convertible preferred stock. The shares of common stock expected to be issued and the proceeds expected to be received in the qualified IPO are excluded from such pro forma financial information. For purposes of the pro forma balance sheet, the Company has assumed an as converted value per common share of \$15.00 for the shares of its Series A-2 Convertible Preferred Stock issued to Alexion that will automatically convert into 1,109,910 shares of the Company's common stock upon the closing of the Company's initial public offering. The actual per share amount will be determined in connection with the Company's issuance of its consolidated financial statements for the three months ended September 30, 2020. The value of the acquired in process research and development assets to be recognized in the three months ended September 30, 2020.

The unaudited pro forma basic and diluted weighted-average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2019 and the three months ended March 31, 2020 have been prepared to give effect, upon a qualified IPO, to the automatic conversion of all then-outstanding shares of convertible preferred stock into common stock as if the qualified IPO had occurred at the beginning of each period.

#### **Deferred Issuance Costs**

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings, including the qualified IPO, as deferred issuance costs until such financings are consummated. After consummation of such an equity financing, these costs are recorded as a reduction of the proceeds generated as a result of the offering. Should the planned equity financing be abandoned, the deferred issuance costs, currently recorded within Other assets, will be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss. The Company recorded deferred issuance costs at December 31, 2019 and March 31, 2020 (unaudited) of \$0.1 million and \$0.3 million, respectively.

#### Net Loss Per Share

The Company follows the two-class method when computing net loss allocable to common securities per share as the Company has issued shares that meet the definition of participating securities, which include shares of: (i) Series A Convertible Preferred Stock; (ii) Series A-2 Convertible Preferred Stock. The two-class method requires a portion of net income to be allocated to the participating securities to determine net loss allocable to the common securities. During periods of loss, there is no allocation required under the two-class method since the participating securities do not have a contractual obligation to fund the losses of the Company.

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock and potentially dilutive securities outstanding during the period determined using the treasury-stock and if-converted methods. For purposes of the diluted net loss per share calculation, diluted net loss per share attributable to common stockholders is calculated by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding after giving consideration to the dilutive effect of convertible preferred stock, restricted common stock, restricted stock units and stock options that are outstanding during the period. The Company has generated a net loss in all periods presented, therefore the basic and diluted net loss per share attributable to common stockholders are the same as the inclusion of the potentially dilutive securities would be anti-dilutive.

#### **Segments**

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its Chief Executive Officer. The Company has determined it operates in a single operating segment and has one reportable segment. All long-lived assets of the Company reside in the United States.

#### Comprehensive Loss

The Company is required to report all components of comprehensive loss, including net loss, in the financial statements in the period in which they are recognized. Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources.

Comprehensive loss is comprised of the Company's net loss and unrealized gains and losses on the Company's short-term investments and is presented within the continuous consolidated statements of operations and comprehensive loss.

#### **Foreign Currency Transactions**

The Company maintains a foreign bank account denominated in euros. Foreign currency transactions are initially recorded by the Company using the exchange rates prevailing at the date of the transaction. At the balance sheet date, cash denominated in foreign currencies is translated at the period-end rates of exchange. Exchange gains and losses arising from the translation of foreign currency items are included in other income (expense), net in the consolidated statements of operations and comprehensive loss. The Company recognized net foreign exchange losses of \$11 thousand and \$23 thousand for the years ended December 31, 2018 and 2019, and \$17 thousand and \$3 thousand for the three months ended March 31, 2019 and 2020 (unaudited), respectively.

#### Fair Value Measurements

The Company categorizes its assets and liabilities measured at fair value in accordance with the authoritative accounting guidance that establishes a consistent framework for measuring fair value, and expands disclosures for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as the exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- · Level 1- Unadjusted quoted prices in active markets that are accessible at the measurement date for identical assets or liabilities;
- Level 2- Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; or
- Level 3- Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

#### **Subsequent Events**

The Company has considered subsequent events for recognition and measurement purposes through May 8, 2020, the date the audited consolidated financial statements were issued, and July 20, 2020, the date the revised consolidated financial statements were issued. In preparing the unaudited interim consolidated financial statements as of March 31, 2020 and for the three-month period then ended, the Company has evaluated subsequent events for recognition and measurement purposes through June 12, 2020, the date the unaudited interim consolidated financial statements were issued, and July 20, 2020, the date the revised unaudited interim consolidated financial statements were issued. Refer to Note 13.

#### **Emerging Growth Company Status**

The Company is an "emerging growth company," ("EGC") as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and the Company may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not EGCs. As an EGC, the Company can elect to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. The Company has elected to use the extended transition period for complying with new or revised accounting standards, and as a result of this election, the Company's consolidated financial statements may not be comparable to companies that comply with public company FASB

standards' effective dates. The Company will remain an EGC until the last day of the fiscal year in which the fifth anniversary of the date of the first sale of common equity securities of the Company under an effective Securities Act registration statement occurs, although if the market value of the Company's common stock that is held by non-affiliates exceeds \$700 million as of any June 30 before that time or if the Company has annual gross revenues of \$1.07 billion or more in any fiscal year, the Company would cease to be an EGC as of December 31 of the applicable year. The Company would cease to be an EGC if it issued more than \$1 billion of non-convertible debt over a three-year period.

#### 3. Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

## Recently Issued and Adopted Accounting Standards

In the first quarter of the year ending December 31, 2018, the Company made an accounting policy election to recognize forfeitures as they occur upon adoption of guidance per ASU No. 2016-09, *Compensation—Stock Compensation ("ASU 2016-09")*. The adoption of ASU 2016-09 did not have a material impact on the Company's consolidated financial statements. In reporting periods prior to the year ending December 31, 2018, the Company estimated forfeitures at the time of grant and revised the forfeitures rate in subsequent periods as necessary if actual forfeitures differed from estimates.

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement ("ASU 2018-13")*, which modifies certain disclosure requirements on fair value measurements. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. ASU 2018-13 is effective for fiscal years beginning after December 15, 2019. The Company adopted ASU 2018-13 on January 1, 2020 and the adoption did not have a material impact on its consolidated financial statements (unaudited).

#### Recently Issued Accounting Standards Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, *Leases* ("*Topic 842*"). The new standard, as amended, establishes a right-of-use model and requires a lessee to recognize on the balance sheet a right-of-use asset and corresponding lease liability for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the consolidated statements of operations and comprehensive loss. As a result of the FASB's issuance of ASU No. 2020-05, "*Revenue From Contracts With Customers (Topic 606) and Leases (Topic 842): Effective Dates for Certain Entities*", the new standard is effective for annual periods beginning after December 15, 2021 for nonpublic entities, with early adoption permitted. The Company is currently assessing the impact that adopting this standard will have on its consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses ("Topic 326"): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13")*. ASU 2016-13 and its subsequent related updates establish a new forward-looking "expected loss model" that requires entities to estimate current expected credit losses on accounts receivable and financial instruments by using all practical and relevant information. The new standard and its subsequent related updates are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, with early adoption permitted. The

Company is currently assessing the impact that adopting this standard will have on its consolidated financial statements but does not expect it to be material.

In August 2018, the FASB issued ASU 2018-15, *Intangibles-Goodwill and Other-Internal Use Software: Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract ("ASU 2018-15")*. ASU 2018-15 aligns the requirements for capitalizing implementation costs incurred in a cloud computing arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The accounting for the service element of a hosting arrangement that is a service contract is not affected by these amendments. ASU 2018-15 is effective for fiscal years beginning after December 15, 2020, and interim periods within fiscal years beginning after December 15, 2021 for all non-public entities, with early adoption permitted. The Company is currently assessing the impact that adopting this standard will have on its consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes* – *Simplifying the Accounting for Income Taxes*. The new guidance simplifies the accounting for income taxes by removing several exceptions in the current standard and adding guidance to reduce complexity in certain areas, such as requiring that an entity reflect the effect of an enacted change in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date. The new standard is effective for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022 for all non-public entities, with early adoption permitted. The Company is currently assessing the impact that adopting this standard will have on its consolidated financial statements.

December 31, 2018

#### 4. Balance Sheet Details

Short-term investments consisted of the following (dollar amounts in thousands):

Description	Maturity	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper	1 year or less	\$ 3,980	<del>\$</del> —	\$ (1)	\$ 3,979
Corporate debt securities	1 year or less	2,720	_	(1)	2,719
U.S. Treasury securities	1 year or less	499	_	_	499
		\$ 7,199	<u> </u>	\$ (2)	\$ 7,197
Description	Maturity	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper	1 year or less	\$ 10,903	\$ 3	<del>\$</del> —	\$ 10,906
Corporate debt securities	1 year or less	3,370	1	_	3,371
U.S. Treasury securities	1 year or less	1,249	1	_	1,250
		\$ 15,522	\$ 5	<u> </u>	\$ 15,527
		March 31, 2020 (unaudited)			
<u>Description</u>	Maturity	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper	1 year or less	\$ 10,195	\$ 16	<del>\$</del> —	\$ 10,211
Corporate debt securities	1 year or less	2,751	_	(4)	2,747
U.S. Treasury securities	1 year or less	5,929	16	_	5,945

\$ 18,875

32

(4)

\$ 18,903

The Company did not have any short-term investments with unrealized losses at December 31, 2019. Total short-term investments at December 31, 2018 and March 31, 2020 (unaudited) with unrealized losses were as follows (dollar amounts in thousands):

Description Maturity	Fair Value	**	
<u> </u>	ran value	Unr	ealized Losses
Commercial paper 1 year or less	\$ 3,979	\$	(1)
Corporate debt securities 1 year or less	2,222		(1)
	\$ 6,201	\$	(2)

		March 31, 2020 (unaudited)			
Description	Maturity	Fair Value	Unrealize	d Losses	
Corporate debt securities	1 year or less	2,747		(4)	
		\$ 2,747	\$	(4)	

The Company concluded that the net declines in market value of available-for-sale securities were temporary in nature and did not consider any of the investments to be other-than-temporarily impaired. In accordance with its investment policy, the Company invests in investment grade securities with high credit quality issuers, and generally limits the amount of credit exposure to any one issuer. The Company evaluates securities for other-than-temporary impairment at the end of each reporting period. Impairment is evaluated considering numerous factors, and their relative significance varies depending on the situation. Factors considered include the length of time and extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the issuer, and the Company's intent and ability to hold the investment to allow for an anticipated recovery in fair value. Furthermore, the aggregate of individual unrealized losses that had been outstanding for 12 months or less was not significant as of December 31, 2018, December 31, 2019 and March 31, 2020 (unaudited). The Company does not intend to sell these investments and it is not more likely than not that the Company will be required to sell the investments before a recovery of their amortized cost bases, which may be maturity. The Company also believes that it will be able to collect both principal and interest amounts due at maturity.

Prepaid expenses and other current assets consisted of the following (dollar amounts in thousands):

	At Do	At December 31,		
	2018	2019	2020 (unaudit	
Interest receivable	\$ 31	\$ 104	¢	44
	Ψ 31	ψ 10 <del>4</del>	Ψ	
Prepaid seminars	_	_		116
Prepaid insurance	21	47		26
Prepaid taxes	_	42		42
Prepaid other	52	135	-	195
Total	\$ 104	\$ 328	\$ 4	423

Property and equipment consisted of the following (dollar amounts in thousands):

	At De	cember 31,	At March 31		
	2018	2019		2020	
			(una	udited)	
Laboratory equipment and manufacturing equipment	\$ 187	\$ 308	\$	312	
Furniture and fixtures	_	_		68	
Computer equipment	35	53		71	
Leasehold improvements	47	47		58	
	269	408		509	
Less accumulated depreciation	(27)	(110)		(135)	
Total	\$ 242	\$ 298	\$	374	

Depreciation expense for the years ended December 31, 2018 and 2019 totaled \$26 thousand and \$83 thousand, respectively. Depreciation expense for the three months ended March 31, 2019 and 2020 (unaudited) totaled \$19 thousand and \$25 thousand, respectively.

Accrued expenses consisted of the following (dollar amounts in thousands):

	At Dece 2018	At December 31, 2018 2019		arch 31, 020 udited)
Payroll and related liabilities	\$ 829	\$ 861	\$	326
Professional fees	452	268		413
Research and development costs	82	1,086		2,465
Other	42	120		136
Total	\$1,405	\$2,335	\$	3,340

#### 5. Fair Value Measurement

At December 31, 2018, December 31, 2019 and March 31, 2020 (unaudited), the Company valued its short-term investments at fair value on a recurring basis. The carrying amounts of the Company's other financial instruments, which include prepaid expenses and other assets, accounts payable and accrued expenses approximate their fair values at December 31, 2018, December 31, 2019 and March 31, 2020 (unaudited), primarily due to their short-term nature.

The convertible preferred stock tranche liability represents the fair value of the Tranche Right discussed in Note 8. The fair value of Tranche Right is based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The Company's valuation of the Tranche Right utilized the Black-Scholes option-pricing model, which incorporates assumptions and estimates.

Assets and liabilities measured at fair value on a recurring basis as of December 31, 2018, December 31, 2019 and March 31, 2020 (unaudited) are as follows (dollar amounts in thousands):

			Fair Value Measurements at Reporting Date Using					
				oted Prices in ve Markets for		ificant Other bservable		nificant bservable
	Dece	mber 31,		entical Assets	O	Inputs		nputs
Description		2018		(Level 1)		(Level 2)		evel 3)
Assets:								
Money market funds (included in cash and cash equivalents)	\$	2,980	\$	2,980	\$		\$	_
Commercial paper (included in cash and cash equivalents)		497		_		497		_
Corporate debt securities (included in cash and cash								
equivalents)		500				500		
Commercial paper		3,979		_		3,979		_
Corporate debt securities		2,719				2,719		
U.S. Treasury securities		499		499		<u> </u>		
Total assets	\$	11,174	\$	3,479	\$	7,695	\$	
	-		=				=	

			_	Fair Value Measurements at Reporting Date Using					
					ted Prices in Markets for		icant Other servable		nificant servable
	Dec	cember 31,	1	Ider	ntical Assets	I	nputs	I	nputs
<u>Description</u>		2019	_	(	Level 1)	(I_	Level 2)	(L	evel 3)
Assets:									
Money market funds (included in cash and cash									
equivalents)	\$	11,709	9	\$	11,709	\$		\$	_
Commercial paper (included in cash and cash equivalents)		1,992			_		1,992		
Corporate debt securities (included in cash and cash									
equivalents)		2,189			_		2,189		
Commercial paper		10,906			_		10,906		_
Corporate debt securities		3,371					3,371		
U.S. Treasury securities		1,250	_		1,250		<u> </u>		
Total assets	\$	31,417	9	\$	12,959	\$	18,458	\$	

		Fair Value Measurements at Reporting Date Using					
<u>Description</u>	March 31, 2020	Active Iden	ted Prices in Markets for htical Assets Level 1)	0	ficant Other bservable Inputs Level 2)	Unobs In	ificant servable puts vel 3)
			(una	udited)			
Assets:							
Money market funds (included in cash and cash equivalents)	\$ 12,699	\$	12,699	\$	_	\$	_
Commercial paper	10,211		_		10,211		_
Corporate debt securities	2,747		_		2,747		_
U.S. Treasury securities	5,945		5,945		_		_
Total assets	\$ 31,602	\$	18,644	\$	12,958	\$	_

The Tranche Right was classified as a liability and initially recorded at fair value. The liability was subject to revaluation at each balance sheet date prior to the exercise or expiration of the Tranche Right. The

change in the preferred stock tranche liability consists of the re-measurement gains or losses associated with changes in the fair value of the Tranche Right. Upon issuance of the additional shares of Series A Convertible Preferred Stock in November 2018, the Tranche Right was settled. The following table provides a roll forward of the aggregate fair value of the Company's Tranche Right (dollar amounts in thousands):

Balance at December 31, 2017	\$ 4,546
Change in fair value of Tranche Right upon re-measurement included in other income (expense), net	(4,374)
Closing of Tranche Right, upon settlement	(172)
Balance at December 31, 2018	\$ —

#### 6. License and Sponsored Research Agreements

In January 2017, the Company entered into a license agreement with Yale University ("Yale"), which was amended in May 2020 and July 2020, under which the Company licensed certain intellectual property related to ectonucleotide pyrophosphatase/phosphodiesterase enzymes, that is the basis for the Company's INZ-701 development program. Pursuant to the license agreement, as partial upfront consideration, the Company made a payment of approximately \$60,000 to Yale, which amount reflected unreimbursed patent expenses incurred by Yale prior to the date of the license agreement. The Company is responsible for paying Yale an annual license maintenance fee in varying amounts throughout the term ranging from the low tens of thousands of dollars to the high tens of thousands of dollars. As of December 31, 2019 and March 31, 2020 (unaudited), the Company incurred a total of \$30,000 and \$42,500, respectively, in license maintenance fees to Yale. The Company is required to pay Yale \$3.0 million, based on the achievement of a specified net product sales milestone or specified development and commercialization milestones, for each therapeutic and prophylactic licensed product developed. In addition, the Company is required to pay Yale an amount in the several hundreds of thousands of dollars, based on the achievement of a specified net product sales milestone or specified development and commercialization milestones, for each diagnostic licensed product developed. While the agreement remains in effect, the Company is required to pay Yale low single-digit percentage royalties on aggregate worldwide net sales of certain licensed products. Yale is guaranteed a minimum royalty payment amount (ranging in dollar amounts from the mid six figures to low seven figures) for each year after the first sale of a therapeutic or prophylactic licensed product that results in net sales. Yale is guaranteed a minimum royalty payment amount (ranging from the low tens of thousands of dollars to the mid tens of thousands of dollars) for each year after the first sale of a diagnostic licensed product that results in net sales. The Company must also pay Yale a percentage in the twenties of certain types of income it receives from sublicensees. The Company is also responsible for costs relating to the prosecution and maintenance of the licensed patents. Finally, subject to certain conditions, all payments due by the Company to Yale will be tripled following any patent challenge or challenge to a claim by Yale that a product is a licensed product under the agreement made by the Company against Yale if Yale prevails in such challenge.

In January 2017, the Company also entered into a corporate sponsored research agreement with Yale (the "Sponsored Research Agreement"), which was amended in February 2019, under which the Company agreed to provide research support funding in the aggregate amount of \$2.4 million over the five year period from contract inception through 2021. The Company recorded research and development expenses associated with this arrangement of \$0.4 million and \$0.5 million in the years ended December 31, 2018 and 2019, respectively, and \$0.1 million and \$0.2 million in the three months ended March 31, 2019 and 2020 (unaudited), respectively.

The Company recorded research and development expense associated with other arrangements with Yale of \$0.4 million and \$0.3 million in the years ended December 31, 2018 and 2019, and \$0.2 million and none in the three months ended March 31, 2019 and 2020 (unaudited), respectively.

#### 7. Commitments

On April 1, 2017, the Company entered into a non-cancellable sub-lease agreement for office space for a term of six months. The lease was amended in September 2017 for an additional six-month period and expired in May 2018.

In March 2018, the Company entered into a non-cancelable agreement to lease 2,605 square feet of office space in Boston, Massachusetts. The lease term for this office space began in June 2018 and ended in April 2020. Additionally, in July 2018, the Company entered into an agreement to lease 3,560 square feet of laboratory space in Boston, Massachusetts. The lease term for this laboratory space began in July 2018 and ends in August 2020. The Company provided security deposits to the landlords totaling \$34 thousand, which is included in prepaid expenses and other current assets in the accompanying balance sheet as of December 31, 2019 and March 31, 2020 (unaudited).

In December 2019, the Company entered into a non-cancelable agreement to lease 8,599 square feet of office space in Boston, Massachusetts. The lease term for this office space began in May 2020 and is expected to end in the second half of 2025. The Company shall have one option to extend the term of this lease for a term of five years. The Company provided a security deposit to the landlord in the form of a letter of credit totaling \$130 thousand. The cash collateralizing the letter of credit is included in restricted cash in the accompanying balance sheet as of December 31, 2019 and March 31, 2020 (unaudited).

Total future minimum commitments under non-cancellable leases as of December 31, 2019 are as follows (dollar amount in thousands):

	Less than		More than		
	1 year	1-3 years	3-5 years	5 years	Total
Future minimum operating lease payments	\$ 512	\$ 1,056	\$ 1,099	\$ 327	\$2,994

Rent expense recognized on a straight-line basis over the terms of the leases for the years ended December 31, 2018 and 2019 was \$291 thousand and \$449 thousand, respectively. Rent expense recognized on a straight-line basis over the terms of the leases for the three months ended March 31, 2019 and 2020 (unaudited) was \$101 thousand and \$138 thousand, respectively.

#### 8. Convertible Preferred Stock and Stockholders' Equity

#### Convertible Preferred Stock

Series A Convertible Preferred Stock

In January 2017, the Company converted from a Delaware limited liability company to a Delaware corporation. In connection with the conversion to a corporation, 100,000 shares of Series A Convertible Preferred Stock of the Company were issued to stockholders upon conversion of all outstanding shares of Series A-1 Convertible Preferred Stock of the limited liability company.

In January 2017, the Company entered into a Series A Convertible Preferred Stock Purchase Agreement, which was amended and restated in April 2017 (as amended and restated, the "Series A Agreement") under which it agreed to issue up to 48,750,000 shares of Series A Convertible Preferred Stock in two tranches. Under the Series A Agreement, the Company initially issued 27,083,333 shares at a price of \$1.00 per share for net cash proceeds of \$26.7 million from January 2017 through May 2017. The Series A Agreement provided for a second tranche closing based on the achievement of a defined milestone (the "Tranche Right"), pursuant to which the investors were required to purchase, and the Company to sell, an additional 21,666,667 shares of Series A Convertible Preferred Stock at a price of \$1.00 per share upon the achievement of the defined milestone or waiver of the milestone. In November 2018, the Company sold 21,666,667 shares of Series A Convertible Preferred Stock at a price of \$1.00 per share for proceeds of \$21.6 million.

The Company concluded that the Tranche Right met the definition of a freestanding financial instrument, as the Tranche Right was legally detachable and separately exercisable from the Series A Convertible Preferred Stock. Therefore, the Company allocated the net proceeds between the Tranche Right and the Series A Convertible Preferred Stock. Since the Series A Convertible Preferred Stock was contingently redeemable upon the occurrence of a deemed liquidation event, the Tranche Right was classified as a liability under ASC Topic 480 *Distinguishing Liabilities from Equity*, and was initially recorded at fair value. The estimated fair value of the Tranche Right was determined using a Black-Scholes option-pricing model. The Tranche Right was remeasured at fair value at each reporting period prior to settlement in November 2018, with changes in fair value recorded as a component of other income (expense) in the accompanying consolidated statements of operations and comprehensive loss. The fair value of the Tranche Right was reclassified to Series A Convertible Preferred Stock at settlement.

#### Series A-2 Convertible Preferred Stock

In November 2018, the Company entered into a Series A-2 Convertible Preferred Stock Purchase Agreement, which was amended in March 2019 (as so amended, the "Series A-2 Agreement") under which it agreed to issue up to 47,132,862 shares of Series A-2 Convertible Preferred Stock. Under the Series A-2 Agreement, the Company initially issued 7,482,515 shares at a price of \$1.43 per share for net proceeds of \$10.4 million in November 2018 and 16,083,916 shares at a price of \$1.43 per share for net proceeds of \$22.9 million in March 2019. The A-2 Agreement provides for a second tranche closing based on the achievement of a defined milestone (the "A-2 Tranche Right"), pursuant to which the investors are required to purchase, and the Company to sell, an additional 23,566,431 shares of Series A-2 Convertible Preferred Stock at \$1.43 per share upon the achievement of the defined milestone (the "Milestone"), or earlier upon board of directors and requisite stockholder approval to waive such requirement. In June 2020, the board of directors and requisite stockholders approved such waiver and the Company issued 23,566,431 shares of Series A-2 Convertible Preferred Stock at a price of \$1.43 per share for net proceeds of \$33.7 million. The Company concluded that the A-2 Tranche Right did not meet the definition of a freestanding financial instrument as it was not legally detachable, and therefore did not require separate accounting.

The rights, preferences and privileges of the Company's Series A and Series A-2 Convertible Preferred Stock are as follows (dollar amounts in thousands):

December 31, 2018

Common

Preferred

<u>Description</u>	Preferred stock authorized	stock issued and outstanding	Carrying value	Liquidation preference	stock issuable upon conversion
Series A Convertible Preferred Stock	48,850,000	48,850,000	\$ 44,657	\$ 48,850	6,536,856
Series A-2 Convertible Preferred Stock	28,951,044	7,482,515	10,372	10,700	1,001,270
	77,801,044	56,332,515	\$ 55,029	\$ 59,550	7,538,126
			cember 31, 201	9	
Description	Preferred stock authorized	Preferred stock issued and	Carrying	Liquidation	Common stock issuable upon
<u>Description</u> Series A Convertible Preferred Stock		Preferred stock			stock
	stock authorized	Preferred stock issued and outstanding	Carrying value	Liquidation preference	stock issuable upon conversion

		March 31, 2020 (unaudited)						
		Preferred			Common			
	Preferred	stock issued	C	T !! d-4!	stock			
Description	stock authorized	and outstanding	Carrying value	Liquidation preference	issuable upon conversion			
Series A Convertible Preferred Stock	48,850,000	48,850,000	\$ 44,657	\$ 48,850	6,536,856			
Series A-2 Convertible Preferred Stock	47,132,862	23,566,431	33,270	33,700	3,153,537			
	95,982,862	72,416,431	\$ 77,927	\$ 82,550	9,690,393			

#### Dividends

The holders of Series A Convertible Preferred Stock and Series A-2 Convertible Preferred Stock (collectively referred to herein as "Series A Preferred") are entitled to receive dividends at the amount of dividend per share of common stock multiplied by the number of shares of common stock into which one share of Series A Preferred is convertible at the close of business on the record date for such dividend when and if declared by the board of directors, and in preference and in priority to any dividends on common stock. There have been no dividends declared by the board of directors as of December 31, 2019 or March 31, 2020 (unaudited).

#### Liquidation

Upon any liquidation, dissolution, or winding up of the Company, whether voluntary or involuntary, asset transfer or acquisition (a "Liquidation Event"), before any distribution or payment shall be made to the holders of any common stock, the holders of Series A Preferred shall be entitled to be paid, on a pari passu basis, out of the assets of the Company legally available for distribution (or the consideration received by the Company or its stockholders in an acquisition) for each share of Series A Preferred held by them, an amount per share of the applicable series of Series A Preferred equal to the applicable original issue price of the security (\$1.00 for the Series A Convertible Preferred Stock and \$1.43 for the Series A-2 Convertible Preferred Stock) plus all declared and unpaid dividends on each such series of Series A Preferred. If, upon any such Liquidation Event, the assets of the Company are insufficient to make payment in full to all holders of Series A Preferred of the liquidation preference, then such assets (or consideration) shall be distributed among the holders of Series A Preferred at the time outstanding, ratably in proportion to the full amounts to which they would otherwise be respectively entitled.

After the payment of the full liquidation preference of the Series A Preferred as set forth above, the remaining assets of the Company legally available for distribution in such Liquidation Event (or the consideration received by the Company or its stockholders in an acquisition) shall be distributed ratably to the holders of common stock and Series A Preferred, with each share of Series A Preferred being treated as if converted into the number of shares of common stock into which such share was convertible on the date of the Liquidation Event.

#### **Optional Conversion**

Each share of Series A Preferred may, at the option of the holder, be converted at any time after the Conversion Trigger Date (as defined below), into such number of shares of common stock as is determined by dividing the applicable original issue price of such series of convertible preferred stock by the applicable conversion price of such series of convertible preferred stock. As of December 31, 2019 and March 31, 2020 (unaudited), the conversion price of the Series A Convertible Preferred Stock is \$7.47 and the conversion price of the Series A-2 Convertible Preferred Stock is \$10.69.

The Conversion Trigger Date means the earliest to occur of: (i) the business day following the second tranche closing under the Series A-2 Agreement, (ii) the business day following the closing of a qualified

financing with respect to the Series A Preferred held by purchasers who participate in such qualified financing, (iii) September 30, 2021, (iv) the date upon which the Company and the stockholders determine that the Milestone will not occur, and (v) the day following the date on which the Company's board of directors or stockholders adopt a resolution to effect a Liquidation Event.

#### Automatic Conversion

Each share of Series A Preferred is automatically convertible into such number of shares of common stock as is determined by dividing the applicable original issue price of such series of convertible preferred stock by the applicable conversion price of such series of convertible preferred stock, (a) at any time upon the written consent of the holders of a majority of the outstanding shares of the Series A Preferred, including at least one of Pivotal bioVenture Partners Fund I, Sofinnova Venture Partners X, L.P. or RA Capital Healthcare Fund, L.P. or (b) immediately upon the closing of a firmly underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, in which the per share price is at least \$22.42 (as appropriately adjusted for any stock dividends, combinations, splits, recapitalizations and the like) and the gross cash proceeds to the Company are at least \$50 million. Refer to Note 13 for discussion of the subsequent amendment to the automatic conversion per share and gross proceeds thresholds.

If an investor fails to fund its second tranche closing commitment, then such investor's shares of Series A Preferred will automatically convert into common stock at a conversion price of five times the conversion price in effect at that time. As of December 31, 2019 and March 31, 2020 (unaudited), no investor has failed to fund its second tranche closing commitment.

#### Voting

The holders of each share of Series A Preferred are entitled to vote on all matters submitted to stockholders for a vote. Each holder shall have the right to cast the number of votes equal to the number of shares of common stock into which such holder's shares of Series A Preferred would be converted. The holders of Series A Preferred will vote together with the holders of Common Stock as a single class, on an as-converted basis, unless otherwise specified by law or the Certificate of Incorporation.

#### Anti-Dilution

The conversion prices of the Series A Convertible Preferred Stock and the Series A-2 Convertible Preferred Stock will be subject to a broad-based weighted average anti-dilution adjustment in the event that the Company issues additional equity securities (other than the issuance of shares reserved under any employee incentive plan and certain other customary exceptions) at a purchase price less than the applicable conversion price.

#### Stock Incentive Plan

In January 2017, the Company's board of directors and stockholders adopted the 2017 Equity Incentive Plan, which was amended and restated in July 2017, (as so amended and restated, the "Plan"), which initially reserved 671,484 shares of common stock for issuance to employees, directors, advisors and consultants. The Plan allows for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and other stock awards. Recipients of stock options or stock appreciation rights shall be eligible to purchase shares of the Company's common stock at an exercise price equal to the estimated fair market value of such stock on the date of grant.

The maximum term of options granted under the Plan is ten years, and stock options typically vest over a four-year period. The board of directors may assign vesting terms to the stock options grants as deemed appropriate. The Company also has the right of refusal to purchase any proposed disposition of shares issued under the Plan. The Company has the option to repurchase any unvested shares underlying restricted stock

awards at the original purchase price upon any voluntary or involuntary termination. At the discretion of the board of directors, unvested shares held by employees may accelerate vesting in the event of a change of control of the Company unless assumed or substituted by the acquirer or surviving entity.

As of December 31, 2019 and March 31, 2020, the maximum number of shares of common stock reserved for issuance under the Plan was 2,730,496. As of December 31, 2019 and March 31, 2020 (unaudited), 1,025,425 and 1,034,263 shares of common stock remain available for future issuance under the Plan, respectively.

The following table summarizes stock option activity under the Plan since December 31, 2017:

	Options Outstanding	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (in years)	Iì	ggregate ntrinsic Value housands)
Outstanding at December 31, 2017	624,903	\$ 0.98	9.19	\$	141
Granted	197,654	1.28			
Exercised	_	_			
Forfeited					
Outstanding at December 31, 2018	822,557	\$ 1.05	8.43	\$	678
Granted	1,009,125	2.02			
Exercised	(69,615)	1.04			
Forfeited	(126,640)	1.51			
Outstanding at December 31, 2019	1,635,427	\$ 1.64	8.81	\$	668
Granted	_	_			
Exercised	(2,677)	1.96			
Forfeited	(8,839)	1.97			
Outstanding at March 31, 2020 (unaudited)	1,623,911	\$ 1.64	8.56	\$	1,881
Exercisable at December 31, 2019	521,327	\$ 1.15	7.91	\$	452
Vested and expected to vest at December 31, 2019	1,635,427	\$ 1.64	8.81	\$	668
Exercisable at March 31, 2020 (unaudited)	598,439	\$ 1.20	7.75	\$	939
Vested and expected to vest at March 31, 2020 (unaudited)	1,623,911	\$ 1.64	8.56	\$	1,881

The Company granted options to non-employees to purchase 12,327 and 83,633 shares of common stock in the years ended December 31, 2018 and 2019, respectively, which are included in the table above. No options were granted to non-employees during the three months ended March 31, 2019 and 2020 (unaudited).

The weighted-average grant date fair values of options granted in the years ended December 31, 2018 and 2019 and the three months ended March 31, 2019 (unaudited) were \$0.94, \$1.51, and \$1.87 per share, respectively. No options were granted during the three months ended March 31, 2020 (unaudited).

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The total intrinsic values of options exercised during the years ended December 31, 2018, and 2019, were zero and \$31 thousand, respectively. The total intrinsic values of options exercised during the three months ended March 31, 2019 and 2020 (unaudited) were \$31 thousand and \$2 thousand, respectively.

For purposes of calculating stock-based compensation, the Company estimates the fair value of stock options using the Black-Scholes option-pricing model. This model incorporates various assumptions, including the expected volatility, expected term, and interest rates. The underlying assumptions used to value stock options granted to employees using the Black-Scholes option-pricing were as follows:

	Years Ended I	December 31,	Three Months Ended March 31,		
	2018	2019	2019	2020	
	<u> </u>		(unaudited)	(unaudited)	
Risk-free interest rate range	2.35% to 3.01%	1.63% to 2.51%	2.51%	N/A	
Dividend yield	0%	0%	0%	N/A	
Expected term of options (years)	6.08	6.78	6.78	N/A	
Volatility rate range	100.11% to 103.48%	85.02% to 103.76%	85.02%	N/A	

No stock options were granted to non-employees during the three months ended March 31, 2019 and 2020 (unaudited). The fair values of stock options granted to non-employees during the years ended December 31, 2018 and 2019 were estimated using the following assumptions:

	Years E	nded December 31,
	2018	2019
Risk-free interest rate range	2.18%	1.84%
Dividend yield	0%	0%
Expected term of options (years)	10	10
Volatility rate range	101.87%	85.02%

Expected Term—The expected term of stock options represents the weighted average period the stock options are expected to be outstanding. The Company uses the simplified method for estimating the expected term, which calculates the expected term as the average time-to-vesting and the contractual life of the options for stock options issued to employees. The expected term for options granted to non-employees is based on the contractual life of the options.

Expected Volatility—Due to the Company's limited operating history and lack of company-specific historical or implied volatility, the expected volatility assumption was determined by examining the historical volatilities of a group of industry peers whose share prices are publicly available. The Company expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price.

*Risk-Free Interest Rate*—The risk-free rate assumption is based on U.S. Treasury instruments, the terms of which were consistent with the expected term of the Company's stock options.

*Expected Dividend*—The expected dividend assumption is based on the Company's history and expectation of dividend payouts. The Company has not paid and does not intend to pay dividends.

Fair Value of Common Stock —Historically, the fair value of the shares of common stock underlying the stock options has been the responsibility of and is determined by the Company's board of directors. Because there was no public market for the Company's common stock, the board of directors determined fair value of common stock at the time of grant of the option by considering a number of objective and subjective factors including independent third-party valuations of the Company's common stock, sales of convertible preferred stock to unrelated third parties, operating and financial performance, the lack of liquidity of capital stock and the general and industry specific economic outlook, among other factors.

For the year ended December 31, 2018, the Company recognized employee-related stock-based compensation expense of \$0.2 million and nonemployee stock-based compensation expense of \$0.2 million. For the year ended December 31, 2019, the Company recognized employee-related stock-based compensation

expense of \$0.3 million and an immaterial amount of non-employee stock-based compensation expense. For the three months ended March 31, 2019 (unaudited), the Company recognized an immaterial amount of employee and non-employee related stock-based compensation expense. For the three months ended March 31, 2020 (unaudited), the Company recognized employee-related stock-based compensation expense of \$0.1 million and an immaterial amount of non-employee stock-based compensation expense.

The fair value of shares vested for the years ended December 31, 2018 and 2019 was \$0.2 million and \$0.3 million, respectively. The fair value of shares vested for the three months ended March 31, 2019 and 2020 (unaudited) was not material and \$0.1 million, respectively.

The total unrecognized compensation cost related to outstanding employee awards as of December 31, 2019 was \$1.4 million, and is expected to be recognized over a weighted-average period of 3.1 years. The total unrecognized compensation cost related to outstanding non-employee awards as of December 31, 2019 was \$0.1 million, and is expected to be recognized over a weighted-average period of 2.2 years. The total unrecognized compensation cost related to outstanding employee awards as of March 31, 2020 (unaudited) was \$1.2 million, and is expected to be recognized over a weighted-average period of 2.4 years. The total unrecognized compensation cost related to outstanding non-employee awards as of March 31, 2020 (unaudited) was \$0.1 million, and is expected to be recognized over a weighted-average period of 2.0 years.

#### Restricted Common Stock

For restricted stock awards granted to employees and to non-employees, the fair value on the date of grant is recognized as stock-based compensation expense ratably over the period in which the restrictions lapse. These shares of restricted common stock generally have vesting terms which require the holders to provide ongoing service to the Company and typically vest over a three-year term. If any of these individuals cease to provide services for the Company prior to vesting, the Company has the right to repurchase any unvested shares of restricted common stock at the price paid by the holder. The consideration received for the shares of restricted common stock is initially included in other liabilities on the balance sheet and is reclassified into stockholder's (deficit) equity as the shares vest. Stock-based compensation associated with the issuance of restricted stock for the years ended December 31, 2018 and 2019 of \$0.3 million and none, respectively, are included in total stock-based compensation expense. There was no restricted stock activity during the three months ended March 31, 2019 and 2020.

The following table summarizes the restricted stock award activity for the year ended December 31, 2018:

	Shares	Weighted- Average Purchase Price
Unvested at December 31, 2017	241,191	\$ 0.0007
Granted	_	_
Vested	241,191	0.0007
Cancelled		
Unvested at December 31, 2018	_	\$ —

## 9. Income Taxes

On December 22, 2017, the Tax Cuts and Jobs Act ("TCJA") was enacted, reducing the U.S. federal corporate income tax rate from 35% to 21%, among other changes. As a result of the enacted law, the Company was required to revalue deferred tax assets and liabilities existing as of December 31, 2017 from the 34% federal rate in effect through the end of 2017 to the new 21% rate. The Company has recognized the impact of the TCJA

in these financial statements and related disclosures. Due to the complexities involved in accounting for the enactment of the TCJA, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118"), which allowed a registrant to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. Although not a registrant, the Company has applied the provisions of SAB 118 to its financial statements. As of December 31, 2018, the Company had finalized its analysis of the impact of the TCJA and noted there were no material changes from its initial assessment.

During the years ended December 31, 2018 and 2019, the Company recorded net losses of \$7.0 million and \$19.7 million, respectively. During the three months ended March 31, 2019 and 2020 (unaudited), the Company recorded net losses of \$5.0 million and \$7.7 million, respectively. Since it maintains a full valuation allowance on its deferred tax assets, the Company did not record an income tax benefit for the years ended December 31, 2018 and 2019 or the three months ended March 31, 2019 and 2020 (unaudited).

Deferred taxes are recognized for temporary differences between the bases of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets as of December 31, 2018 and 2019 are comprised of the following (dollar amounts in thousands):

	Decen	ıber 31,	
	2018	2019	
Deferred tax assets:			
Net operating losses	\$ 3,916	\$ 8,584	
Research and development credits	237	429	
Stock options	226	20	
Accrued expenses	17	222	
Other	80	77	
Gross deferred tax assets	4,476	9,332	
Less: Valuation allowance	(4,474)	(9,320)	
Net deferred tax assets	2	12	
Deferred tax liabilities:			
Depreciation of fixed assets	(2)	(12)	
Gross deferred tax liabilities	(2)	(12)	
Non-current net deferred tax assets (liabilities)	<u> </u>	\$ —	

As of December 31, 2019, the Company had gross federal operating loss carryforwards of \$34.6 million, which may be available to offset future taxable income. Of the federal operating loss carryforwards, \$5.9 million begin to expire in 2037 and \$28.7 million do not expire. As of December 31, 2019, the Company had gross state operating loss carryforwards of \$21.6 million, which may be available to offset future taxable income and which begin to expire in 2037.

As required by FASB ASC Topic 740, *Income Taxes*, management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating loss carryforwards and research and development credits. Under the applicable accounting standards, management has considered the Company's history of losses and concluded that it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets. Accordingly, a full valuation allowance of \$4.5 million and \$9.3 million has been established at December 31, 2018 and December 31, 2019, respectfully. The increase in the valuation allowance of \$4.8 million during 2019 was primarily due to the increase in net operating loss generated by the Company.

The Company also has federal and state research and development credit carryforwards totaling \$0.4 million as of December 31, 2019. The federal research and development credit carryforwards will begin to

expire in 2038, unless previously utilized. The Company has generated research credits, but has not conducted a study to document the qualified activity. This study may result in an adjustment to the Company's research and development credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the deferred tax asset established for the research and development credit carryforwards and the valuation allowance.

The Company's ability to use its net operating loss carryforwards ("NOLs") and tax credit carryforwards to offset taxable income is subject to restrictions under Sections 382 and 383 of the United States Internal Revenue Code (the "Internal Revenue Code"). Under the Internal Revenue Code provisions, certain substantial changes in the Company's ownership, including the sale of the Company or significant changes in ownership due to sales of equity, have limited and may limit in the future, the amount of NOLs which could be used annually to offset future taxable income. The Company has not yet completed an analysis of ownership changes. The Company may also experience ownership changes in the future as a result of subsequent shifts in its stock ownership, some of which may be outside the Company's control. As a result, the Company's ability to use its pre-change NOLs to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to the Company. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. Under the TCJA, the use of federal NOLs arising in taxable years beginning after December 31, 2017 is limited to 80% of current year taxable income and NOLs arising in taxable years ending after December 31, 2017 may not be carried back (though any such NOLs may be carried forward indefinitely). The Coronavirus Aid, Relief, and Economic Security (CARES) Act, enacted on March 27, 2020, retroactively and temporarily (for taxable years beginning before January 1, 2021) suspends application of the 80%-of-income limitation on the use of NOLs and provides that NOLs arising in any taxable year beginning after December 31, 2017, and before January 1, 2021 are generally eligible to be carried back up to five years.

The Company establishes reserves for uncertain tax positions based on management's assessment of exposures associated with tax positions taken on tax return filings. The tax reserves are analyzed periodically and adjustments are made as events occur to warrant adjustment to the reserve. The Company does not have any reserves for uncertain tax positions as of December 31, 2019 and any change in position would result in a change in the valuation allowance maintained against its net deferred tax assets.

Interest and penalty charges, if any, related to unrecognized tax benefits would be classified as income tax expense in the accompanying consolidated statements of operations and comprehensive loss. As of December 31, 2019, the Company had no accrued interest related to uncertain tax positions. Since the Company is in a loss carryforward position, the Company is generally subject to examination by the U.S. federal, state and local income tax authorities for all tax years in which a loss carryforward is available.

#### 10. Net Loss per Share and Unaudited Pro Forma Net Loss per Share

#### Net Loss per Share Attributable to Common Stockholders

For purposes of the diluted net loss per share calculation, stock options, unvested restricted stock, and convertible preferred stock are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same.

The Company excluded the following potential dilutive securities, presented based on amounts outstanding at December 31, 2018 and 2019, and March 31, 2019 and 2020 (unaudited), from the computation of

diluted net loss per share attributable to common stockholders because including them would have had an anti-dilutive effect:

	Years Ended I	Years Ended December 31		Three Months Ended March 31,	
	2018	2019	2019	2020	
	·		(unaudited)	(unaudited)	
Series A Convertible Preferred Stock (as converted to common stock)	6,536,856	6,536,856	6,536,856	6,536,856	
Series A-2 Convertible Preferred Stock (as converted to common stock)	1,001,270	3,153,537	3,153,537	3,153,537	
Options to purchase common stock	822,557	1,635,427	788,184	1,623,911	

#### Unaudited Pro Forma Net Loss per Share Attributable to Common Stockholders

The unaudited pro forma basic and diluted weighted-average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2019 and the three months ended March 31, 2020 have been prepared to give effect, upon a qualified IPO, to the automatic conversion of all then-outstanding shares of convertible preferred stock into common stock as if the qualified IPO had occurred at the beginning of each period.

A reconciliation of pro forma net loss and the pro forma weighted-average number of common shares used in computing pro forma basic and diluted net loss per share applicable to common stockholders is as follows (dollar amounts, except per share amounts, in thousands):

	Year Ended December 31, 2019	Three Months Ended March 31, 2020 (unaudited)	
Numerator:		,	
Net loss attributable to common stockholders—basic and diluted	\$ (19,724)	\$ (7,738)	
Pro forma net loss attributable to common stockholders—basic and diluted	\$ (19,724)	\$ (7,738)	
Denominator:	·		
Weighted-average common stock outstanding—basic and diluted	1,183,144	1,205,346	
Pro forma adjustment to reflect automatic conversion of convertible preferred stock to			
common stock upon completion of a qualified IPO	13,953,850	13,953,850	
Pro forma weighted-average common stock outstanding—basic and diluted	15,136,994	15,159,196	
Pro forma net loss per share attributable to common stockholders—basic and diluted	\$ (1.30)	\$ (0.51)	

#### 11. Employee Benefit Plans

The Company established a defined contribution savings plan in 2018 for all eligible U.S. employees under Section 401(k) of the Internal Revenue Code. During the years ended December 31, 2018 and 2019, the Company did not make any employer contributions to the plan. Employees can designate the investment of their 401(k) accounts into several mutual funds. Administrative costs of the plan for each of the years ended December 31, 2018 and 2019, were \$1 thousand.

#### 12. Related Party Transactions

For each of the years ended December 31, 2018 and 2019, the Company made payments of \$0.1 million to one of its directors for scientific consulting and other expenses. For each of the three-month periods ended March 31, 2019 and 2020 (unaudited), the Company made payments of \$34 thousand to one of its directors for scientific consulting and other expenses. In addition, in connection with his service as a consultant, the Company granted this director an option to purchase 10,036 shares at an exercise price per share of \$0.98 in 2017 and an option to purchase 66,907 shares at an exercise price per share of \$2.02 in 2019. As of December 31, 2018, December 31, 2019 and March 31, 2020 (unaudited), \$11 thousand was due to this director, who resigned from the board of directors in May 2020.

See Note 6 for a description of the Company's License and Sponsored Research Agreement with Yale.

#### 13. Subsequent Events

In preparing the consolidated financial statements as of and for the year ended December 31, 2019, the Company evaluated subsequent events for recognition and measurement purposes through May 8, 2020, the date the consolidated financial statements were issued, and July 20, 2020, the date the revised consolidated financial statements were issued. In preparing the unaudited consolidated interim financial statements as of March 31, 2020 and for the three-month period then ended, the Company evaluated subsequent events for recognition and measurement purposes through June 12, 2020, the date the unaudited consolidated interim financial statements were issued, and July 20, 2020, the date the revised condensed consolidated financial statements were issued. The Company has concluded that no events or transactions have occurred that require disclosure in the accompanying consolidated financial statements, other than the following.

# (a) Lease Agreement (unaudited)

On May 13, 2020, the Company entered into a non-cancelable agreement to lease 6,244 square feet of laboratory space in Boston, Massachusetts. The lease term for the laboratory space will begin following the substantial completion of the construction work which is anticipated around late 2020 and ends in late 2025. Total future lease commitments are \$2.3 million.

#### (b) Series A-2 Tranche Right Milestone (unaudited)

In June 2020, the board of directors and requisite stockholders approved a waiver of the A-2 Tranche Right Milestone. Pursuant to this waiver, the Company sold to investors an additional 23,566,431 shares of Series A-2 Convertible Preferred Stock at \$1.43 per share for net proceeds of \$33.7 million.

#### (c) Acquisition of intellectual property (unaudited)

In July 2020, the Company entered into an intellectual property asset purchase agreement with Alexion pursuant to which Alexion sold and assigned to the Company Alexion's right, title and interest in and to specified patent rights and other specified assets solely related to ENPP1. The Company issued 8,294,360 shares of its Series A-2 Convertible Preferred Stock to Alexion in consideration for the sale and assignment to the Company of such assets. The Company will expense the assets acquired from Alexion as of the acquisition date because the Company will use them in research and development activities and believes they have no alternative future uses.

(d) Automatic conversion waiver and reverse stock split (unaudited)

On July 17, 2020, the Company eliminated the per share and gross proceeds thresholds for a firm-commitment underwritten public offering that triggers the automatic conversion of all outstanding shares of preferred stock into common stock. In addition, on July 17, 2020, the Company effected a one-for-7.4730 reverse stock split of the Company's common stock. All share and per share amounts in the consolidated financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to this reverse stock split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital. Shares of common stock underlying outstanding stock options and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the appropriate securities agreements. Shares of common stock reserved for issuance upon the conversion of our convertible preferred stock were proportionately reduced and the respective conversion prices were proportionately increased. Stockholders entitled to fractional shares as a result of the reverse stock split will receive a cash payment in lieu of receiving fractional shares.

(e) Increase in Authorized Series A-2 Convertible Preferred Stock (unaudited)

On July 17, 2020, the Company increased the number of authorized shares of Series A-2 Convertible Preferred Stock from 47,132,862 to 55,427,222.

(f) Increase in Authorized Common Stock (unaudited)

On July 17, 2020, the Company increased the number of authorized shares of common stock from 129,000,000 to 138,000,000.

Through and including , 2020, (the 25th day after the date of this prospectus), all dealers effecting transactions in the Common Stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

5,000,000 Shares



**Common Stock** 

**PROSPECTUS** 

BofA Securities Cowen Piper Sandler

**Wedbush PacGrow** 

#### PART II

## INFORMATION NOT REQUIRED IN PROSPECTUS

### Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the expenses to be incurred in connection with the offering described in this Registration Statement, other than underwriting discounts and commissions, all of which will be paid by the Registrant. All amounts are estimates except the Securities and Exchange Commission, or SEC, registration fee, the Financial Industry Regulatory Authority, Inc. filing fee and the Nasdaq Global Market initial listing fee.

	Amount	t
SEC registration fee	\$ 11,9	142
Financial Industry Regulatory Authority, Inc. filing fee	14,3	301
Nasdaq Global Market initial listing fee	150,0	000
Accountants' fees and expenses	1,000,0	000
Legal fees and expenses	1,800,0	000
Transfer agent's fees and expenses	5,0	000
Printing and engraving expenses	80,0	000
Miscellaneous	238,7	'57
Total expenses	\$ 3,300,0	000

## Item 14. Indemnification of Directors and Officers.

Section 102 of the Delaware General Corporation Law, or the DGCL, permits a corporation to eliminate the personal liability of its directors or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his or her duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our certificate of incorporation that will be effective upon the closing of this offering provides that no director shall be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the DGCL prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the DGCL provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he or she is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnification for such expenses which the Court of Chancery or such other court shall deem proper.

Our certificate of incorporation that will be effective upon the closing of the offering provides that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of us), by reason of the fact that he or she is or was, or has agreed to become, our director or

officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an Indemnitee), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful.

Our certificate of incorporation that will be effective upon the closing of the offering also provides that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, our director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred by him or her or on his or her behalf in connection therewith. If we do not assume the defense, expenses must be advanced to an Indemnitee under certain circumstances.

In addition, we intend to enter into indemnification agreements with all of our executive officers and directors prior to the completion of this offering. In general, these agreements provide that we will indemnify the executive officer or director to the fullest extent permitted by law for claims arising in his or her capacity as an executive officer or director of our company or in connection with his or her service at our request for another corporation or entity. The indemnification agreements also provide for procedures that will apply in the event that an executive officer or director makes a claim for indemnification and establish certain presumptions that are favorable to the executive officer or director.

We maintain a general liability insurance policy that covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers.

The underwriting agreement we will enter into in connection with the offering of common stock being registered hereby provides that the underwriters will indemnify, under certain conditions, our directors and officers (as well as certain other persons) against certain liabilities arising in connection with such offering.

Insofar as the foregoing provisions permit indemnification of directors, executive officers or persons controlling us for liability arising under the Securities Act of 1933, as amended, or the Securities Act, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

# Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding shares of our common stock, shares of our convertible preferred stock and stock options granted by us within the past three years that were not registered under the Securities Act. Also included is the consideration, if any, received by us for such shares and options and information relating to the section of the Securities Act, or rule of the SEC, under which exemption from registration was claimed.

### (a) Issuances of Preferred Stock

On November 8, 2018, we issued and sold 21,666,667 shares of our Series A convertible preferred stock to 13 investors at a price per share of \$1.00 in cash, for an aggregate purchase price of \$21,666,667.

On November 9, 2018, we issued and sold 7,482,515 shares of our Series A-2 convertible preferred stock to five investors at a price per share of \$1.43 in cash, for an aggregate purchase price of \$10,699,996.45.

On March 22, 2019, we issued and sold 16,083,916 shares of our Series A-2 convertible preferred stock to six investors at a price per share of \$1.43 in cash, for an aggregate purchase price of \$22,999,999.88.

On June 5, 2020, we issued and sold 23,566,431 shares of our Series A-2 convertible preferred stock to 12 investors at a price per share of \$1.43 in cash, for an aggregate purchase price of \$33,699,996.33.

On July 17, 2020, we issued 8,294,360 shares of our Series A-2 convertible preferred stock to one investor as consideration for our purchase of assets from such investor.

No underwriters were involved in the foregoing issuances of securities. The securities described in this section (a) of Item 15 were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act and, in certain cases, Regulation D thereunder, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

# (b) Stock Option Grants and Exercises

Between January 1, 2017 and July 20, 2020, we granted options to purchase an aggregate of 2,439,867 shares of our common stock, with exercise prices ranging from \$0.98 to \$2.77 per share, to our employees, directors, advisors and consultants pursuant to our Amended and Restated 2017 Equity Incentive Plan. Between January 1, 2017 and July 20, 2020, we issued 225,986 shares of our common stock upon the exercise of stock options outstanding under our Amended and Restated 2017 Equity Incentive Plan for aggregate consideration of \$242,602.

The stock options and the shares of our common stock issued upon the exercise of stock options described in this section (b) of Item 15 were issued pursuant to written compensatory plans or arrangements with our employees, directors, advisors and consultants, in reliance on the exemption provided by Rule 701 promulgated under the Securities Act, or pursuant to Section 4(a)(2) under the Securities Act, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All recipients either received adequate information about our company or had access, through employment or other relationships, to such information.

# Item 16. Exhibits and Financial Statement Schedules.

### (a) Exhibits

Exhibit Number	<u>Description of Exhibit</u>
1.1	Form of Underwriting Agreement
2.1†	Intellectual Property Asset Purchase Agreement, dated July 17, 2020, by and between the Registrant and Alexion Pharmaceuticals, Inc.
3.1	Second Amended and Restated Certificate of Incorporation, as amended, of the Registrant
3.2*	By-laws of the Registrant
3.3	Form of Restated Certificate of Incorporation of the Registrant (to be effective upon the closing of this offering)

Exhibit Number	Description of Exhibit
3.4	Form of Amended and Restated Bylaws of the Registrant (to be effective upon the closing of this offering)
4.1	Specimen Stock Certificate evidencing the shares of common stock
5.1	Opinion of Wilmer Cutler Pickering Hale and Dorr LLP
10.1	Second Amended and Restated Investor Rights Agreement, dated as of November 9, 2018, by and among the Registrant and the other parties thereto, as amended
10.2*	Registration Rights Agreement, dated as of June 1, 2016, by and among the Registrant and the other parties thereto
10.3*	Amended and Restated 2017 Equity Incentive Plan, as amended
10.4*	Form of Stock Option Agreement Granted under Amended and Restated 2017 Equity Incentive Plan
10.5	2020 Stock Incentive Plan
10.6	Form of Stock Option Agreement under the 2020 Stock Incentive Plan
10.7	Form of Restricted Stock Unit Agreement under the 2020 Stock Incentive Plan
10.8	2020 Employee Stock Purchase Plan
10.9	Summary of Non-Employee Director Compensation Program
10.10†*	License Agreement, dated January 6, 2017, by and between Yale University and the Registrant, as amended by Amendment No. 1 to License Agreement, dated May 2, 2020, by and between Yale University and the Registrant and Amendment No. 2 to License Agreement, dated July 1, 2020, by and between Yale University and the Registrant
10.11†*	Corporate Sponsored Research Agreement, dated January 6, 2017, by and between Yale University and the Registrant, as amended by Amendment No. 1 to Corporate Sponsored Research Agreement, dated February 19, 2019, by and between Yale University and the Registrant
10.12*	Form of Restricted Stock Agreement between the Registrant and Axel Bolte
10.13*	Lease, dated December 13, 2019, by and between 321 Summer Street LLC and the Registrant
10.14*	Lease, dated May 13, 2020, by and between RREF II 451D, LLC and the Registrant
10.15	Form of Indemnification Agreement between the Registrant and each of its Executive Officers and Directors
10.16	Employment Agreement, dated July 1, 2020, by and between the Registrant and Axel Bolte (to be effective upon the effectiveness of this Registration Statement)
10.17	Employment Agreement, dated July 1, 2020, by and between the Registrant and Henric Bjarke (to be effective upon the effectiveness of this Registration Statement)
10.18	Employment Agreement, dated July 1, 2020, by and between the Registrant and Steven Jungles (to be effective upon the effectiveness of this Registration Statement)
10.19	Employment Agreement, dated July 1, 2020, by and between the Registrant and Pedro Huertas (to be effective upon the effectiveness of this Registration Statement)
10.20	Employment Agreement, dated July 1, 2020, by and between the Registrant and Stephen Basso (to be effective upon the effectiveness of this Registration Statement)
21.1*	Subsidiaries of the Registrant

Exhibit <u>Number</u>	Description of Exhibit
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm
23.2	Consent of Wilmer Cutler Pickering Hale and Dorr LLP (included in Exhibit 5.1)
24.1*	Power of Attorney (included on signature page)

<sup>\*</sup> Previously filed.

## (b) Financial Statement Schedules

No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or the related notes.

## Item 17. Undertakings.

(a) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

- (b) The undersigned registrant hereby undertakes that:
- (1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

<sup>†</sup> Certain portions of this exhibit have been omitted because they are not material and would likely cause competitive harm to the Registrant if disclosed.

## **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused Amendment No. 1 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Boston, Commonwealth of Massachusetts, on this 20<sup>th</sup> day of July, 2020.

# INOZYME PHARMA, INC.

By: /s/ Axel Bolte

Axel Bolte

President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, Amendment No. 1 to the Registration Statement has been signed by the following persons in the capacities held on the dates indicated.

Signature	<u>Title</u>	<u>Date</u>
/s/ Axel Bolte Axel Bolte	President and Chief Executive Officer, Director (Principal Executive Officer)	July 20, 2020
/s/ Stephen Basso Stephen Basso	Senior Vice President, Finance (Principal Financial Officer and Principal Accounting Officer)	July 20, 2020
* Douglas Treco	_ Chairman	July 20, 2020
* Sarah Bhagat	Director	July 20, 2020
* Reinaldo Diaz	Director	July 20, 2020
* Martin Edwards	Director	July 20, 2020
* Robert Hopfner	Director	July 20, 2020
*	Director	July 20, 2020
Edward Mathers	Director	July 20, 2020
Lynne Sullivan		
*By: /s/ Axel Bolte Axel Bolte Attorney-in-fact		

# INOZYME PHARMA, INC.

(a Delaware corporation)

[ullet] Shares of Common Stock

# **UNDERWRITING AGREEMENT**

Dated: [●], 2020

### INOZYME PHARMA, INC.

(a Delaware corporation)

[•] Shares of Common Stock

### UNDERWRITING AGREEMENT

 $[\bullet]$ , 2020

BofA Securities, Inc. Cowen and Company, LLC Piper Sandler & Co.

as Representatives of the several Underwriters c/o BofA Securities, Inc. One Bryant Park New York, New York 10036

> Cowen and Company, LLC 599 Lexington Avenue, 25th Floor New York, New York 10022

Piper Sandler & Co. 345 Park Avenue, Suite 1200 New York, New York 10154

### Ladies and Gentlemen:

Inozyme Pharma, Inc., a Delaware corporation (the "Company"), confirms its agreement with BofA Securities, Inc. ("BofAS"), Cowen and Company, LLC ("Cowen") and Piper Sandler & Co. ("Piper Sandler") and each of the other underwriters named in Schedule A hereto (collectively, the "Underwriters," which term shall also include any underwriter substituted as hereinafter provided in Section 10 hereof), for whom BofAS, Cowen and Piper Sandler are acting as representatives (in such capacity, the "Representatives"), with respect to (i) the sale by the Company and the purchase by the Underwriters, acting severally and not jointly, of the respective numbers of shares of common stock, par value \$0.0001 per share, of the Company ("Common Stock") set forth in Schedule A hereto and (ii) the grant by the Company to the Underwriters, acting severally and not jointly, of the option described in Section 2(b) hereof to purchase all or any part of [•] additional shares of Common Stock. The aforesaid [•] shares of Common Stock (the "Initial Securities") to be purchased by the Underwriters and all or any part of the [•] shares of Common Stock subject to the option described in Section 2(b) hereof (the "Option Securities") are herein called, collectively, the "Securities."

The Company understands that the Underwriters propose to make a public offering of the Securities as soon as the Representatives deem advisable after this Underwriting Agreement (this "Agreement") has been executed and delivered.

The Company has filed with the Securities and Exchange Commission (the "Commission") a registration statement on Form S-1 (No. 333-239648), including the related preliminary prospectus or prospectuses, covering the registration of the sale of the Securities under the Securities Act of 1933, as

amended (the "1933 Act"). Promptly after execution and delivery of this Agreement, the Company will prepare and file a prospectus in accordance with the provisions of Rule 430A ("Rule 430A") of the rules and regulations of the Commission under the 1933 Act (the "1933 Act Regulations") and Rule 424(b) ("Rule 424(b)") of the 1933 Act Regulations. The information included in such prospectus that was omitted from such registration statement at the time it became effective but that is deemed to be part of such registration statement at the time it became effective pursuant to Rule 430A(b) is herein called the "Rule 430A Information." Such registration statement, including the amendments thereto, the exhibits thereto and any schedules thereto, at the time it became effective, and including the Rule 430A Information, is herein called the "Registration Statement." Any registration statement filed pursuant to Rule 462(b) of the 1933 Act Regulations is herein called the "Rule 462(b) Registration Statement" and, after such filing, the term "Registration Statement" shall include the Rule 462(b) Registration Statement. Each prospectus used prior to the effectiveness of the Registration Statement, and each prospectus that omitted the Rule 430A Information that was used after such effectiveness and prior to the execution and delivery of this Agreement, is herein called a "preliminary prospectus." The final prospectus, in the form first furnished to the Underwriters for use in connection with the offering of the Securities, is herein called the "Prospectus." For purposes of this Agreement, all references to the Registration Statement, any preliminary prospectus, the Prospectus or any amendment or supplement to any of the foregoing shall be deemed to include the copy filed with the Commission pursuant to its Electronic Data Gathering, Analysis and Retrieval system or any successor system ("EDGAR").

## As used in this Agreement:

"Applicable Time" means [•]:00 [P.M./A.M.], New York City time, on [•], 2020 or such other time as agreed by the Company and BofAS.

"General Disclosure Package" means any Issuer General Use Free Writing Prospectuses issued at or prior to the Applicable Time, the most recent preliminary prospectus that is distributed to investors prior to the Applicable Time and the information included on Schedule B-1 hereto, all considered together.

"Issuer Free Writing Prospectus" means any "issuer free writing prospectus," as defined in Rule 433 of the 1933 Act Regulations ("Rule 433"), including without limitation any "free writing prospectus" (as defined in Rule 405 of the 1933 Act Regulations ("Rule 405")) relating to the Securities that is (i) required to be filed with the Commission by the Company, (ii) a "road show that is a written communication" within the meaning of Rule 433(d)(8)(i), whether or not required to be filed with the Commission, or (iii) exempt from filing with the Commission pursuant to Rule 433(d)(5)(i) because it contains a description of the Securities or of the offering that does not reflect the final terms, in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g).

"Issuer General Use Free Writing Prospectus" means any Issuer Free Writing Prospectus that is intended for general distribution to prospective investors (other than a "bona fide electronic road show," as defined in Rule 433 (the "Bona Fide Electronic Road Show")), as evidenced by its being specified in Schedule B-2 hereto.

"Issuer Limited Use Free Writing Prospectus" means any Issuer Free Writing Prospectus that is not an Issuer General Use Free Writing Prospectus.

"Testing-the-Waters Communication" means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the 1933 Act.

"Written Testing-the-Waters Communication" means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the 1933 Act.

## SECTION 1. Representations and Warranties.

- (a) *Representations and Warranties by the Company*. The Company represents and warrants to each Underwriter as of the date hereof, the Applicable Time, the Closing Time (as defined below) and any Date of Delivery (as defined below), and agrees with each Underwriter, as follows:
  - (i) <u>Registration Statement and Prospectuses</u>. Each of the Registration Statement and any amendment thereto has become effective under the 1933 Act. No stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto has been issued under the 1933 Act, no order preventing or suspending the use of any preliminary prospectus or the Prospectus has been issued and no proceedings for any of those purposes have been instituted or are pending or, to the Company's knowledge, contemplated by the Commission. The Company has complied with each request (if any) from the Commission for additional information.

Each of the Registration Statement and any post-effective amendment thereto, at the time it became effective, the Applicable Time, the Closing Time and any Date of Delivery complied and will comply in all material respects with the requirements of the 1933 Act and the 1933 Act Regulations. Each preliminary prospectus, the Prospectus and any amendment or supplement thereto, at the time each was filed with the Commission, and, in each case at the Applicable Time, the Closing Time and any Date of Delivery complied and will comply in all material respects with the requirements of the 1933 Act and the 1933 Act Regulations. Each preliminary prospectus delivered to the Underwriters for use in connection with this offering and the Prospectus was or will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(ii) Accurate Disclosure. Neither the Registration Statement nor any amendment thereto, at its effective time, on the date hereof, at the Closing Time or at any Date of Delivery, contained, contains or will contain an untrue statement of a material fact or omitted, omits or will omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. At the Applicable Time and any Date of Delivery, none of (A) the General Disclosure Package, (B) any individual Issuer Limited Use Free Writing Prospectus, when considered together with the General Disclosure Package, and (C) any individual Written Testing-the-Waters Communication, when considered together with the General Disclosure Package, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. Neither the Prospectus nor any amendment or supplement thereto, when considered together with the Prospectus, as of its issue date, at the time of any filing with the Commission pursuant to Rule 424(b), at the Closing Time or at any Date of Delivery, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

The representations and warranties in this subsection shall not apply to statements in or omissions from the Registration Statement (or any amendment thereto), the General Disclosure Package or the Prospectus (or any amendment or supplement thereto) made in reliance upon and

in conformity with written information furnished to the Company by any Underwriter through the Representatives expressly for use therein. For purposes of this Agreement, the only information so furnished shall be the information in the first paragraph under the heading "Underwriting—Commissions and Discounts," the information in the second, third and fourth paragraphs under the heading "Underwriting—Price Stabilization, Short Positions and Penalty Bids" and the information under the heading "Underwriting—Electronic Distribution" in each case contained in the Prospectus (collectively, the "Underwriter Information").

- (iii) <u>Issuer Free Writing Prospectuses</u>. No Issuer Free Writing Prospectus conflicts or will conflict with the information contained in the Registration Statement or the Prospectus, and any preliminary or other prospectus deemed to be a part thereof that has not been superseded or modified. The Company has made available a Bona Fide Electronic Road Show in compliance with Rule 433(d)(8)(ii) such that no filing of any "road show" (as defined in Rule 433(h)) is required in connection with the offering of the Securities.
- (iv) <u>Testing-the-Waters Materials</u>. The Company (A) has not engaged in any Testing-the-Waters Communication other than Testing-the-Waters Communications with the consent of the Representatives with entities that are qualified institutional buyers within the meaning of Rule 144A under the 1933 Act or institutions that are accredited investors within the meaning of Rule 501 under the 1933 Act and (B) has not authorized anyone other than the Representatives to engage in Testing-the-Waters Communications. The Company reconfirms that the Representatives have been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications other than those listed on Schedule B-3 hereto.
- (v) <u>Company Not Ineligible Issuer</u>. At the time of filing the Registration Statement and any post-effective amendment thereto, at the earliest time thereafter that the Company or another offering participant made a *bona fide* offer (within the meaning of Rule 164(h)(2) of the 1933 Act Regulations) of the Securities and at the date hereof, the Company was not and is not an "ineligible issuer," as defined in Rule 405, without taking account of any determination by the Commission pursuant to Rule 405 that it is not necessary that the Company be considered an ineligible issuer.
- (vi) <u>Emerging Growth Company Status</u>. From the time of the initial confidential submission of the Registration Statement to the Commission (or, if earlier, the first date on which the Company engaged directly or through any individual or entity ("Person") authorized to act on its behalf in any Testing-the-Waters Communication) through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the 1933 Act (an "Emerging Growth Company").
- (vii) <u>Independent Accountants</u>. The accountants who certified the financial statements and supporting schedules included in the Registration Statement, the General Disclosure Package and the Prospectus are independent public accountants as required by the 1933 Act, the 1933 Act Regulations and the Public Company Accounting Oversight Board.
- (viii) <u>Financial Statements</u>. The financial statements included in the Registration Statement, the General Disclosure Package and the Prospectus, together with the related schedules and notes, present fairly, in all material respects, the financial position of the Company and its consolidated subsidiaries at the dates indicated and the statement of operations, stockholders' equity and cash flows of the Company and its consolidated subsidiaries for the periods specified; said financial statements have been prepared in conformity with U.S. generally

accepted accounting principles ("GAAP") applied on a consistent basis throughout the periods involved, except for normal year-end audit adjustments and the exclusion of certain footnotes as permitted by the applicable rules of the Commission in the case of unaudited interim financial statements. The supporting schedules, if any, present fairly, in all material respects, in accordance with GAAP the information required to be stated therein. The selected financial data and the summary financial information included in the Registration Statement, the General Disclosure Package and the Prospectus present fairly, in all material respects, the information shown therein and have been compiled on a basis consistent with that of the audited financial statements included therein. Except as included therein, no historical or pro forma financial statements or supporting schedules are required to be included in the Registration Statement, the General Disclosure Package or the Prospectus under the 1933 Act or the 1933 Act Regulations.

- (ix) No Material Adverse Change in Business. Except as otherwise stated therein, since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package or the Prospectus, (A) there has been no material adverse change in the condition, financial or otherwise, or in the earnings, business affairs or business prospects of the Company and its subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business (a "Material Adverse Effect"), (B) there have been no transactions entered into by the Company or any of its subsidiaries, other than those in the ordinary course of business, which are material with respect to the Company and its subsidiaries considered as one enterprise, and (C) there has been no dividend or distribution of any kind declared, paid or made by the Company on any class of its capital stock.
- (x) Good Standing of the Company. The Company has been duly organized and is validly existing as a corporation in good standing under the laws of the State of Delaware and has corporate power and authority to own, lease and operate its properties and to conduct its business as described in the Registration Statement, the General Disclosure Package and the Prospectus and to enter into and perform its obligations under this Agreement; and the Company is duly qualified as a foreign corporation to transact business and is in good standing in each other jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure so to qualify or to be in good standing would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect.
- (xi) Good Standing of Subsidiaries. Each "significant subsidiary" of the Company (as such term is defined in Rule 1-02 of Regulation S-X) (each, a "Subsidiary" and, collectively, the "Subsidiaries") has been duly organized and is validly existing in good standing under the laws of the jurisdiction of its incorporation or organization, has corporate or similar power and authority to own, lease and operate its properties and to conduct its business as described in the Registration Statement, the General Disclosure Package and the Prospectus and is duly qualified to transact business and is in good standing in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure to so qualify or to be in good standing would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect. Except as otherwise disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, all of the issued and outstanding capital stock of each Subsidiary has been duly authorized and validly issued, is fully paid and non-assessable and is owned by the Company, directly or through subsidiaries, free and clear of any security interest, mortgage, pledge, lien, encumbrance, claim or equity. None of the outstanding shares of capital stock of any Subsidiary were issued in violation of the preemptive or similar rights of any securityholder of such Subsidiary. The only subsidiaries of the Company are (A) the subsidiaries listed on Exhibit 21.1 to the Registration Statement and (B) certain other subsidiaries which, considered in the aggregate as a single subsidiary, do not constitute a "significant subsidiary" as defined in Rule 1-02 of Regulation S-X.

- (xii) <u>Capitalization</u>. The authorized, issued and outstanding shares of capital stock of the Company are as set forth in the Registration Statement, the General Disclosure Package and the Prospectus in the column entitled "Actual" under the caption "Capitalization" (except for subsequent issuances, if any, pursuant to this Agreement, pursuant to reservations, agreements or employee benefit or equity incentive plans referred to in the Registration Statement, the General Disclosure Package and the Prospectus or pursuant to the conversion or exercise of convertible securities or options referred to in the Registration Statement, the General Disclosure Package and the Prospectus). The outstanding shares of capital stock of the Company have been duly authorized and validly issued and are fully paid and non-assessable. None of the outstanding shares of capital stock of the Company were issued in violation of the preemptive or other similar rights of any securityholder of the Company.
  - (xiii) Authorization of Agreement. This Agreement has been duly authorized, executed and delivered by the Company.
- (xiv) Authorization and Description of Securities. The Securities to be purchased by the Underwriters from the Company have been duly authorized for issuance and sale to the Underwriters pursuant to this Agreement and, when issued and delivered by the Company pursuant to this Agreement against payment of the consideration set forth herein, will be validly issued and fully paid and non-assessable; and the issuance of the Securities is not subject to the preemptive or other similar rights of any securityholder of the Company. The Common Stock conforms in all material respects to the description thereof contained in the Registration Statement, the General Disclosure Package and the Prospectus and such description conforms in all material respects to the rights set forth in the instruments defining the same. No holder of Securities will be subject to personal liability solely by reason of being such a holder.
- (xv) Registration Rights. There are no persons with registration rights or other similar rights to have any securities registered for sale pursuant to the Registration Statement or otherwise registered for sale or sold by the Company under the 1933 Act pursuant to this Agreement, other than those rights that have been disclosed in the Registration Statement, the General Disclosure Package and the Prospectus and have been waived.
- (xvi) Absence of Violations, Defaults and Conflicts. Neither the Company nor any of its subsidiaries is (A) in violation of its charter, by-laws or similar organizational document, (B) in default in the performance or observance of any obligation, agreement, covenant or condition contained in any contract, indenture, mortgage, deed of trust, loan or credit agreement, note, lease or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which it or any of them may be bound or to which any of the properties or assets of the Company or any subsidiary is subject (collectively, "Agreements and Instruments"), except for such defaults that would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect, or (C) in violation of any law, statute, rule, regulation, judgment, order, writ or decree of any arbitrator, court, governmental body, regulatory body, administrative agency or other authority, body or agency having jurisdiction over the Company or any of its subsidiaries or any of their respective properties, assets or operations (each, a "Governmental Entity"), except for such violations that would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect. The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated herein and in the Registration Statement, the General Disclosure Package and the Prospectus (including the issuance and sale of the Securities

and the use of the proceeds from the sale of the Securities as described therein under the caption "Use of Proceeds") and compliance by the Company with its obligations hereunder have been duly authorized by all necessary corporate action and do not and will not, whether with or without the giving of notice or passage of time or both, conflict with or constitute a breach of, or default or Repayment Event (as defined below) under, or result in the creation or imposition of any lien, charge or encumbrance upon any properties or assets of the Company or any subsidiary pursuant to, the Agreements and Instruments (except for such conflicts, breaches, defaults or Repayment Events or liens, charges or encumbrances that would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect), nor will such action result in any violation of the provisions of (i) the charter, by-laws or similar organizational document of the Company or any of its subsidiaries or (ii) any law, statute, rule, regulation, judgment, order, writ or decree of any Governmental Entity, except in the case of clause (ii) for such violations that would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect and as would not materially and adversely affect the consummation of the transactions contemplated in this Agreement. As used herein, a "Repayment Event" means any event or condition which gives the holder of any note, debenture or other evidence of indebtedness (or any person acting on such holder's behalf) the right to require the repurchase, redemption or repayment of all or a portion of such indebtedness by the Company or any of its subsidiaries.

- (xvii) <u>Absence of Labor Dispute</u>. Except as would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect, (a) no labor dispute with the employees of the Company or any of its subsidiaries exists or, to the knowledge of the Company, is imminent, and (b) to the Company's knowledge, there is no existing or imminent labor disturbance by the employees of any of its or any subsidiary's principal suppliers, manufacturers or contractors.
- (xviii) Absence of Proceedings. Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, there is no action, suit, proceeding, inquiry or investigation before or brought by any Governmental Entity (including, without limitation, the U.S. Food and Drug Administration (the "FDA") and the European Medicines Agency (the "EMA")) now pending or, to the knowledge of the Company, threatened, against or affecting the Company or any of its subsidiaries, which would reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect, or which would reasonably be expected to, singly or in the aggregate, materially and adversely affect the consolidated properties or assets of the Company and its subsidiaries or the consummation of the transactions contemplated in this Agreement or the performance by the Company of its obligations hereunder; and the aggregate of all pending legal or governmental actions, suits, inquiries, investigations or proceedings to which the Company or any such subsidiary is a party or of which any of their respective properties or assets is the subject which are not described in the Registration Statement, the General Disclosure Package and the Prospectus, including ordinary routine litigation incidental to the business, would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect.
- (xix) Accuracy of Exhibits. There are no contracts or documents which are required under the 1933 Act Regulations to be described in the Registration Statement, the General Disclosure Package or the Prospectus or to be filed as exhibits to the Registration Statement which have not been so described and filed as required.
- (xx) <u>Absence of Further Requirements</u>. No filing with, or authorization, approval, consent, license, order, registration, qualification or decree of, any Governmental Entity is necessary or required for the performance by the Company of its obligations hereunder, in connection with the offering, issuance or sale of the Securities hereunder or the consummation of

the transactions contemplated by this Agreement, except (A) such as have been already obtained or as may be required under the 1933 Act, the 1933 Act Regulations, the rules of the Nasdaq Global Market, state securities laws or the rules of FINRA and (B) if not made or obtained would not, singly or in the aggregate, reasonably be expected to have a Material Adverse Effect or materially and adversely affect the consummation of the transactions contemplated in this Agreement.

(xxi) Possession of Licenses and Permits. The Company and its subsidiaries possess such permits, licenses, approvals, consents and other authorizations issued by the appropriate Governmental Entities necessary to conduct the business now operated by them (including, without limitation, all such permits, licenses, approvals, consents and other authorizations required by the FDA, the EMA, or any other federal, state, local or foreign agencies or bodies engaged in the regulation of clinical trials or activities related to the business now operated by the Company and its subsidiaries) (collectively, "Governmental Licenses"), except where the failure so to possess would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect. The Company and its subsidiaries are in compliance with the terms and conditions of all Governmental Licenses, except where the failure so to comply would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect. All of the Governmental Licenses are valid and in full force and effect, except where the invalidity of such Governmental Licenses or the failure of such Governmental Licenses to be in full force and effect would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect. Neither the Company nor any of its subsidiaries has received any notice of proceedings relating to the revocation or modification of any Governmental Licenses which, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would reasonably be expected to result in a Material Adverse Effect. The Company and its subsidiaries (i) are, and at all times have been, in compliance with all statutes, rules and regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, storage, import, export or disposal of any product manufactured or distributed by them ("Applicable Laws"), except where such noncompliance would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect; and (ii) have not received any FDA Form 483, written notice of adverse finding, warning letter, untitled letter or other correspondence or written notice from any court or arbitrator or governmental or regulatory authority alleging or asserting noncompliance with (x) any Applicable Laws or (y) any Governmental Licenses required by any such Applicable Laws, except where being in contravention of any of the foregoing representations or warranties, singly or in the aggregate, would not reasonably be expected to result in a Material Adverse Effect.

(xxii) <u>Title to Property.</u> The Company and its subsidiaries do not own any real property and have good title to all other properties owned by them, free and clear of all mortgages, pledges, liens, security interests, claims, restrictions or encumbrances of any kind except such as (A) are described in the Registration Statement, the General Disclosure Package and the Prospectus or (B) do not, singly or in the aggregate, materially adversely affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company or any of its subsidiaries. All of the leases and subleases material to the business of the Company and its subsidiaries, considered as one enterprise, and under which the Company or any of its subsidiaries holds properties described in the Registration Statement, the General Disclosure Package or the Prospectus, are in full force and effect, and neither the Company nor any such subsidiary has received any notice of any material claim of any sort that has been asserted by anyone adverse to the rights of the Company or any subsidiary under any of the leases or subleases mentioned above, or affecting or questioning the rights of the Company or such subsidiary to the continued possession of the leased or subleased premises

under any such lease or sublease, except to the extent any such failure to be in effect or such claim or adverse effect on the Company's rights would not reasonably be expected to result in a Material Adverse Effect.

(xxiii) <u>Possession of Intellectual Property</u>. The Company and its subsidiaries own or possess, have a valid license to, or can acquire on reasonable terms, adequate rights to all patents, patent applications, statutory invention rights, community designs, invention disclosures, rights in utility models and industrial designs, inventions, registered and unregistered copyrights (including copyrights in software), intellectual property rights in technology and software, data, know-how (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures), trademarks, service marks, business names, trade names, logos, slogans, trade dress, design rights, Internet domain names, social media accounts, any other designations of source or origin, and any applications (including provisional applications), registrations, or renewals for any of the foregoing, together with the goodwill associated with any of the foregoing, rights to publicity and privacy and/or other intellectual property (collectively, "Intellectual Property") necessary to carry on in all material respects the business now operated by them and as currently proposed to be operated as described in the Registration Statement, the General Disclosure Package and the Prospectus. In addition, (i) neither the Company nor any of its subsidiaries has received any notice of nor has it engaged in any infringement, misappropriation or other violation of or conflict regarding any Intellectual Property of any third party by the Company or its subsidiaries, (ii) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim regarding the subject matter of the foregoing and (iii) the Company and its subsidiaries are unaware of any facts or circumstances which would form a reasonable basis for any such claim, except in each case as would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect. Further, (a) all Intellectual Property owned by or exclusively licensed to the Company or any of its subsidiaries that is necessary to carry on the business now operated by them and as currently proposed to be operated as described in the Registration Statement, the General Disclosure Package and the Prospectus (such Intellectual Property, the "Company Intellectual Property") is valid, subsisting and enforceable, (b) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by any third party challenging the validity, ownership, registrability, enforceability or scope of any such Company Intellectual Property and (c) the Company and its subsidiaries are unaware of any facts or circumstances which would form a reasonable basis for any such claim. No third party is, to the Company's knowledge, infringing, misappropriating or otherwise violating any of the Company Intellectual Property in any material respect and there is no pending or threatened action, suit, proceeding or claim by the Company or any of its subsidiaries against a third party regarding the foregoing. In addition, (1) the Company and its subsidiaries have complied in all material respects with the terms of each agreement pursuant to which Intellectual Property has been licensed to the Company or its subsidiaries, (2) neither the Company nor any of its subsidiaries has received any written notice alleging any such noncompliance and are unaware of any facts or circumstances which would form a reasonable basis for any such claim, and (3) all such agreements are in full force and effect, except in each case as would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect. All Company Intellectual Property has been duly maintained and is in full force and effect and there are no material defects in, including in connection with the filing or prosecuting of, any of the Company Intellectual Property. Each person who is or was an employee or contractor of the Company or any of its subsidiaries and who is or was involved in the creation or development of any Intellectual Property for or on behalf of the Company has executed a valid agreement containing an enforceable assignment to the Company or any of its subsidiaries of such person's rights in and to such Intellectual Property. To the Company's knowledge, no employee of the Company or any of its subsidiaries is in or has

ever been in material violation of any term of any agreement with or covenant to a former employer where the basis of such violation relates to such employee's employment with the Company or any of its subsidiaries. The Company and its subsidiaries have taken all reasonable steps necessary to maintain and protect the confidentiality of the material trade secrets and other material confidential Intellectual Property necessary to carry on in all material respects the business now operated by them and as currently proposed to be operated as described in the Registration Statement, the General Disclosure Package and the Prospectus and, to the Company's knowledge, the confidentiality of such material trade secrets and material confidential Intellectual Property has not been compromised or disclosed to or accessed by any third party except pursuant to appropriate nondisclosure and confidentiality agreements. No university, military, educational institution, research center, Governmental Entity or other organization has funded, sponsored or contributed to research and development conducted in connection with the business of the Company or any of its subsidiaries that (i) has any claim of right to, ownership of or other lien on any Company Intellectual Property or (ii) would affect the proprietary nature of any Company Intellectual Property or restrict the ability of the Company or any of its subsidiaries to enforce, license or exclude others from using any Company Intellectual Property, except in each case as would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect.

(xxiv) Environmental Laws. Except as described in the Registration Statement, the General Disclosure Package and the Prospectus or as would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect, (A) neither the Company nor any of its subsidiaries is in violation of any federal, state, local or foreign statute, law, rule, regulation, ordinance, code, policy or rule of common law or any judicial or administrative interpretation thereof, including any judicial or administrative order, consent, decree or judgment, relating to pollution or protection of human health, the environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata) or wildlife, including, without limitation, laws and regulations relating to the release or threatened release of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum or petroleum products, asbestos-containing materials or mold (collectively, "Hazardous Materials") or to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials (collectively, "Environmental Laws"), (B) the Company and its subsidiaries have all permits, authorizations and approvals required under any applicable Environmental Laws and are each in compliance with their requirements, (C) there are no pending or, to the Company's knowledge, threatened administrative, regulatory or judicial actions, suits, demands, demand letters, claims, liens, notices of noncompliance or violation, investigations or proceedings relating to any Environmental Law against the Company or any of its subsidiaries and (D) to the Company's knowledge, there are no events or circumstances that would reasonably be expected to form the basis of an order for clean-up or remediation, or an action, suit or proceeding by any private party or Governmental Entity, against or affecting the Company or any of its subsidiaries relating to Hazardous Materials or

(xxv) Accounting Controls. The Company and each of its subsidiaries maintain effective internal control over financial reporting (as defined under Rules 13a-15 and 15d-15 under the 1934 Act Regulations (as defined below)) and a system of internal accounting controls sufficient to provide reasonable assurances that (A) transactions are executed in accordance with management's general or specific authorization; (B) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain accountability for assets; (C) access to assets is permitted only in accordance with management's general or specific authorization; and (D) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any

differences. Except as described in the Registration Statement, the General Disclosure Package and the Prospectus, since the end of the Company's most recent audited fiscal year, there has been (1) no material weakness in the Company's internal control over financial reporting (whether or not remediated) and (2) no change in the Company's internal control over financial reporting that has materially adversely affected, or is reasonably likely to materially adversely affect, the Company's internal control over financial reporting.

- (xxvi) <u>Compliance with the Sarbanes-Oxley Act</u>. The Company has taken all necessary actions to ensure that, upon the effectiveness of the Registration Statement, it will be in compliance in all material respects with all provisions of the Sarbanes-Oxley Act of 2002 and all rules and regulations promulgated thereunder or implementing the provisions thereof (the "Sarbanes-Oxley Act") that are then in effect and with which the Company is required to comply as of the effectiveness of the Registration Statement, and is taking reasonable steps to enable it to be in compliance with other provisions of the Sarbanes-Oxley Act not currently in effect, upon the effectiveness of such provisions, or which will become applicable to the Company at all times after the effectiveness of the Registration Statement.
- (xxvii) Payment of Taxes. All United States federal, state, local and non-U.S. income tax returns of the Company and its subsidiaries required by law to be filed have been filed and all taxes shown by such returns or otherwise assessed, which are due and payable, have been paid, except assessments, if any, as are being contested in good faith and as to which adequate reserves have been provided in accordance with GAAP by the Company. Through the fiscal year ended December 31, 2019, no assessment in connection with United States federal, state, local and non-U.S. income tax returns of the Company and its subsidiaries has been made against the Company or its subsidiaries, as applicable. The Company and its subsidiaries have filed all other tax returns that are required to have been filed by them pursuant to applicable foreign, state, local or other law except insofar as the failure to file such returns would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect, and has paid all taxes due pursuant to such returns or pursuant to any assessment received by the Company and its subsidiaries, except for such taxes, if any, as are being contested in good faith and as to which adequate reserves have been established by the Company. The charges, accruals and reserves on the books of the Company in respect of any income and corporation tax liability for any years for which the applicable statute of limitations has not yet expired are adequate to meet any assessments or re-assessments for additional income tax for any such years, except to the extent of any inadequacy that would not, singly or in the aggregate, result in a Material Adverse Effect.
- (xxviii) <u>Insurance</u>. The Company and its subsidiaries carry or are entitled to the benefits of insurance, with financially sound and reputable insurers, in such amounts and covering such risks as is generally maintained by similarly-situated companies of established repute engaged in the same or similar business, and all such insurance is in full force and effect. The Company has no reason to believe that it or any of its subsidiaries will not be able (A) to renew its existing insurance coverage as and when such policies expire or (B) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect. Neither the Company nor any of its subsidiaries has been denied any insurance coverage which it has sought or for which it has applied.
- (xxix) <u>Investment Company Act</u>. The Company is not required, and upon the issuance and sale of the Securities as herein contemplated and the application of the net proceeds therefrom as described in the Registration Statement, the General Disclosure Package and the Prospectus will not be required, to register as an "investment company" under the Investment Company Act of 1940, as amended (the "1940 Act").

- (xxx) Absence of Manipulation. None of the Company or any controlled affiliate, or to the knowledge of the Company, any non-controlled affiliate, has taken, nor will the Company or any controlled affiliate, or to the knowledge of the Company, any non-controlled affiliate, take, directly or indirectly, any action which is designed, or would reasonably be expected, to cause or result in, or which constitutes, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities or to result in a violation of Regulation M under the Securities Exchange Act of 1934, as amended (the "1934 Act").
- (xxxi) Foreign Corrupt Practices Act. None of the Company, any of its subsidiaries or, to the knowledge of the Company, any director, officer, agent, employee, affiliate or other person acting on behalf of the Company or any of its subsidiaries is aware of or has taken any action, directly or indirectly, that would result in a violation by such persons of the Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (the "FCPA"), including, without limitation, making use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay or authorization of the payment of any money, or other property, gift, promise to give, or authorization of the giving of anything of value to any "foreign official" (as such term is defined in the FCPA) or any foreign political party or official thereof or any candidate for foreign political office, in contravention of the FCPA, and the Company and, to the knowledge of the Company, its affiliates have conducted their businesses in compliance with the FCPA and have instituted and maintain policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith.
- (xxxii) Money Laundering Laws. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all applicable jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any Governmental Entity (collectively, the "Money Laundering Laws"); and no action, suit or proceeding by or before any Governmental Entity involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.
- (xxxiii) OFAC. None of the Company, any of its subsidiaries or, to the knowledge of the Company, any director, officer, agent, employee, controlled affiliate or representative of the Company or any of its subsidiaries is a Person currently the subject or target of any sanctions administered or enforced by the United States Government, including, without limitation, the U.S. Department of the Treasury's Office of Foreign Assets Control, the United Nations Security Council, the European Union, Her Majesty's Treasury, or other relevant sanctions authority (collectively, "Sanctions"), nor is the Company located, organized or resident in a country or territory that is the subject of Sanctions; and the Company will not directly or indirectly use the proceeds of the sale of the Securities, or lend, contribute or otherwise make available such proceeds to any subsidiaries, joint venture partners or other Person, to fund any activities of or business with any Person, or in any country or territory, that, at the time of such funding, is the subject of Sanctions or in any other manner that will result in a violation by any Person (including any Person participating in the transaction, whether as underwriter, advisor, investor or otherwise) of Sanctions.

(xxxiv) <u>Lending Relationship</u>. Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, the Company (i) does not have any material lending or other relationship with any banking or lending affiliate of any Underwriter and (ii) does not intend to use any of the proceeds from the sale of the Securities to repay any outstanding debt owed to any affiliate of any Underwriter.

(xxxv) Statistical and Market-Related Data. Any statistical and market-related data included in the Registration Statement, the General Disclosure Package or the Prospectus are based on or derived from sources that the Company believes, after reasonable inquiry, to be reliable and accurate in all material respects and, to the extent required, the Company has obtained the written consent to the use of such data from such sources.

(xxxvi) Cybersecurity and Data Protection. Except as would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect, (A) there has been no security breach or incident, unauthorized access or disclosure, or other compromise of or relating to the Company's or its subsidiaries' information technology and computer systems, networks, hardware, software, data and databases (including the data and information of their respective customers, employees, suppliers, vendors and any third party data maintained, processed or stored by the Company or its subsidiaries, and any such data processed or stored by third parties on behalf of the Company or its subsidiaries), equipment or technology (collectively, "IT Systems and Data"); (B) neither the Company nor its subsidiaries have been notified of, nor have any knowledge of any event or condition that would result in, any security breach or incident, unauthorized access or disclosure of or other compromise to their IT Systems and Data; (C) the Company and its subsidiaries have implemented appropriate controls, policies, procedures, and technological safeguards to maintain and protect the integrity, continuous operation, redundancy and security of their IT Systems and Data reasonably consistent with industry standards and practices, or as required by applicable regulatory standards; (D) the IT Systems and Data are adequate and operational for, in accordance with their documentation and functional specifications, the business of the Company and its subsidiaries as now operated by them and as currently proposed to be operated as described in the Registration Statement, the General Disclosure Package and the Prospectus; and (E) the Company and its subsidiaries are in compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of the IT Systems and Data, including the collection, use, transfer, processing, disposal, disclosure, handling, storage and analysis of personally identifiable information, protected health information, consumer information and other confidential information of the Company, its subsidiaries and any third parties in their possession ("Sensitive Company Data"), and to the protection of such IT Systems and Data and Sensitive Company Data from unauthorized use, access, misappropriation or modification. The Company and its subsidiaries have taken all reasonable steps necessary to maintain the confidentiality of the Sensitive Company Data. The Company and its subsidiaries have not received any written notice, claim, complaint, demand or letter from any person or Governmental Entity in respect of their businesses under applicable data security and data protection laws and regulations and industry standards regarding misuse, loss, unauthorized destruction or unauthorized disclosure of any Sensitive Company Data. To the Company's knowledge, there has been no unauthorized or illegal use of or access to any Sensitive Company Data by any third party. The Company and its subsidiaries have not been required to notify any individual, Governmental Entity or data protection authority of any information security breach, compromise or incident involving Sensitive Company Data and, to the Company's knowledge, are not the subject of any inquiry or investigation by any Governmental Entity or data protection authority regarding any of the foregoing.

(xxxvii) <u>No Rated Securities</u>. Neither the Company nor its subsidiaries have any debt securities or preferred stock that are rated by any "nationally recognized statistical rating organization" (as defined in Section 3(a)(62) of the 1934 Act).

(xxxviii) ERISA Compliance. The Company and its subsidiaries and any "Employee Benefit Plan" (as defined under the Employee Retirement Income Security Act of 1974, as amended, and the regulations and published interpretations promulgated thereunder (collectively, "ERISA")) for which the Company, its subsidiaries or its or their "ERISA Affiliates" (as defined below) would have any liability (each, a "Plan") are in compliance in all material respects with ERISA and each Plan has been maintained in compliance with its terms and the requirements of any applicable statutes, orders, rules and regulations, including but not limited to, ERISA and the Internal Revenue Code of 1986, as amended, and the regulations and published interpretations thereunder (the "Code"). "ERISA Affiliate" means, with respect to the Company, any member of any group of organizations described in Sections 414(b), (c), (m) or (o) of the Code of which the Company or such subsidiary is a member. No "reportable event" (as defined under ERISA) has occurred or is reasonably expected to occur with respect to any Plan, No Plan, if such Plan were terminated, would have any "amount of unfunded benefit liabilities" (as defined under ERISA), as the fair market value of the assets under each Plan (excluding for these purposes accrued but unpaid contributions) exceeds the present value of all benefits accrued under such Plan (determined based on those assumptions used to fund such Plan). Neither the Company, its subsidiaries nor any of its or their ERISA Affiliates has incurred or reasonably expects to incur any obligation or liability under (i) Title IV of ERISA with respect to termination of, or withdrawal from, any Plan, (ii) Sections 412 and 430, 4971 or 4975 of the Code or (iii) Sections 302 and 303, 406, 4063 and 4064 of ERISA. Each Plan that is intended to be qualified under Section 401(a) of the Code is so qualified and nothing has occurred, whether by action or failure to act, which would cause the loss of such qualification. There is no pending audit or investigation by the Internal Revenue Service, the U.S. Department of Labor, the Pension Benefit Guaranty Corporation or any other governmental or foreign regulatory entity or agency with respect to any Plan that would reasonably be expected to result in liability to the Company or any of its subsidiaries. Neither the Company nor any of its subsidiaries have any "accumulated post-retirement benefit obligations" (within the meaning of Statement of Financial Accounting Standards 106).

(xxxix) Regulatory Matters. Except as would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect: (i) neither the Company nor its Subsidiaries has received any written notice of adverse finding, warning letter, untitled letter or other correspondence or notice from the FDA, the EMA or other relevant regulatory authorities, or any other court or arbitrator or federal, state, local or foreign governmental or regulatory authority, alleging or asserting material noncompliance with the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 et seq.), as amended, and the regulations promulgated thereunder (the "FFDCA"), or similar state, federal or foreign law or regulation (collectively, "Health Care Laws"); (ii) the Company and its Subsidiaries are and have been in compliance in all material respects with applicable Health Care Laws; (iii) neither the Company nor its Subsidiaries received written notice of any ongoing claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any U.S. or non-U.S. federal, national, state, local or other governmental or regulatory authority, governmental or regulatory agency or body, court, arbitrator or self-regulatory organization (each, a "Governmental Authority") or third party alleging that any product operation or activity is in violation of any Health Care Laws; (iv) the Company and its Subsidiaries have filed, obtained, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by applicable Health Care Laws, and all such reports, documents, forms,

notices, applications, records, claims, submissions and supplements or amendments were complete, correct and not misleading on the date filed (or were corrected or supplemented by a subsequent submission); (v) neither the Company nor its Subsidiaries or any of their respective directors, officers, employees or agents is or has been debarred, suspended or excluded, or has been convicted of any crime or engaged in any conduct that would result in a debarment, suspension or exclusion from any federal or state government health care program; and (vi) the Company is not a party to and the Company does not have any ongoing reporting obligations pursuant to, any corporate integrity agreements, deferred prosecution agreements, monitoring agreements, consent decrees, settlement orders, plans of correction or similar agreements with or imposed by an Governmental Authority.

- (xl) <u>Preclinical Studies and Tests</u>. The preclinical studies and tests conducted by or, to the knowledge of the Company, after due inquiry, on behalf of or sponsored by the Company or its Subsidiaries or in which the Company or its Subsidiaries has participated that are described in, or the results of which are referred to in, the Registration Statement, the General Disclosure Package and the Prospectus, as applicable, were, and if still pending are, being conducted in accordance with the experimental protocols established for each study or trial, as well as any conditions of approval and policies imposed by any institutional review board, ethics review board or committee responsible for the oversight of such preclinical studies and tests, and all applicable local, state and federal laws, rules and regulations of the FDA, the EMA and comparable drug regulatory agencies outside of the United States to which they are subject (collectively, the "Regulatory Authorities"), except in each case where the failure to be so in compliance has not resulted and would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect; the descriptions in the Registration Statement, the General Disclosure Package or the Prospectus of the results of such studies and tests are accurate and not misleading in all material respects with respect to the portions of such studies being described and fairly present the data derived from such studies or tests in all material respects; the Company has no knowledge of any other studies or tests not described in the Registration Statement, the General Disclosure Package and the Prospectus, the results of which are materially inconsistent with or reasonably call into question the results described or referred to in the Registration Statement, the General Disclosure Package and the Prospectus when viewed in the context in which such results are described and the current state of development; neither the Company nor its Subsidiaries have received any written notice, correspondence or other communications from the Regulatory Authorities requiring or threatening (i) the termination or suspension of any preclinical studies or tests that are described in, or the results of which are referred to in, the Registration Statement, the General Disclosure Package and the Prospectus, or (ii) the material modification of any preclinical studies or tests that would cause them to differ from their descriptions in the Registration Statement, the General Disclosure Package and the Prospectus, other than ordinary course communications with respect to modifications in connection with the design and implementation of such studies or tests, and, to the Company's knowledge, there are no reasonable grounds for the same. The Company is taking all reasonable steps necessary to ensure that its clinical trials will be conducted in accordance with any conditions of approval and policies imposed by Regulatory Authorities for such clinical trials.
- (xli) No Safety Notices. (i) There have been no recalls, field notifications, field corrections, market withdrawals or replacements, warnings, "dear doctor" letters, investigator notices, safety alerts or other notice of action relating to an alleged lack of safety, efficacy, or regulatory compliance of the Company's or its subsidiaries' product candidates ("Safety Notices"), except as would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect, and (ii) there are no facts that would be reasonably likely to result in (x) a Safety Notice with respect to the Company's or its subsidiaries' product candidates, or (y) a

termination or suspension of testing of any of the Company's or its subsidiaries' product candidates, except, in each of cases (x) or (y) such as would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect.

(b) *Officer's Certificates*. Any certificate signed by any officer of the Company or any of its subsidiaries delivered to the Representatives or to counsel for the Underwriters shall be deemed a representation and warranty by the Company to each Underwriter as to the matters covered thereby.

### SECTION 2. Sale and Delivery to Underwriters; Closing.

- (a) *Initial Securities*. On the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, the Company agrees to sell to each Underwriter, severally and not jointly, and each Underwriter, severally and not jointly, agrees to purchase from the Company, at the price per share set forth in Schedule A, that number of Initial Securities set forth in Schedule A opposite the name of such Underwriter, plus any additional number of Initial Securities which such Underwriter may become obligated to purchase pursuant to the provisions of Section 10 hereof, subject, in each case, to such adjustments among the Underwriters as BofAS in its sole discretion shall make to eliminate any sales or purchases of fractional shares.
- (b) Option Securities. In addition, on the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, the Company hereby grants an option to the Underwriters, severally and not jointly, to purchase up to an additional [●] shares of Common Stock, at the price per share set forth in Schedule A, less an amount per share equal to any dividends or distributions declared by the Company and payable on the Initial Securities but not payable on the Option Securities. The option hereby granted may be exercised for 30 days after the date hereof and may be exercised in whole or in part at any time and from time to time upon notice by the Representatives to the Company setting forth the number of Option Securities as to which the several Underwriters are then exercising the option and the time and date of payment and delivery for such Option Securities. Any such time and date of delivery (a "Date of Delivery") shall be determined by the Representatives, but shall not be earlier than one full business day after the exercise of said option (without the consent of the Company), nor later than seven full business days after the exercise of said option, nor in any event prior to the Closing Time. If the option is exercised as to all or any portion of the Option Securities, each of the Underwriters, acting severally and not jointly, will purchase that proportion of the total number of Option Securities then being purchased which the number of Initial Securities set forth in Schedule A opposite the name of such Underwriter bears to the total number of Initial Securities, subject, in each case, to such adjustments as BofAS in its sole discretion shall make to eliminate any sales or purchases of fractional shares.
- (c) Payment. Payment of the purchase price for, and delivery of certificates or security entitlements for, the Initial Securities shall be made at the offices of Shearman & Sterling LLP, 599 Lexington Avenue, New York, New York 10022, or at such other place as shall be agreed upon by the Representatives and the Company, at 9:00 A.M. (New York City time) on the second (third, if the pricing occurs after 4:30 P.M. (New York City time) on any given day) business day after the date hereof (unless postponed in accordance with the provisions of Section 10), or such other time not later than ten business days after such date as shall be agreed upon by the Representatives and the Company (such time and date of payment and delivery being herein called the "Closing Time").

In addition, in the event that any or all of the Option Securities are purchased by the Underwriters, payment of the purchase price for, and delivery of certificates or security entitlements for, such Option Securities shall be made at the above-mentioned offices, or at such other place as shall be agreed upon by the Representatives and the Company, on each Date of Delivery as specified in the notice from the Representatives to the Company.

Payment shall be made to the Company by wire transfer of immediately available funds to a bank account designated by the Company against delivery to the Representatives for the respective accounts of the Underwriters of certificates or security entitlements for the Securities to be purchased by them. It is understood that each Underwriter has authorized the Representatives, for its account, to accept delivery of, receipt for, and make payment of the purchase price for, the Initial Securities and the Option Securities, if any, which it has agreed to purchase. BofAS, individually and not as representative of the Underwriters, may (but shall not be obligated to) make payment of the purchase price for the Initial Securities or the Option Securities, if any, to be purchased by any Underwriter whose funds have not been received by the Closing Time or the relevant Date of Delivery, as the case may be, but such payment shall not relieve such Underwriter from its obligations hereunder.

## SECTION 3. Covenants of the Company. The Company covenants with each Underwriter as follows:

- (a) Compliance with Securities Regulations and Commission Requests. The Company, subject to Section 3(b), will comply with the requirements of Rule 430A, and will promptly notify the Representatives, and confirm the notice in writing, (i) when any post-effective amendment to the Registration Statement shall become effective or any amendment or supplement to the Prospectus shall have been filed, (ii) of the receipt of any comments from the Commission, (iii) of any request by the Commission for any amendment to the Registration Statement or any amendment or supplement to the Prospectus or for additional information, (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment or of any order preventing or suspending the use of any preliminary prospectus or the Prospectus, or of the suspension of the qualification of the Securities for offering or sale in any jurisdiction, or of the initiation or threatening of any proceedings for any of such purposes or of any examination pursuant to Section 8(d) or 8(e) of the 1933 Act concerning the Registration Statement and (v) if the Company becomes the subject of a proceeding under Section 8A of the 1933 Act in connection with the offering of the Securities. The Company will effect all filings required under Rule 424(b), in the manner and within the time period required by Rule 424(b) (without reliance on Rule 424(b)(8)), and will take such steps as it deems necessary to ascertain promptly whether the form of prospectus transmitted for filing under Rule 424(b) was received for filing by the Commission and, in the event that it was not, it will promptly file such prospectus. The Company will use reasonable best efforts to prevent the issuance of any stop order, prevention or suspension and, if any such order is issued, to obtain the lifting thereof as soon as practicable.
- (b) Continued Compliance with Securities Laws. The Company will comply with the 1933 Act and the 1933 Act Regulations so as to permit the completion of the distribution of the Securities as contemplated in this Agreement and in the Registration Statement, the General Disclosure Package and the Prospectus. If at any time when a prospectus relating to the Securities is (or, but for the exception afforded by Rule 172 of the 1933 Act Regulations ("Rule 172"), would be) required by the 1933 Act to be delivered in connection with sales of the Securities, any event shall occur or condition shall exist as a result of which it is necessary, in the opinion of counsel for the Underwriters or for the Company, to (i) amend the Registration Statement in order that the Registration Statement will not include an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, (ii) amend or supplement the General Disclosure Package or the Prospectus in order that the General Disclosure Package or the Prospectus, as the case may be, will not include any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein not misleading in the light of the circumstances existing at the time it is

delivered to a purchaser or (iii) amend the Registration Statement or amend or supplement the General Disclosure Package or the Prospectus, as the case may be, in order to comply with the requirements of the 1933 Act or the 1933 Act Regulations, the Company will promptly (A) give the Representatives notice of such event, (B) prepare any amendment or supplement as may be necessary to correct such statement or omission or to make the Registration Statement, the General Disclosure Package or the Prospectus comply with such requirements and, a reasonable amount of time prior to any proposed filing or use, furnish the Representatives with copies of any such amendment or supplement and (C) file with the Commission any such amendment or supplement; provided that the Company shall not file or use any such amendment or supplement to which the Representatives or counsel for the Underwriters shall reasonably object. The Company will furnish to the Underwriters such number of copies of such amendment or supplement as the Underwriters may reasonably request. The Company has given the Representatives notice of any filings made pursuant to the 1934 Act or the rules and regulations of the Commission under the 1934 Act (the "1934 Act Regulations") within 48 hours prior to the Applicable Time; the Company will give the Representatives notice of its intention to make any such filing from the Applicable Time to the Closing Time and will furnish the Representatives with copies of any such documents a reasonable amount of time prior to such proposed filing, as the case may be, and will not file or use any such document to which the Representatives or counsel for the Underwriters shall reasonably object.

- (c) *Delivery of Registration Statements*. The Company has furnished or will deliver to the Representatives and counsel for the Underwriters, without charge, signed copies of the Registration Statement as originally filed and each amendment thereto (including exhibits filed therewith) and signed copies of all consents and certificates of experts, and will also deliver to the Representatives, without charge, a conformed copy of the Registration Statement as originally filed and each amendment thereto (without exhibits) for each of the Underwriters. The copies of the Registration Statement and each amendment thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.
- (d) *Delivery of Prospectuses*. The Company has delivered to each Underwriter, without charge, as many copies of each preliminary prospectus as such Underwriter reasonably requested, and the Company hereby consents to the use of such copies for purposes permitted by the 1933 Act. The Company will furnish to each Underwriter, without charge, during the period when a prospectus relating to the Securities is (or, but for the exception afforded by Rule 172, would be) required to be delivered under the 1933 Act, such number of copies of the Prospectus (as amended or supplemented) as such Underwriter may reasonably request. The Prospectus and any amendments or supplements thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.
- (e) Blue Sky Qualifications. The Company will use its reasonable best efforts, in cooperation with the Underwriters, to qualify the Securities for offering and sale under the applicable securities laws of such states and other jurisdictions (domestic or foreign) as the Representatives may reasonably designate and to maintain such qualifications in effect so long as required to complete the distribution of the Securities; provided, however, that the Company shall not be obligated to file any general consent to service of process or to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified or to subject itself to taxation in respect of doing business in any jurisdiction in which it is not otherwise so subject.
- (f) *Rule 158*. The Company will timely file such reports pursuant to the 1934 Act as are necessary in order to make generally available to its securityholders as soon as reasonably practicable an earnings statement for the purposes of, and to provide to the Underwriters the benefits contemplated by, the last paragraph of Section 11(a) of the 1933 Act.

- (g) *Use of Proceeds*. The Company will use the net proceeds received by it from the sale of the Securities in the manner specified in the Registration Statement, the General Disclosure Package and the Prospectus under "Use of Proceeds."
- (h) *Listing*. The Company will use its reasonable best efforts to effect and maintain the listing of the Common Stock (including the Securities) on the Nasdaq Global Market.
- (i) Restriction on Sale of Securities. During a period of 180 days from the date of the Prospectus, the Company will not, without the prior written consent of BofAS, Cowen and Piper Sandler, (i) directly or indirectly, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock or file or confidentially submit any registration statement under the 1933 Act with respect to any of the foregoing, (ii) enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the Common Stock, whether any such swap or transaction described in clause (i) or (ii) above is to be settled by delivery of Common Stock or other securities, in cash or otherwise or (iii) publicly disclose the intention to do any of the foregoing described in clauses (i) and (ii). The foregoing sentence shall not apply to (A) the Securities to be sold hereunder, (B) any shares of Common Stock issued by the Company upon the exercise of an option or warrant or the conversion of a security outstanding on the date hereof and referred to in the Registration Statement, the General Disclosure Package and the Prospectus, (C) any shares of Common Stock issued or options to purchase Common Stock or other equity awards covering Common Stock granted, in either case, pursuant to existing employee benefit or equity incentive plans of the Company referred to in the Registration Statement, the General Disclosure Package and the Prospectus, (D) any shares of Common Stock issued pursuant to any non-employee director stock plan or dividend reinvestment plan referred to in the Registration Statement, the General Disclosure Package and the Prospectus, (E) the filing by the Company of a registration statement with the Commission on Form S-8 or any successor form thereto in respect of any shares or other equity instruments issued pursuant to any plans or programs described in (C) or (D) above, or (F) the sale or issuance of or entry into an agreement to sell or issue shares of Common Stock or securities convertible into or exercisable or exchangeable for Common Stock in connection with any (1) merger, (2) acquisition of securities, businesses, property or other assets, (3) licensing of technologies, property or other assets, (4) joint ventures or (5) strategic alliances or relationships, collaborations, marketing or distribution arrangements or other transactions that include a commercial relationship; provided, that the aggregate number of shares of Common Stock or securities convertible into or exercisable for Common Stock (on an as-converted or as-exercised basis, as the case may be) that the Company may sell or issue or agree to sell or issue pursuant to this clause (F) shall not exceed 5.0% of the total number of shares of the Company's Common Stock issued and outstanding immediately following the completion of the transactions contemplated by this Agreement; and provided further, that each recipient of shares of Common Stock or securities convertible into or exercisable for Common Stock pursuant to this clause (F) during the 180-day restricted period described above shall execute a lock-up agreement substantially in the form of Exhibit A hereto.
- (j) *Press Releases*. If BofAS, Cowen and Piper Sandler, in their sole discretion, agree to release or waive the restrictions set forth in a lock-up agreement described in Section 5(i) hereof for an officer or director of the Company and provide the Company with notice of the impending release or waiver at least three business days before the effective date of the release or waiver, the Company agrees to announce the impending release or waiver by a press release substantially in the form of Exhibit B hereto through a major news service at least two business days before the effective date of the release or waiver.

- (k) *Reporting Requirements*. The Company, during the period when a Prospectus relating to the Securities is (or, but for the exception afforded by Rule 172, would be) required to be delivered under the 1933 Act, will file all documents required to be filed with the Commission pursuant to the 1934 Act within the time periods required by the 1934 Act and 1934 Act Regulations. Additionally, the Company shall report the use of proceeds from the issuance of the Securities as may be required under Rule 463 under the 1933 Act.
- (l) Issuer Free Writing Prospectuses. The Company agrees that, unless it obtains the prior written consent of the Representatives, it will not make any offer relating to the Securities that would constitute an Issuer Free Writing Prospectus or that would otherwise constitute a "free writing prospectus," or a portion thereof, required to be filed by the Company with the Commission or retained by the Company under Rule 433; provided that the Representatives will be deemed to have consented to the Issuer Free Writing Prospectuses listed on Schedule B-2 hereto and any "road show that is a written communication" within the meaning of Rule 433(d)(8)(i) that has been reviewed by the Representatives. The Company represents that it has treated or agrees that it will treat each such free writing prospectus consented to, or deemed consented to, by the Representatives as an "issuer free writing prospectus," as defined in Rule 433, and that it has complied and will comply with the applicable requirements of Rule 433 with respect thereto, including timely filing with the Commission where required, legending and record keeping. If at any time following issuance of an Issuer Free Writing Prospectus there occurred or occurs an event or development as a result of which such Issuer Free Writing Prospectus conflicted or would conflict with the information contained in the Registration Statement which has not been superseded or modified, any preliminary prospectus or the Prospectus or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representatives and will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement or omission.
- (m) *Certification Regarding Beneficial Owners*. The Company will deliver to the Representatives, on the date of execution of this Agreement, a properly completed and executed Certification Regarding Beneficial Owners of Legal Entity Customers, together with copies of identifying documentation, and the Company undertakes to provide such additional supporting documentation as the Representatives may reasonably request in connection with the verification of the foregoing certification.
- (n) <u>Testing-the-Waters Materials</u>. If at any time following the distribution of any Written Testing-the-Waters Communication there occurred or occurs an event or development as a result of which such Written Testing-the-Waters Communication included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representatives and will promptly amend or supplement, at its own expense, such Written Testing-the-Waters Communication to eliminate or correct such untrue statement or omission.
- (o) <u>Emerging Growth Company Status</u>. The Company will promptly notify the Representatives if the Company ceases to be an Emerging Growth Company at any time prior to the later of (i) completion of the distribution of the Securities within the meaning of the 1933 Act and (ii) completion of the 180-day restricted period referred to in Section 3(i).

### SECTION 4. Payment of Expenses.

- (a) Expenses. The Company will pay or cause to be paid all expenses incident to the performance of its obligations under this Agreement, including (i) the preparation, printing and filing of the Registration Statement (including financial statements and exhibits) as originally filed and each amendment thereto, (ii) the preparation, printing and delivery to the Underwriters of copies of each preliminary prospectus, each Issuer Free Writing Prospectus and the Prospectus and any amendments or supplements thereto and any costs associated with electronic delivery of any of the foregoing by the Underwriters to investors, (iii) the preparation, issuance and delivery of the certificates or security entitlements for the Securities to the Underwriters, including any stock or other transfer taxes and any stamp or other duties payable upon the sale, issuance or delivery of the Securities to the Underwriters, (iv) the fees and disbursements of the Company's counsel, accountants and other advisors, (v) subject to the limitation set forth in clause (viii), the qualification of the Securities under securities laws in accordance with the provisions of Section 3(e) hereof, including filing fees and the reasonable and documented fees and disbursements of counsel for the Underwriters in connection therewith and in connection with the preparation of the Blue Sky Survey and any supplement thereto, (vi) the fees and expenses of any transfer agent or registrar for the Securities, (vii) the costs and expenses of the Company relating to investor presentations on any "road show" undertaken in connection with the marketing of the Securities, including, without limitation, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged by the Company in connection with the road show presentations, travel and lodging expenses of the representatives and officers of the Company and any such consultants (provided that the travel, lodging and any car travel expenses of the representatives of the Underwriters shall be paid by the Underwriters), and 50% of the cost of aircraft and other transportation chartered in connection with the road show, (viii) the filing fees incident to, and the reasonable and documented fees and disbursements of counsel to the Underwriters in connection with, the review by FINRA of the terms of the sale of the Securities, with such legal fees, taken together with the legal fees described in clause (v) above, not to exceed \$50,000, (ix) the fees and expenses incurred in connection with the listing of the Securities on the Nasdaq Global Market, and (x) the costs and expenses (including, without limitation, any damages or other amounts payable in connection with legal or contractual liability) associated with the reforming of any contracts for sale of the Securities made by the Underwriters caused by a breach of the representation contained in the third sentence of Section 1(a)(ii).
- (b) *Termination of Agreement*. If this Agreement is terminated by the Representatives in accordance with the provisions of Section 5, Section 9(a)(i) or (iii), or Section 10 hereof, the Company shall reimburse the non-defaulting Underwriters for all of their reasonable and documented out-of-pocket expenses, including the reasonable and documented fees and disbursements of counsel for the Underwriters.
- SECTION 5. <u>Conditions of Underwriters' Obligations</u>. The obligations of the several Underwriters hereunder are subject to the accuracy of the representations and warranties of the Company contained herein or in certificates of any officer of the Company or any of its subsidiaries delivered pursuant to the provisions hereof, to the performance by the Company of its covenants and other obligations hereunder, and to the following further conditions:
- (a) *Effectiveness of Registration Statement; Rule 430A Information.* The Registration Statement, including any Rule 462(b) Registration Statement, has become effective and, at the Closing Time, no stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto has been issued under the 1933 Act, no order preventing or suspending the use of any preliminary prospectus or the Prospectus has been issued and no proceedings for any of those purposes have been instituted or are pending or, to the Company's knowledge, contemplated by the Commission; and the Company has complied with each request (if any) from the Commission for additional

information. A prospectus containing the Rule 430A Information shall have been filed with the Commission in the manner and within the time frame required by Rule 424(b) without reliance on Rule 424(b)(8) or a post-effective amendment providing such information shall have been filed with, and declared effective by, the Commission in accordance with the requirements of Rule 430A.

- (b) Opinion of Counsel for Company. At the Closing Time, the Representatives shall have received:
- (i) the opinion, dated the Closing Time, of Wilmer Cutler Pickering Hale and Dorr LLP, counsel for the Company, including the negative assurance reflected therein, in form and substance reasonably satisfactory to counsel for the Underwriters, together with signed or reproduced copies of such letter for each of the other Underwriters; and
- (ii) the opinion, dated the Closing Time, of Nutter McClennen & Fish LLP, intellectual property counsel for the Company, in form and substance reasonably satisfactory to counsel for the Underwriters, together with signed or reproduced copies of such letter for each of the other Underwriters.
- (c) *Opinion of Counsel for Underwriters*. At the Closing Time, the Representatives shall have received the opinion and negative assurance letter, dated the Closing Time, of Shearman & Sterling LLP, counsel for the Underwriters, together with signed or reproduced copies of such letter for each of the other Underwriters, in form and substance reasonably satisfactory to the Underwriters.
- (d) Officers' Certificate. At the Closing Time, there shall not have been, since the date hereof or since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package or the Prospectus, any material adverse change in the condition, financial or otherwise, or in the earnings, business affairs or business prospects of the Company and its subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business, and the Representatives shall have received a certificate of the Chief Executive Officer or the President of the Company and of the principal financial or principal accounting officer of the Company, dated the Closing Time, to the effect that (i) there has been no such material adverse change, (ii) the representations and warranties of the Company in this Agreement are true and correct with the same force and effect as though expressly made at and as of the Closing Time, (iii) the Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied at or prior to the Closing Time, and (iv) no stop order suspending the effectiveness of the Registration Statement under the 1933 Act has been issued, no order preventing or suspending the use of any preliminary prospectus or the Prospectus has been issued and no proceedings for any of those purposes have been instituted or are pending or, to their knowledge, contemplated by the Commission.
- (e) Accountant's Comfort Letter. At the time of the execution of this Agreement, the Representatives shall have received from Ernst & Young LLP a letter, dated such date, in form and substance satisfactory to the Representatives, together with signed or reproduced copies of such letter for each of the other Underwriters containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement, the General Disclosure Package and the Prospectus.
- (f) *Bring-down Comfort Letter*. At the Closing Time, the Representatives shall have received from Ernst & Young LLP a letter, dated as of the Closing Time, to the effect that they reaffirm the statements made in the letter furnished pursuant to subsection (e) of this Section, except that the specified date referred to shall be a date not more than three business days prior to the Closing Time.

- (g) Approval of Listing. At the Closing Time, the Securities shall have been approved for listing on the Nasdaq Global Market, subject only to official notice of issuance.
- (h) *No Objection*. FINRA shall have confirmed that it has not raised any objection with respect to the fairness and reasonableness of the underwriting terms and arrangements relating to the offering of the Securities.
- (i) *Lock-up Agreements*. At the date of this Agreement, the Representatives shall have received an agreement substantially in the form of Exhibit A hereto signed by (i) each of the Company's directors and officers and (ii) each holder of shares of Common Stock or any security convertible into or exercisable for shares of Common Stock.
- (j) *Principal Financial Officer's Certificate*. On the date of this Agreement and at the Closing Time, as the case may be, the Representatives shall have received from the Company a certificate of its principal financial officer with respect to certain financial data contained in the General Disclosure Package and the Prospectus, which certificate shall be in form and substance reasonably satisfactory to counsel for the Underwriters.
- (k) Conditions to Purchase of Option Securities. In the event that the Underwriters exercise their option provided in Section 2(b) hereof to purchase all or any portion of the Option Securities, the representations and warranties of the Company contained herein and the statements in any certificates furnished by the Company and any of its subsidiaries hereunder shall be true and correct as of each Date of Delivery and, at the relevant Date of Delivery, the Representatives shall have received:
  - (i) Officers' Certificate. A certificate, dated such Date of Delivery, of the President or a Vice President of the Company and of the principal financial or principal accounting officer of the Company confirming that the certificate delivered at the Closing Time pursuant to Section 5(d) hereof remains true and correct as of such Date of Delivery.
  - (ii) <u>Opinion of Counsel for Company</u>. If requested by the Representatives, the opinion of Wilmer Cutler Pickering Hale and Dorr LLP, counsel for the Company, together with the opinion of Nutter McClennen & Fish LLP, intellectual property counsel for the Company, each in form and substance reasonably satisfactory to counsel for the Underwriters, dated such Date of Delivery, relating to the Option Securities to be purchased on such Date of Delivery and otherwise to the same effect as the respective opinion required by Section 5(b) hereof.
  - (iii) Opinion of Counsel for Underwriters. If requested by the Representatives, the opinion of Shearman & Sterling LLP, counsel for the Underwriters, dated such Date of Delivery, relating to the Option Securities to be purchased on such Date of Delivery and otherwise to the same effect as the opinion required by Section 5(e) hereof.
  - (iv) <u>Bring-down Comfort Letter</u>. If requested by the Representatives, a letter from Ernst & Young LLP, in form and substance satisfactory to the Representatives and dated such Date of Delivery, substantially in the same form and substance as the letter furnished to the Representatives pursuant to Section 5(e) hereof, except that the "specified date" in the letter furnished pursuant to this paragraph shall be a date not more than three business days prior to such Date of Delivery.
  - (v) <u>Principal Financial Officer's Certificate</u>. If requested by the Representatives, a certificate, dated such Date of Delivery, of the principal financial or chief accounting officer of the Company confirming that the certificate delivered at the Closing Time pursuant to Section 5(j) hereof remains true and correct as of such Date of Delivery.

- (l) Additional Documents. At the Closing Time and at each Date of Delivery (if any), counsel for the Underwriters shall have been furnished with such other documents and opinions as they may reasonably require for the purpose of enabling them to pass upon the issuance and sale of the Securities as herein contemplated, or in order to evidence the accuracy of any of the representations or warranties, or the fulfillment of any of the conditions, herein contained; and all proceedings taken by the Company in connection with the issuance and sale of the Securities as herein contemplated shall be reasonably satisfactory in form and substance to the Representatives and counsel for the Underwriters.
- (m) *Termination of Agreement*. If any condition specified in this Section shall not have been fulfilled when and as required to be fulfilled, this Agreement, or, in the case of any condition to the purchase of Option Securities on a Date of Delivery which is after the Closing Time, the obligations of the several Underwriters to purchase the relevant Option Securities, may be terminated by the Representatives by notice to the Company at any time at or prior to Closing Time or such Date of Delivery, as the case may be, and such termination shall be without liability of any party to any other party except as provided in Section 4 and except that Sections 1, 6, 7, 8, 14, 15, 16 and 17 shall survive any such termination and remain in full force and effect.

## SECTION 6. <u>Indemnification</u>.

- (a) *Indemnification of Underwriters*. The Company agrees to indemnify and hold harmless each Underwriter, its affiliates (as such term is defined in Rule 501(b) under the 1933 Act (each, an "Affiliate")), its selling agents and each person, if any, who controls any Underwriter within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act as follows:
  - (i) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, arising out of any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or any amendment thereto), including the Rule 430A Information, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading or arising out of any untrue statement or alleged untrue statement of a material fact included (A) in any preliminary prospectus, any Issuer Free Writing Prospectus, any Written Testing-the-Waters Communication, the General Disclosure Package or the Prospectus (or any amendment or supplement thereto), or (B) in any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the offering of the Securities ("Marketing Materials"), including any roadshow or investor presentations made to investors by the Company (whether in person or electronically), or the omission or alleged omission in any preliminary prospectus, Issuer Free Writing Prospectus, any Written Testing-the-Waters Communication, Prospectus or in any Marketing Materials of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading;
  - (ii) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, to the extent of the aggregate amount paid in settlement of any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or of any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission; provided that (subject to Section 6(d) below) any such settlement is effected with the written consent of the Company; and

(iii) against any and all expense whatsoever, as incurred (including the fees and disbursements of counsel chosen by the Representatives), reasonably incurred in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission, to the extent that any such expense is not paid under (i) or (ii) above;

provided, however, that this indemnity agreement shall not apply to any loss, liability, claim, damage or expense to the extent arising out of any untrue statement or omission or alleged untrue statement or omission made in the Registration Statement (or any amendment thereto), including the Rule 430A Information, the General Disclosure Package or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with the Underwriter Information.

- (b) *Indemnification of Company, Directors and Officers*. Each Underwriter, severally and not jointly, agrees to indemnify and hold harmless the Company, its directors, each of its officers who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act, against any and all loss, liability, claim, damage and expense described in the indemnity contained in subsection (a) of this Section, as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions, made in the Registration Statement (or any amendment thereto), including the Rule 430A Information, the General Disclosure Package or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with the Underwriter Information.
- (c) Actions against Parties; Notification. Each indemnified party shall give notice as promptly as reasonably practicable to each indemnifying party of any action commenced against it in respect of which indemnity may be sought hereunder, but failure to so notify an indemnifying party shall not relieve such indemnifying party from any liability hereunder to the extent it is not materially prejudiced as a result thereof and in any event shall not relieve it from any liability which it may have otherwise than on account of this indemnity agreement. In the case of parties indemnified pursuant to Section 6(a) above, counsel to the indemnified parties shall be selected by the Representatives, and, in the case of parties indemnified pursuant to Section 6(b) above, counsel to the indemnified parties shall be selected by the Company. An indemnifying party may participate at its own expense in the defense of any such action; provided, however, that counsel to the indemnifying party shall not (except with the consent of the indemnified party) also be counsel to the indemnified party. In no event shall the indemnifying parties be liable for fees and expenses of more than one counsel (in addition to any local counsel) separate from their own counsel for all indemnified parties in connection with any one action or separate but similar or related actions in the same jurisdiction arising out of the same general allegations or circumstances. No indemnifying party shall, without the prior written consent of the indemnified parties, settle or compromise or consent to the entry of any judgment with respect to any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever in respect of which indemnification or contribution could be sought under this Section 6 or Section 7 hereof (whether or not the indemnified parties are actual or potential parties thereto), unless such settlement, compromise or consent (i) includes an unconditional release of each indemnified party from all liability arising out of such litigation, investigation, proceeding or claim and (ii) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.
- (d) Settlement without Consent if Failure to Reimburse. If at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by this Section, such indemnifying party agrees that it shall be liable for any settlement of the nature contemplated by Section 6(a)(ii) effected without its written consent if (i) such

settlement is entered into more than 60 days after receipt by such indemnifying party of the aforesaid request, (ii) such indemnifying party shall have received notice of the terms of such settlement at least 30 days prior to such settlement being entered into and (iii) such indemnifying party shall not have reimbursed such indemnified party in accordance with such request prior to the date of such settlement.

SECTION 7. <u>Contribution</u>. If the indemnification provided for in Section 6 hereof is for any reason unavailable to or insufficient to hold harmless an indemnified party in respect of any losses, liabilities, claims, damages or expenses referred to therein, then each indemnifying party shall contribute to the aggregate amount of such losses, liabilities, claims, damages and expenses incurred by such indemnified party, as incurred, (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and the Underwriters, on the other hand, from the offering of the Securities pursuant to this Agreement or (ii) if the allocation provided by clause (i) is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and of the Underwriters, on the other hand, in connection with the statements or omissions which resulted in such losses, liabilities, claims, damages or expenses, as well as any other relevant equitable considerations.

The relative benefits received by the Company, on the one hand, and the Underwriters, on the other hand, in connection with the offering of the Securities pursuant to this Agreement shall be deemed to be in the same respective proportions as the total net proceeds from the offering of the Securities pursuant to this Agreement (before deducting expenses) received by the Company, on the one hand, and the total underwriting discount received by the Underwriters, on the other hand, in each case as set forth on the cover of the Prospectus, bear to the aggregate initial public offering price of the Securities as set forth on the cover of the Prospectus.

The relative fault of the Company, on the one hand, and the Underwriters, on the other hand, shall be determined by reference to, among other things, whether any such untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or by the Underwriters and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The Company and the Underwriters agree that it would not be just and equitable if contribution pursuant to this Section 7 were determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take account of the equitable considerations referred to above in this Section 7. The aggregate amount of losses, liabilities, claims, damages and expenses incurred by an indemnified party and referred to above in this Section 7 shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue or alleged untrue statement or omission or alleged omission.

Notwithstanding the provisions of this Section 7, no Underwriter shall be required to contribute any amount in excess of the underwriting commissions received by such Underwriter in connection with the Securities underwritten by it and distributed to the public.

No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the 1933 Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation.

For purposes of this Section 7, each person, if any, who controls an Underwriter within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act and each Underwriter's Affiliates and selling agents shall have the same rights to contribution as such Underwriter, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act shall have the same rights to contribution as the Company. The Underwriters' respective obligations to contribute pursuant to this Section 7 are several in proportion to the number of Initial Securities set forth opposite their respective names in Schedule A hereto and not joint.

SECTION 8. <u>Representations, Warranties and Agreements to Survive</u>. All representations, warranties and agreements contained in this Agreement or in certificates of officers of the Company or any of its subsidiaries submitted pursuant hereto, shall remain operative and in full force and effect regardless of (i) any investigation made by or on behalf of any Underwriter or its Affiliates or selling agents, any person controlling any Underwriter, its officers or directors or any person controlling the Company and (ii) delivery of and payment for the Securities.

# SECTION 9. <u>Termination of Agreement</u>.

- (a) *Termination*. The Representatives may terminate this Agreement, by written notice to the Company, at any time at or prior to the Closing Time (i) if there has been, in the judgment of the Representatives, since the time of execution of this Agreement or since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package or the Prospectus, any material adverse change in the condition, financial or otherwise, or in the earnings, business affairs or business prospects of the Company and its subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business or (ii) if there has occurred any material adverse change in the financial markets in the United States or the international financial markets, any outbreak of hostilities or escalation thereof or other calamity or crisis or any change or development involving a prospective change in national or international political, financial or economic conditions, in each case the effect of which is such as to make it, in the judgment of the Representatives, impracticable or inadvisable to proceed with the completion of the offering or to enforce contracts for the sale of the Securities, or (iii) if trading in any securities of the Company has been suspended or materially limited by the Commission or the Nasdaq Global Market, or (iv) if trading generally on the NYSE MKT or the New York Stock Exchange or in the Nasdaq Global Market has been suspended or materially limited, or minimum or maximum prices for trading have been fixed, or maximum ranges for prices have been required, by any of said exchanges or by order of the Commission, FINRA or any other governmental authority, or (v) a material disruption has occurred in commercial banking or securities settlement or clearance services in the United States or with respect to Clearstream or Euroclear systems in Europe, or (vi) if a banking moratorium has been declared by either Federal or New York authorities.
- (b) *Liabilities*. If this Agreement is terminated pursuant to this Section, such termination shall be without liability of any party to any other party except as provided in Section 4 hereof, and provided further that Sections 1, 6, 7, 8, 14, 15, 16 and 17 shall survive such termination and remain in full force and effect.

SECTION 10. <u>Default by One or More of the Underwriters</u>. If one or more of the Underwriters shall fail at the Closing Time or a Date of Delivery to purchase the Securities which it or they are obligated to purchase under this Agreement (the "Defaulted Securities"), the Representatives shall have the right, within 24 hours thereafter, to make arrangements for one or more of the non-defaulting Underwriters, or any other underwriters reasonably satisfactory to the Company, to purchase all, but not less than all, of the Defaulted Securities in such amounts as may be agreed upon and upon the terms herein set forth; if, however, the Representatives shall not have completed such arrangements within such 24-hour period, then:

- (i) if the number of Defaulted Securities does not exceed 10% of the number of Securities to be purchased on such date, each of the non-defaulting Underwriters shall be obligated, severally and not jointly, to purchase the full amount thereof in the proportions that their respective underwriting obligations hereunder bear to the underwriting obligations of all non-defaulting Underwriters, or
- (ii) if the number of Defaulted Securities exceeds 10% of the number of Securities to be purchased on such date, this Agreement or, with respect to any Date of Delivery which occurs after the Closing Time, the obligation of the Underwriters to purchase, and the Company to sell, the Option Securities to be purchased and sold on such Date of Delivery shall terminate without liability on the part of any non-defaulting Underwriter.

No action taken pursuant to this Section shall relieve any defaulting Underwriter from liability in respect of its default.

In the event of any such default which does not result in a termination of this Agreement or, in the case of a Date of Delivery which is after the Closing Time, which does not result in a termination of the obligation of the Underwriters to purchase and the Company to sell the relevant Option Securities, as the case may be, either the (i) Representatives or (ii) the Company shall have the right to postpone the Closing Time or the relevant Date of Delivery, as the case may be, for a period not exceeding seven days in order to effect any required changes in the Registration Statement, the General Disclosure Package or the Prospectus or in any other documents or arrangements. As used herein, the term "Underwriter" includes any person substituted for an Underwriter under this Section 10.

SECTION 11. Notices. All notices and other communications hereunder shall be in writing and shall be deemed to have been duly given if mailed or transmitted by any standard form of telecommunication. Notices to the Underwriters shall be directed to BofAS at One Bryant Park, New York, New York 10036, Attention of Syndicate Department (facsimile: (646) 855-3073), with a copy to ECM Legal (facsimile: (212) 230-8730); to Cowen and Company, LLC at 599 Lexington Avenue, 27th Floor, New York, New York 10022, Attention: Bradley Friedman, with a copy to the Legal Department; to Piper Sandler & Co., 345 Park Avenue, Suite 1200, New York, New York 10154, Attention: General Counsel; and to Shearman & Sterling LLP, 599 Lexington Avenue, New York, New York 10013, Attention: Ilir Mujalovic; notices to the Company shall be directed to it at 321 Summer Street, Suite 400, Boston, Massachusetts 02210, attention of Chief Executive Officer, with a copy to Wilmer Cutler Pickering Hale and Dorr LLP, 7 World Trade Center, 250 Greenwich Street, New York, New York 10007, Attention: Brian A. Johnson.

SECTION 12. No Advisory or Fiduciary Relationship. The Company acknowledges and agrees that (a) the purchase and sale of the Securities pursuant to this Agreement, including the determination of the initial public offering price of the Securities and any related discounts and commissions, is an arm's-length commercial transaction between the Company, on the one hand, and the several Underwriters, on the other hand, and does not constitute a recommendation, investment advice, or solicitation of any actions by the Underwriters, (b) in connection with the offering of the Securities and the process leading thereto, each Underwriter is and has been acting solely as a principal and is not the agent or fiduciary of the Company, any of its subsidiaries or their respective stockholders, creditors, employees or any other party, (c) no Underwriter has assumed or will assume an advisory or fiduciary responsibility in favor of the Company with respect to the offering of the Securities or the process leading thereto (irrespective of whether such Underwriter has advised or is currently advising the Company or any of its subsidiaries on other matters) and no Underwriter has any obligation to the Company with respect to the offering of the Securities except the obligations expressly set forth in this Agreement, (d) the Underwriters and their respective affiliates may be engaged in a broad range of transactions that involve interests that differ from

those of the Company, (e) the Underwriters have not provided any legal, accounting, regulatory, investment or tax advice with respect to the offering of the Securities and the Company has consulted its own respective legal, accounting, financial, regulatory and tax advisors to the extent it deemed appropriate and (f) none of the activities of the Underwriters in connection with the transactions contemplated herein constitutes a recommendation, investment advice or solicitation of any action by the Underwriters with respect to any entity or natural person.

#### SECTION 13. Recognition of the U.S. Special Resolution Regimes.

- (a) In the event that any Underwriter that is a Covered Entity (as defined below) becomes subject to a proceeding under a U.S. Special Resolution Regime (as defined below), the transfer from such Underwriter of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.
- (b) In the event that any Underwriter that is a Covered Entity or a BHC Act Affiliate (as defined below) of such Underwriter becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights (as defined below) under this Agreement that may be exercised against such Underwriter are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

For purposes of this Section 13, a "BHC Act Affiliate" has the meaning assigned to the term "affiliate" in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k). "Covered Entity" means any of the following: (i) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b); (ii) a "covered bank" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or (iii) a "covered FSI" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b). "Default Right" has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable. "U.S. Special Resolution Regime" means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

SECTION 14. Parties. This Agreement shall inure to the benefit of and be binding upon the Underwriters and the Company and their respective successors. Nothing expressed or mentioned in this Agreement is intended or shall be construed to give any person, firm or corporation, other than the Underwriters and the Company and their respective successors and the controlling persons and officers and directors referred to in Sections 6 and 7 and their heirs and legal representatives, any legal or equitable right, remedy or claim under or in respect of this Agreement or any provision herein contained. This Agreement and all conditions and provisions hereof are intended to be for the sole and exclusive benefit of the Underwriters and the Company and their respective successors, and said controlling persons and officers and directors and their heirs and legal representatives, and for the benefit of no other person, firm or corporation. No purchaser of Securities from any Underwriter shall be deemed to be a successor by reason merely of such purchase.

SECTION 15. <u>Trial by Jury</u>. The Company (on its behalf and, to the extent permitted by applicable law, on behalf of its stockholders and affiliates) and each of the Underwriters hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

SECTION 16. GOVERNING LAW. THIS AGREEMENT AND ANY CLAIM, CONTROVERSY OR DISPUTE ARISING UNDER OR RELATED TO THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF, THE STATE OF NEW YORK WITHOUT REGARD TO ITS CHOICE OF LAW PROVISIONS.

SECTION 17. Consent to Jurisdiction; Waiver of Immunity. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby shall be instituted in (i) the federal courts of the United States of America located in the City and County of New York, Borough of Manhattan or (ii) the courts of the State of New York located in the City and County of New York, Borough of Manhattan (collectively, the "Specified Courts"), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any such court, as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party's address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding brought in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

SECTION 18. TIME. TIME SHALL BE OF THE ESSENCE OF THIS AGREEMENT. EXCEPT AS OTHERWISE SET FORTH HEREIN, SPECIFIED TIMES OF DAY REFER TO NEW YORK CITY TIME.

SECTION 19. <u>Counterparts</u>. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, but all such counterparts shall together constitute one and the same agreement. Counterparts may be delivered via facsimile, electronic mail (including any electronic signature covered by the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act, the Electronic Signatures and Records Act or other applicable law, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

SECTION 20. Effect of Headings. The Section headings herein are for convenience only and shall not affect the construction hereof.

terms.	
	Very truly yours,
	INOZYME PHARMA, INC.
	ByTitle:

If the foregoing is in accordance with your understanding of our agreement, please sign and return to the Company a counterpart hereof, whereupon this instrument, along with all counterparts, will become a binding agreement among the Underwriters and the Company in accordance with

[Signature Page to Underwriting Agreement – Company]

CONFIRMED AND ACCEPTED, as of the date first above written:	
BOFA SECURITIES, INC.	
Ву	_
Authorized Signatory	-
COWEN AND COMPANY, LLC	
Ву	
Authorized Signatory	-
PIPER SANDLER & CO.	
Ву	_
Authorized Signatory	

For themselves and as Representatives of the other Underwriters named in Schedule A hereto.

[Signature Page to Underwriting Agreement – Underwriters]

### SCHEDULE A

The initial public offering price per share for the Securities shall be \$[●].

The purchase price per share for the Securities to be paid by the several Underwriters shall be  $\{\bullet\}$ , being an amount equal to the initial public offering price set forth above less  $\{\bullet\}$  per share, subject to adjustment in accordance with Section 2(b) for dividends or distributions declared by the Company and payable on the Initial Securities but not payable on the Option Securities.

Name of Underwriter	Number of Initial Securities
BofA Securities, Inc.	[•]
Cowen and Company, LLC	[•]
Piper Sandler & Co.	[•]
Wedbush Securities Inc.	<u> </u>
Total	[•]

Sch A-1

## SCHEDULE B-1

## **Pricing Terms**

- 1 The Company is selling [ullet] shares of Common Stock.
- 2 The Company has granted an option to the Underwriters, severally and not jointly, to purchase up to an additional [●] shares of Common Stock.
- 3 The initial public offering price per share for the Securities shall be  $\{\bullet\}$ .

Sch B-1-1

## SCHEDULE B-2

## Free Writing Prospectuses

[SPECIFY EACH ISSUER GENERAL USE FREE WRITING PROSPECTUS]

Sch B-2-1

SCHEDULE B-3

## Written Testing-the-Waters Communication

Sch B-3-1

#### Exhibit A

### FORM OF LOCK-UP FROM DIRECTORS, OFFICERS OR OTHER STOCKHOLDERS PURSUANT TO SECTION 5(i)

BofA Securities, Inc. Cowen and Company, LLC Piper Sandler & Co.

> as Representatives of the several Underwriters to be named in the within-mentioned Underwriting Agreement

c/o BofA Securities, Inc. One Bryant Park New York, New York 10036

> Cowen and Company, LLC 599 Lexington, 25th Floor New York, New York 10022

Piper Sandler & Co. 345 Park Avenue, Suite 1200 New York, New York 10154

Re: <u>Proposed Public Offering by Inozyme Pharma, Inc.</u>

Dear Sirs/Madams:

The undersigned, a stockholder, optionholder, officer and/or director of Inozyme Pharma, Inc., a Delaware corporation (the "Company"), understands that BofA Securities, Inc., Cowen and Company, LLC and Piper Sandler & Co. (together, the "Representatives") propose to enter into an Underwriting Agreement (the "Underwriting Agreement") with the Company and the other underwriters party thereto providing for the public offering (the "Public Offering") of shares of the Company's common stock, par value \$0.0001 per share (the "Common Stock"). In recognition of the benefit that such an offering will confer upon the undersigned as a stockholder, optionholder, officer and/or director of the Company, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the undersigned agrees with each underwriter to be named in the Underwriting Agreement that, during the period beginning on the date hereof and ending on the date that is 180 days from the date of the Underwriting Agreement (the "Lock-Up Period"), the undersigned will not, without the prior written consent of the Representatives, (i) directly or indirectly, offer, pledge, sell, contract to sell, sell any option or contract to purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of any shares of the Company's Common Stock or any securities convertible into or exercisable or exchangeable for shares of Common Stock, whether now owned or hereafter acquired by the undersigned or with respect to which the undersigned has or hereafter acquires the power of disposition

(collectively, the "Lock-Up Securities"), or (ii) enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the Lock-Up Securities, whether any such swap or transaction is to be settled by delivery of shares of Common Stock or other securities, in cash or otherwise or (iii) publicly disclose the intention to do any of the foregoing described in clauses (i) and (ii) above. If the undersigned is an officer or director of the Company, the undersigned further agrees that the foregoing provisions shall be equally applicable to any issuer-directed shares of Common Stock the undersigned may purchase in the Public Offering.

If the undersigned is an officer or director of the Company, (1) the Representatives agree that, at least three business days before the effective date of any release or waiver of the foregoing restrictions in connection with a transfer of shares of Common Stock, the Representatives will notify the Company of the impending release or waiver, and (2) the Company has agreed in the Underwriting Agreement to announce the impending release or waiver by press release through a major news service at least two business days before the effective date of the release or waiver. Any release or waiver granted by the Representatives hereunder to any such officer or director shall only be effective two business days after the publication date of such press release. The provisions of this paragraph will not apply if (i) the release or waiver is effected solely to permit a transfer not for consideration and (ii) the transferee has agreed in writing to be bound by the same terms described in this agreement to the extent and for the duration that such terms remain in effect at the time of the transfer.

Notwithstanding the foregoing, and subject to the conditions below, the undersigned may transfer or otherwise dispose of the Lock-Up Securities without the prior written consent of the Representatives, provided that (1) in the case of clauses (i) through (iv) below, the Representatives receive a signed lock-up agreement for the balance of the Lock-Up Period from each donee, trustee, distributee, or transferee, as the case may be, (2) (A) in the case of clauses (i) through (iv) below, such transfers are not required to be reported with the Securities and Exchange Commission (the "SEC") on Form 4 in accordance with Section 16 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and (B) in the case of clauses (v) through (ix) below, any such required Form 4 shall state the reason for such transfer, (3) in the clauses of (i) through (v) below, such transfers are not dispositions for value, and (4) in the case of clauses (i) through (ix) below, the undersigned does not otherwise voluntarily effect any public filing or report regarding such transfers:

- (i) as a bona fide gift or gifts, including to a trust, educational institution or other entity established for charitable purposes; or
- (ii) to any trust for the direct or indirect benefit of the undersigned or the immediate family of the undersigned (for purposes of this agreement, "immediate family" shall mean any relationship by blood, marriage or adoption, not more remote than first cousin); or
- (iii) as a distribution to general or limited partners, members, stockholders or other equity holders or trust beneficiaries of the undersigned; or

- (iv) to the undersigned's affiliates or to any investment fund or other entity that, directly or indirectly, controls or manages, is controlled or managed by, or is under common control or management with, the undersigned; or
- (v) by will or intestacy; or
- (vi) to the Company in connection with the exercise of options, warrants or other rights to acquire shares of Common Stock or any security convertible into or exercisable for shares of Common Stock of the Company by way of net exercise and/or to cover withholding tax obligations in connection with such exercise pursuant to an employee benefit plan, option, warrant or other right disclosed in the prospectus for the Public Offering, provided that any such shares of the Common Stock issued upon exercise of such option, warrant or other right shall be subject to the restrictions set forth herein; or
- (vii) pursuant to a court order or settlement agreement related to the distribution of assets in connection with the dissolution of a marriage or civil union; or
- (viii) to the Company pursuant to agreements under which the Company has exercised its option to repurchase such shares or has exercised a right of first refusal with respect to transfers of such shares upon termination of service of the undersigned; or
- (ix) pursuant to the automatic conversion of outstanding shares of preferred stock of the Company into shares of the Common Stock of the Company in connection with the Public Offering disclosed in the prospectus for the Public Offering, provided that the shares of the Common Stock received upon such conversion shall be subject to the restrictions set forth herein; or
- (x) to any nominee or custodian of a person or entity to whom a transfer or disposition would be permissible under clauses (i) through (ix) above; or
- (xi) to a bona fide third party pursuant to a merger, consolidation, tender offer or other similar transaction made to all holders of shares of the Common Stock and involving a Change of Control (as defined below) of the Company and approved by the Company's board of directors; provided that, in the event that such Change of Control is not completed, the undersigned's Lock-Up Securities shall remain subject to the restrictions contained herein, provided further that any shares of the Common Stock not transferred in such merger, consolidation, tender offer or other transaction shall remain subject to the restrictions contained herein. "Change of Control" shall mean the transfer (whether by tender offer, merger, consolidation or other similar transaction), in one transaction or a series of related transactions, to a person or group of affiliated persons (other than an underwriter pursuant to the Public Offering), of the Company's voting securities if, after such transfer, such person or group of affiliated persons would hold more than 50% of the outstanding voting securities of the Company (or the surviving entity).

Furthermore, notwithstanding anything to the contrary herein, during the Lock-Up Period, the undersigned may sell shares of Common Stock of the Company purchased by the undersigned from the underwriters in the Public Offering (other than any issuer-directed shares of Common Stock purchased in the Public Offering by an officer or director of the Company) or on the open market following the Public Offering if and only if (i) such sales are not required to be reported in any public filing or report with the SEC, or otherwise and (ii) the undersigned does not otherwise voluntarily effect any public filing or report regarding such sales.

The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of the Lock-Up Securities, except in compliance with the foregoing restrictions.

Notwithstanding the foregoing, the undersigned may establish a trading plan pursuant to Rule 10b5-1 under the Exchange Act, provided that (i) the undersigned is not required to and does not otherwise effect any public filing or report regarding the establishment of such plan during the Lock-Up Period and (ii) no sales are made during the Lock-Up Period pursuant to such plan.

In addition, the undersigned hereby agrees to waive any rights the undersigned may have to require registration of shares of the Common Stock in connection with the filing of a registration statement under the Securities Act of 1933, as amended (the "Securities Act"), relating to the Public Offering. The undersigned further agrees that, for the Lock-Up Period, the undersigned will not, without the prior written consent of the Representatives, make any demand for, or exercise any right with respect to, or file or confidentially submit or cause to be filed or confidentially submitted any registration statement under the Securities Act with respect to, the registration of shares of the Common Stock or any securities convertible into or exercisable or exchangeable for shares of the Common Stock, or warrants or other rights to purchase shares of the Common Stock or any such securities. In addition, the undersigned hereby agrees to waive any and all preemptive rights, participation rights (including concurrent private placement rights), resale rights, rights of first refusal and similar rights that the undersigned may have in connection with the Public Offering or with any issuance or sale by the Company of any equity or other securities before the Public Offering, except for any such rights as have been heretofore duly exercised.

In the event that any of the Representatives withdraws from or declines to participate in the Public Offering, all references to the Representatives contained in this agreement shall be deemed to refer to the Representatives that continue to participate in the Public Offering (the "Remaining Representatives"), and, in such event, any written consent, waiver or notice given or delivered in connection with this agreement by the Remaining Representatives shall be deemed to be sufficient and effective for all purposes under this agreement.

This agreement, the Lock-Up Period described herein and related restrictions shall automatically terminate upon the earliest to occur, if any, of (i) either the Company, on the one hand, or the Representatives, on the other hand, advising the other in writing prior to the execution of the Underwriting Agreement that it has determined not to proceed with the Public Offering, (ii) the termination of the Underwriting Agreement before payment for and delivery of the Common Stock to be sold thereunder, (iii) the registration statement filed under the

Securities Act with respect to the Public Offering contemplated by the Underwriting Agreement is withdrawn or (iv) October 31, 2020, in the event the closing of the Public Offering shall not have occurred on or before such date.

[Signature Page Follows]

Very truly your	΄S,
Signature:	
Print Name:	

Exh. A-1

# FORM OF PRESS RELEASE TO BE ISSUED PURSUANT TO SECTION 3(j)

Inozyme Pharma, Inc.

[•], 2020

Inozyme Pharma, Inc. (the "Company") announced today that BofAS, Cowen and Piper Sandler, the lead book-running managers in the Company's recent public sale of [●] shares of common stock, are [waiving] [releasing] a lock-up restriction with respect to [●] shares of the Company's common stock held by [certain officers or directors] [an officer or director] of the Company. The [waiver] [release] will take effect on , 20 and the shares may be sold on or after such date.

This press release is not an offer for sale of the securities in the United States or in any other jurisdiction where such offer is prohibited, and such securities may not be offered or sold in the United States absent registration or an exemption from registration under the United States Securities Act of 1933, as amended.

Exh. B-2

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed.

Double asterisks denote omissions.

#### INTELLECTUAL PROPERTY ASSET PURCHASE AGREEMENT

THIS INTELLECTUAL PROPERTY ASSET PURCHASE AGREEMENT (this "Agreement") is entered into as of July 17, 2020 (the "Effective Date") by and between Inozyme Pharma, Inc., a Delaware corporation with its principal office at 321 Summer Street, Floor 4, Boston, MA 02210 (the "Buyer"), on the one hand, and Alexion Pharmaceuticals, Inc., a Delaware corporation, with its principal office at 121 Seaport Boulevard, Boston, MA 02210 (the "Seller", with Seller and Buyer each, individually, a "Party" and, collectively, the "Parties"), on the other hand.

**WHEREAS** the Buyer desires to purchase, and the Seller desires to sell, the Assets (as defined below), subject to the terms and conditions of this Agreement;

**NOW THEREFORE**, in consideration of the mutual promises hereinafter set forth and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

# ARTICLE 1 INTERPRETATION

#### 1.1 Definitions

The terms defined herein shall have, for all purposes of this Agreement, the following meanings, unless the context expressly or by necessary implication otherwise requires:

"Affiliate" means, with respect to a Party, any Person that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Party. A Person shall be deemed to "control" another Person if the first Person (a) owns, directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding voting securities or capital stock (or such lesser percentage which is the maximum allowed to be owned by such Person in a particular jurisdiction) of such second Person, or has other comparable ownership interest with respect to any entity other than a corporation; or (b) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of the second Person.

"Assets" means, collectively, the Assigned Data, the Assigned Know-How, the Assigned Materials, and the Assigned Patent Rights.

- "Assigned Data" means solely the items described on Exhibit B, which, for the avoidance of doubt, do not include any contractual obligations.
- "Assigned Know-How" means solely the Know-How described on Exhibit B, which, for the avoidance of doubt, do not include any contractual obligations.
- "Assigned Materials" means solely the Materials described on Exhibit B, which, for the avoidance of doubt, do not include any contractual obligations.
- "Assigned Patent Rights" means (a) Seller's exclusive rights in the patents and patent applications identified on Exhibit A-1 and Seller's joint ownership rights in the jointly-owned patents and patent applications identified on Exhibit A-2, (b) Seller's exclusive or joint-ownership rights, as applicable, in all national, regional and international patents and patent applications deriving priority or issuing from any of the patent rights described in clause (a), (c) Seller's exclusive or joint-ownership rights, as applicable, in all patent applications filed after the Effective Date that derive priority from the patent rights described in clause (a), including substitutions, divisionals, continuations, continuations-in-part, provisional patent applications, converted provisional patent applications, re-issues and re-examinations, and continued prosecution applications of such patent rights, (d) Seller's exclusive or joint-ownership rights, as applicable, in any and all patents that have issued or in the future issue from any patent applications covered by clauses (a) (c), including utility models, petty patents and design patents and certificates of invention, and (e) Seller's exclusive or joint-ownership rights, as applicable, in any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates, patent term extensions and the like) of the patents or patent applications covered by clauses (a) (d).
- "Buyer Permitted Encumbrance" means (a) statutory Encumbrances arising out of operation of law with respect to a Liability incurred in the ordinary course of business and which is not delinquent; (b) Encumbrances for taxes not yet due, payable, delinquent or subject to penalties for nonpayment, or which are being contested in good faith through appropriate proceedings; (c) imperfections of title or encumbrances, if any, that, individually or in the aggregate, do not materially impair, and are not reasonably likely to materially impair, the continued operation of Buyer's business, (d) mechanics', materialmens', carriers', workmens', warehousemens', repairmens', landlords' or other like Encumbrances and security obligations that are incurred in the ordinary course of business and are not delinquent, and (e) non-exclusive licenses granted by Buyer or its Affiliates under any assets in the ordinary course of business.
- "Confidentiality Agreements" means each of (i) that certain Confidential Disclosure Agreement by and between Seller and Buyer, dated November 6, 2017, and (ii) that certain Confidential Disclosure Agreement by and between Seller and Buyer, dated May 8, 2020.

"ENPP1" means ectonucleotide pyrophosphatase/phosphodiesterase 1 proteins (NPP1/ENPP1/PC-1), enzymatically active fragments thereof, fusion polypeptides containing such proteins or fragments, and nucleotide sequences encoding any of the foregoing, derived from any species. Exemplary sequences for full-length ENPP1 polypeptides include: Human (NCBI accession no. NP\_006199.2), Mouse (NCBI accession no. NP\_01295256.1), Cow (NCBI accession no. NP\_01193141), Rabbit (NCBI accession no. NP\_01162404.1), and Baboon (NCBI accession no. NP\_01076211.2).

"**Fraud**" means, with respect to any Party, common law fraud, as interpreted under the laws and by the courts of the State of Delaware; provided that Fraud shall only be deemed to exist if such Party had the specific intent to deceive and mislead the other Party.

"Fundamental Representations" means the representations and warranties contained in Sections 3.1(a) (Organization), 3.1(b) (Authorization) and 3.1(e) (Ownership of the Assets).

"GAAP" shall mean generally accepted accounting principles in the United States.

"Know-How" means any and all proprietary and non-public ideas, inventions, discoveries, data, results, records, formulae, designs, specifications, scientific methods, trade secrets, business plans, business methods, processes, formulations, techniques, technology, practices, know-how, technical information (including structural and functional information), process information, pre-clinical information, and clinical information, and any and all proprietary biological, chemical, pharmacological, toxicological, pre-clinical, clinical, assay, control and manufacturing data, in each case whether or not patented or patentable.

"Knowledge of Seller" means the actual knowledge of [\*\*].

"Liabilities" means, with respect to any Person, any and all debts, obligations, Losses, interest obligations, deficiencies and assessments, whether accrued or fixed, absolute or contingent, known or unknown, matured or unmatured or determined or determinable, due or to become due, whether directly incurred or consequential, whether or not required under GAAP to be accrued on the financial statements of such Person, and including those arising under any law, action or order and those arising under any contract, agreement, arrangement, commitment or undertaking.

"Losses", in respect of any matter, means all claims, demands, proceedings, losses, damages, awards, liabilities, penalties, fees, deficiencies, fines, costs and expenses (including all reasonable legal and other professional fees and disbursements, interest, penalties and amounts paid in settlement) and judgments arising directly or indirectly as a consequence of such matter.

- "Materials" means any and all physical embodiments of chemical or biological materials.
- "Person" means any individual, partnership, limited partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture, governmental entity or other entity or organization.
- "Product" means any enzyme replacement therapy, agonist, gene therapy, compound or other pharmaceutical preparation that (a) constitutes ENPP1 or whose primary method of action is to replace ENPP1 or to directly modulate ENPP1 or to directly increase or decrease ENPP1 levels and (b) was researched, developed, manufactured, commercialized or otherwise exploited by or on behalf of Seller prior to the Effective Date. For clarity, Product shall include prodrugs, analogs, salts, free acids, free bases, clathrates, solvates, hydrates, hemihydrates, anhydrides, esters, chelates, conformers, congeners, crystal forms, crystal habits, polymorphs, amorphous solids, homologs, isomers, stereoisomers, enantiomers, racemates, isotopic or radiolabeled equivalents, metabolites and conjugates of any of the above.
- "**Program**" means any program conducted by or on behalf of Seller prior to the Effective Date that was directed to the research, development, manufacture, commercialization or other exploitation any Product.
- "Regulatory Authority" means any governmental entity with jurisdiction or authority over the development, manufacture, commercialization or other exploitation of pharmaceutical products, and any corresponding national or regional regulatory authorities.
- "Regulatory Submissions" means all filings, applications and submissions with or to any Regulatory Authority in support of the development, manufacture, commercialization or other exploitation of any Product, and all formal and informal, written or electronic correspondence or communications with or from any relevant Regulatory Authority with respect to any Product, as well as minutes of any material meetings, telephone conferences, or discussions with any Regulatory Authority with respect to any Product.
- "Representatives" means, with respect to either Party, such Party's Affiliates and its and their respective employees, directors, officers and managers.
- "Seller Permitted Encumbrance" means (a) statutory Encumbrances arising out of operation of law with respect to a Liability incurred in the ordinary course of business and which is not delinquent; (b) Encumbrances for taxes not yet due, payable, delinquent or subject to penalties for nonpayment, or which are being contested in good faith through appropriate proceedings; (c) imperfections of title or encumbrances, if any, that, individually or in the aggregate, do not materially impair, and are not reasonably likely to materially impair, the continued use and operation of the Assets, (d) mechanics', materialmens', carriers', workmens', warehousemens', repairmens', landlords' or other like Encumbrances and security obligations that are incurred in the ordinary course of business and are not delinquent, and (e) non-exclusive licenses granted by Seller or its Affiliates under any Assets in the ordinary course of business.

"Third Party" means any Person other than the Buyer, the Seller or their respective Affiliates.

#### 1.2 Extended Meanings

Grammatical variations of any terms defined herein have similar meanings to such defined terms; words importing number include the singular and the plural; words importing gender include the feminine, neuter and masculine genders; the words "include", "includes," and "including" will be deemed to be followed by the phrase "without limitation,"; the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or"; the word "will" will be construed to have the same meaning and effect as the word "shall"; any reference herein to any Person will be construed to include such Person's successors and assigns; the words "herein," "hereof" and "hereunder," and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof; all references herein to Sections, Schedules or Exhibits will be construed to refer to Sections, Schedules or Exhibits of this Agreement, and references to this Agreement include all Schedules and Exhibits hereto; provisions that require that a Party, the Parties or any committee hereunder "agree," "consent" or "approve" or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, e-mail (solely with return receipt), approved minutes or otherwise (but excluding e-mail without return receipt and instant messaging); references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then current amendments thereto or any replacement or successor law, rule or regulation thereof; and any action or occurrence deemed to be effective as of a particular date will be deemed to be effective as of 11:59 PM ET on such date.

#### 1.3 Captions and Headings

The captions and headings contained herein are for the convenience of the Parties and in no way alter, modify, amend, limit or restrict the contractual obligations of the Parties.

#### 1.4 Drafting

Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party that drafted such terms and provisions.

#### 1.5 Exhibits

The following exhibits and schedules are attached to and form part of this Agreement:

Exhibit A-1 – Assigned Solely-Owned Patent Rights
Exhibit A-2 – Assigned Jointly-Owned Patent Rights

Exhibit B — Assigned Data, Assigned Know-How and Assigned Materials

Exhibit C – Press Release

Disclosure Schedules

# ARTICLE 2 SALE AND DELIVERY OF THE ASSETS

#### 2.1 Transfer of the Assets; Acknowledgement

Subject to and upon the terms and conditions of this Agreement, the Seller hereby sells, transfers, conveys, assigns and delivers to the Buyer, and agrees to cause its Affiliates to sell, assign and transfer to the Buyer, and the Buyer hereby purchases from the Seller and its Affiliates, Seller's and its Affiliates' entire right, title and interest in and to the Assets.

### 2.2 Confirmatory Assignment of Assigned Patent Rights

Without limiting Section 2.1, the Seller hereby sells, assigns and transfers, and agrees to cause its Affiliates to sell, assign and transfer, to the Buyer Seller's and its Affiliates' entire right, title and interest in all countries, including Seller's and its Affiliates' rights of priority and rights to sue for past infringement, in the Assigned Patent Rights, and Seller's and its Affiliates' rights in and to all patents in any country that, following the Effective Date, may be or are granted with respect to the Assigned Patent Rights, including any divisional, continuation, continuation-in-part, reexamination, reissue or other patent applications or patents based in whole or in part thereon. The Seller hereby authorizes and requests the Commissioner of Patents and Trademarks of the United States to issue such rights to the Buyer and its successors and assigns, and further authorizes and requests officials of patent offices in countries other than the United States to issue such rights, as may be granted upon said Assigned Patent Rights, including any divisional, continuation, continuation-in-part, reexamination, reissue or other patent applications or patents based in whole or in part thereon, to the Buyer and its successors and assigns, to the full end of the term for all said patents that may be granted, as fully and entirely as the same would have been held by the Seller had this assignment and sale not been made.

#### 2.3 Further Assurances

(a) At any time and from time to time after the Effective Date, at a Party's request and without further consideration, the other Party shall promptly execute and deliver such instruments of sale, transfer, conveyance, assignment and confirmation, and take such other actions, as the requesting Party may reasonably request to more effectively transfer, convey and assign to (i) the Buyer, and to confirm the Buyer's title to, all of the Assets and Assumed Liabilities, to put the Buyer in actual possession and operating control thereof, and to assist Buyer in exercising all rights with respect thereto and (ii) to Seller, and to confirm Seller's title to, all of the Excluded Assets and Retained Liabilities, to put Seller in actual possession and operating control thereof, and to assist Seller in exercising all rights with respect

- thereto. Notwithstanding anything to the contrary herein, Buyer shall prepare any such additional instruments or documents necessary to assign, convey or transfer the Assets (including the Assigned Patent Rights) at its sole expense, and Buyer shall bear all costs and expenses (including filing fees) associated with such assignment and transfer of the Assigned Patent Rights.
- (b) Without limiting Section 2.3(a), the Seller shall, and shall cause its Representatives to, reasonably cooperate with the Buyer, at the Buyer's expense, to prosecute, maintain, defend, and enforce the Assigned Patent Rights, including by giving testimony and executing and delivering to the Buyer any and all applications, oaths, declarations, affidavits, waivers, assignments and other documents as may be reasonably requested by the Buyer.
- (c) If, at any time within [\*\*] after the Effective Date, Seller's Head of Research & Development becomes aware of the existence of (i) any patent or patent application that claims the composition, formulation, method of making or method of using solely one (1) or more Products or (ii) any (A) research, chemistry, manufacturing, controls, pharmacology, interchangeability, *in vitro*, *in vivo*, pre-clinical, non-clinical or clinical data, protocols or methods, or interests therein, that are solely related to any Product, (B) Know-How, or interests therein, that are solely related to any Product, in each case ((i) and (ii)) that (1) were owned by the Seller or any of its Affiliates as of the Effective Date, (2) remain owned by, and remain in the possession of, Seller or any of its Affiliate when identified by Seller, and (3) have not previously been assigned and transferred by the Seller to the Buyer (collectively, "Additional Assets"), then Seller shall promptly notify the Buyer of such Additional Assets and, if so requested by Buyer, Seller shall, and shall cause its Affiliates to, assign to the Buyer Seller's and its Affiliates' entire right, title and interest in and to such Additional Assets and, if applicable, transfer such Additional Assets to the Buyer, in each case, at Buyer's sole expense.
- (d) If, at any time within [\*\*] after the Effective Date, Seller's Head of Research & Development becomes aware of the existence of any agreement between Seller or any of its Affiliates, on the one hand, and any Third Party, on the other hand, (1) that was in existence as of the Effective Date, (2) that is solely related to any Product, (3) with respect to which Seller or any of its Affiliates remains a counterparty when identified by Seller, and (4) (A) that remains in full force and effect when identified by Seller or (B) that is listed on the Disclosure Schedules and such listed agreement includes surviving grants of licenses (each such agreement, a "Transferred Contract"), then Seller shall promptly notify the Buyer of such Transferred Contract and, if so requested by Buyer, Seller shall, and shall cause its Affiliates to, use commercially reasonable efforts to assign to the Buyer Seller's and its Affiliates' entire right, title and interest in and to such Transferred Contract, in each case, at Buyer's sole expense; provided, that none of Seller or its Affiliates shall be required to pay money to any Third Party,

commence any litigation, offer or grant any accommodation (financial or otherwise) to any Third Party, or breach any terms of the Transferred Contract, in each case, in connection with such efforts. If a Transferred Contract is listed on the Disclosure Schedules, then such listing shall satisfy Seller's notice obligation to Buyer in respect of such Transferred Contract under this Section 2.3(d). Upon the transfer of a Transferred Contract to Buyer, such Transferred Contract shall constitute an Additional Asset for all purposes under this Agreement. Seller provides no assurances to Buyer that any consent, authorization, approval or waiver of a Third Party contemplated by this Section 2.3(d) will be granted. Subject to compliance by Seller with the provisions of this Section 2.3(d), the Parties acknowledge and agree that neither Seller nor its Affiliates shall be obligated to obtain any such authorization, approval, consent or waiver hereunder and neither (i) the failure to so actually obtain any such authorization, approval, consent or waiver in connection with the consummation of the transactions contemplated by this Section 2.3(d) in and of itself nor (ii) any default or termination or any lawsuit, action, claim, proceeding or investigation commenced or threatened by or on behalf of any Person to the extent arising out of any such failure to so actually obtain any such authorization, approval, consent or waiver in connection with the consummation of the transactions contemplated by this Section 2.3(d) in and of itself shall be deemed a breach of any representation, warranty or covenant of Seller contained in this Agreement. If, despite Seller's compliance with the provisions of this Section 2.3(d), any such consent that is necessary to assign any given Transferred Contract to the Buyer is not obtained, Seller will be deemed to have fulfilled its obligations under this Section 2.3(d) with respect to such Transferred Contract. With respect to any contract that (I) is listed on the Disclosure Schedules, (II) is related, but not solely related, to any Product and (III) includes a license to the Seller or any of its Affiliates related to any Product, if so requested by Buyer, Seller shall, and shall cause its Affiliates to, at the Buyer's sole expense, use commercially reasonable efforts to grant to the Buyer a sublicense under such license solely as it relates to any Product; provided, that none of Seller or its Affiliates shall be required to pay money to any Third Party, commence any litigation, offer or grant any accommodation (financial or otherwise) to any Third Party, or breach any terms of the applicable contract, in each case, in connection with such efforts, and, if, despite Seller's compliance with the provisions of this sentence, any such sublicense is not obtained, Seller will be deemed to have fulfilled its obligations under this section with respect to such sublicense.

#### 2.4 Covenant Not to Take Action Adverse to Assigned Patent Rights

The Seller hereby covenants and agrees that neither it nor any of its Affiliates shall institute, participate in, cooperate with or finance, or assist any Third Party to institute, participate in, cooperate with or finance, any proceedings or actions challenging the Buyer's ownership, or the validity or enforceability, of any of the Assigned Patent Rights, including through any interference or similar proceeding, or in connection with any challenge to the

ownership, validity or enforceability of any of the Assigned Patent Rights. Notwithstanding anything to the contrary herein, in no event will the foregoing be deemed to limit or restrict Seller's or its Affiliates' purchase of equity, debt or other convertible securities issued by a Third Party without a bona fide purpose by or on behalf of Seller or its Affiliates to directly finance proceedings or actions challenging the Buyer's ownership, or the validity or enforceability, of any of the Assigned Patent Rights, including through any interference or similar proceeding, or in connection with any challenge to the ownership, validity or enforceability of any of the Assigned Patent Rights.

### 2.5 Equity Issuance

Subject to the terms and conditions of this Agreement and the Series A-2 Convertible Preferred Stock Purchase Agreement by and between the Parties, dated as of the Effective Date (the "SPA"), in consideration for the sale of the Assets by the Seller to the Buyer, the Buyer shall issue to the Seller, pursuant to the terms of the SPA, 8,294,360 shares of the Buyer's Series A-2 Convertible Preferred Stock, par value \$0.0001 per share, as set forth in the SPA.

#### 2.6 Complete Transfer

The Seller expressly agrees that, except for the Internal Research License (as defined below), the sale of the Assets under this Agreement constitutes a complete and irrevocable transfer of all of its and its Affiliates' rights, title and interest in and to the Assets, and that the Seller and its Affiliates reserve no rights to research, develop, manufacture, commercialize or otherwise exploit, or to encumber, market or otherwise transfer the Assets.

#### 2.7 Excluded Assets

Buyer acknowledges and agrees that, other than the Assets and, to the extent assigned pursuant to Section 2.3(c), the Additional Assets, it is not acquiring any right, title or interest in, to or under any assets, property, rights and interests of Seller or its Affiliates (collectively, the "Excluded Assets"). Notwithstanding anything to the contrary herein, to the extent the Assets (other than the Assigned Patent Rights) or Additional Assets include any assets, property, rights and interests of Seller or its Affiliates that are not solely related to any Product, such assets, property, rights and interests of Seller or its Affiliates shall be deemed Excluded Assets for all purposes under this Agreement.

#### 2.8 Retained Liabilities; Assumed Liabilities

Without limiting either Party's indemnification obligations set forth in Article 5, (a) Seller and its Affiliates retain, and will be responsible for and timely satisfy and discharge all Liabilities of Seller and its Affiliates arising out of or relating to (i) the Assets, solely to the extent arising out of or relating to any actions or occurrence prior to the Effective Date, (ii) the Additional Assets, solely to the extent arising out of or relating to any actions or occurrences prior to the date such Additional Assets are assigned and transferred to the Buyer hereunder or (iii) payment of money in respect of any Seller Permitted Encumbrance that attached to the applicable Asset or Additional Asset prior to the effective date of assignment and transfer of

such Asset or Additional Asset, respectively, to the Buyer pursuant to this Agreement; provided, that, notwithstanding anything to the contrary herein, neither Seller nor any of its Affiliates shall have any obligation to satisfy, discharge, terminate, modify or otherwise dispose of any Encumbrance set forth in clause (e) of the definition of "Seller Permitted Encumbrances" (clauses (a)(i)-(a)(iii), collectively, the "Retained Liabilities"), and (b) Buyer agrees to assume and to timely satisfy and discharge all Liabilities (other than the Retained Liabilities) that (i) arise out of or relate to the Assets on or following the Effective Date or the Additional Assets on or after the date such Additional Assets are assigned and transferred to the Buyer hereunder, including Liabilities of Seller or its Affiliates under any Transferred Contract that constitutes an Additional Asset and (ii) are incurred in connection with Buyer's or its Representative's exploitation of the Assets on or after the Effective Date or the Additional Assets on or after the date such Additional Assets are assigned and transferred to the Buyer hereunder (clauses (b)(i)-(b)(ii), collectively, the "Assumed Liabilities").

#### 2.9 Internal Research License

Subject to the terms and conditions of this Agreement, the Buyer hereby grants, and agrees to grant, to the Seller and its Affiliates a non-exclusive, non-assignable, non-sublicensable (except to Representatives acting on behalf of Seller or its Affiliates), fully-paid, royalty-free, perpetual (except as set forth in Section 6.2) license to use the Assets and Additional Assets solely for internal, non-clinical research purposes (the "Internal Research License").

#### 2.10 Taxes

- (a) All transfer, sales, use, rental, customs, value added and consumption taxes, deed excise stamps and similar taxes related to the sale of the Assets and Additional Assets contemplated by this Agreement shall be paid by the Seller. The Seller shall file all necessary tax returns and other documentation with respect to all such taxes, and, if required by any applicable law, rule or regulation, the Buyer will join in the execution of any such tax return or other documentation. Each Party shall be liable for its own income taxes.
- (b) The Buyer will be entitled to deduct and withhold from the amounts payable by it pursuant to this Agreement to the Seller such amounts as it is required to deduct and withhold with respect to the making of such payments under applicable tax law. On the Effective Date, the Seller shall provide an IRS Form W-9 to the Buyer certifying that it a U.S. person and not subject to backup withholding. Notwithstanding anything herein to the contrary, to the extent the Seller has timely provided the Buyer with a duly executed IRS Form W-9, no such deduction or withholding shall be made.
- (c) Following the Closing, the Seller shall prepare and provide to the Buyer an initial allocation of the purchase price (for tax purposes) among the Assets and Additional Assets in accordance with applicable law. The Buyer shall be permitted to review and comment on the initial allocation which comments shall be provided to the Seller not later than within [\*\*] after the initial allocation has been delivered

to the Buyer. The Buyer and the Seller shall use good faith efforts to resolve any dispute regarding the preparation of the allocation. The allocation as finally agreed between the Buyer and the Seller hereunder is referred to as the agreed allocation. The Parties shall, and shall cause their Affiliates to, report, act and file their respective tax returns in accordance with such agreed allocation and any adjustments thereto and shall not take any position on a tax return or in a tax audit or similar proceeding inconsistent with such allocation and any adjustments thereto. To the extent the Buyer and Seller are unable to agree as provided above, then each of the Buyer and the Seller shall use its own allocation. The Buyer shall timely and properly prepare, execute, file and deliver all such documents, forms and other information as the Seller may reasonably request to prepare the allocation and any adjustments thereto.

# ARTICLE 3 REPRESENTATIONS AND WARRANTIES

#### 3.1 Seller's Representations

The Seller hereby represents and warrants to the Buyer that, as of the Effective Date:

- (a) <u>Organization.</u> The Seller is a corporation existing under the laws of the State of Delaware, and has all requisite power and authority to own its properties, to carry on its business as now being conducted, to execute and deliver this Agreement and to consummate the transactions contemplated hereby.
- (b) <u>Authorization.</u> The execution and delivery of this Agreement by the Seller, and the consummation by the Seller of all transactions contemplated hereby, have been duly authorized by all requisite organizational and, if applicable, shareholder action. This Agreement constitutes a valid and legally binding obligation of the Seller, enforceable against the Seller in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium and other similar laws, rules and regulations affecting creditors' rights generally and by general principles of equity.
- (c) Noncontravention. Except as set forth on Schedule 3.1(c), the execution, delivery and performance by the Seller of this Agreement, and the consummation by Seller of the transactions contemplated hereby, will not, with or without the giving of notice or the passage of time or both, (i) violate in any material respect any provision of any law, rule or regulation applicable to the Seller; (ii) violate any provision of the articles or by-laws of the Seller; (iii) violate any judgment, decree, order or award of any arbitrator, court or other governmental entity; or (iv) conflict with or result in the breach or termination of any term or provision of, or constitute a default under, or cause any acceleration under, or cause the creation of any claim, liability, lien, pledge, charge, encumbrance or equity of any kind (each, an "Encumbrance"), other than Seller Permitted Encumbrances, upon the Assets pursuant to any indenture, mortgage, deed of trust or other instrument or

- agreement to which the Seller or any of its Affiliates is a party or by which the Seller or any of its or its Affiliates' properties is or may be bound, except, with respect to clauses (i) and (iii), for any violations that would not, individually or in the aggregate, reasonably be expected to be material to the Assets.
- (d) Third-Party Consents. Except as set forth on Schedule 3.1(d), to the Knowledge of Seller, the Seller is not a party to any agreement solely related to any of the Assets or any associated rights or interests transferred under this Agreement. Except as set forth on Schedule 3.1(d), to the Knowledge of Seller, no consent or approval of any lender, lessor or other Third Party is required in order for the Seller to consummate the transactions contemplated by this Agreement.
- (e) Ownership of the Assets. The execution by the Seller of this Agreement and the delivery to the Buyer of the instruments of transfer of ownership contemplated by this Agreement (i) will vest good, clear, record and marketable title to the Assigned Patent Rights in the Buyer, free and clear of all Encumbrances, other than Seller Permitted Encumbrances and (ii) to the Knowledge of Seller, except as set forth on Schedule 3.1(e), will vest good, clear, record and marketable title to the Assigned Data, the Assigned Know-How and the Assigned Materials in the Buyer, free and clear of all Encumbrances, other than Seller Permitted Encumbrances. Other than Seller Permitted Encumbrances, Other than Seller Permitted Encumbrances, Seller has not granted to any Third Party any rights in or to (i) any of the Assigned Patent Rights or (ii) to the Knowledge of Seller, except as set forth on Schedule 3.1(e), any Know-How or Materials, or interests therein, that are owned by the Seller or any of its Affiliates and are solely related to, and are necessary for the research, development, manufacture, commercialization or other exploitation of, any Product. Other than abandoned or expired Assigned Patent Rights as expressly set forth on Exhibit A-1 or Exhibit A-2, Seller is the true, lawful and exclusive (or, with respect to the jointly-owned patent rights set forth on Exhibit A-2, joint) owner of the Assigned Patent Rights. Except as set forth on Schedule 3.1(e), to the Knowledge of Seller, Seller is the true, lawful and exclusive owner of the Assigned Materials, Assigned Know-How, and Assigned Data.
- (f) No Other Assets. To the Knowledge of Seller, except as set forth on Schedule 3.1(f), Seller does not have any rights, title or interest in or to any Know-How; Materials; filings, applications or submissions with or to any Regulatory Authority; patents, patent applications or other intellectual property rights; or other assets substantially relating to any Program or Product other than the Assets. Exhibit A-1 and Exhibit A-2 sets forth all Assigned Patent Rights existing as of the Effective Date.
- (g) No Litigation. No action, suit, proceeding or investigation is pending or, to the Knowledge of Seller, threatened (i) that would reasonably be likely to have a material adverse effect on any of the Assets, (ii) that challenges the ownership or exploitation, in any respect, of any of the Assets or (iii) that challenges the rights of the Seller under, or the validity or enforceability of, any of the Assigned Patent Rights.

- (h) <u>Validity and Enforceability</u>. Except as expressly set forth on <u>Exhibit A-1</u> or <u>Exhibit A-2</u>, to the Knowledge of Seller, none of the Assigned Patent Rights has (i) been revoked or held by any court or other governmental entity to be invalid or unenforceable, in whole or in part, or (ii) expired or been withdrawn, cancelled, abandoned or finally rejected.
- (i) No Fees. To the Knowledge of Seller, there are no registration, maintenance or renewal costs, fees or charges outstanding in respect of the Assigned Patent Rights.
- (j) No Existing Programs. Neither the Seller nor any of its Affiliates has an active program under which it is researching, developing, manufacturing, commercializing or otherwise exploiting any enzyme replacement therapy, agonist, gene therapy, compound or other pharmaceutical preparation that is intended by Seller to constitute, replace or increase ENPP1 or is intended by Seller to be directed against ENPP1.
- (k) No Regulatory Submissions. Seller and its Affiliates do not own or control any Regulatory Submissions.
- (l) <u>No Seller Permitted Encumbrances</u>. To the Knowledge of Seller, there are no Seller Permitted Encumbrances. This Section 3.1(l) shall not apply to any Seller Permitted Encumbrances described in clause (b) of the definition thereof.

### 3.2 Buyer's Representations

The Buyer hereby represents and warrants to the Seller that, as of the Effective Date:

- (a) <u>Organization.</u> The Buyer is a corporation existing under the laws of the State of Delaware and has all requisite power and authority to own its properties, to carry on its business as now being conducted, to execute and deliver this Agreement, to consummate the transactions contemplated hereby, and to carry out the provisions of this Agreement.
- (b) Authorization. The execution and delivery of this Agreement by the Buyer, and the consummation by the Buyer of all transactions contemplated hereby, have been duly authorized by all requisite corporate action. This Agreement constitutes a valid and legally binding obligation of the Buyer, enforceable against the Buyer in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium and other similar laws, rules and regulations affecting creditors' rights generally and by general principles of equity.

(c) Noncontravention. The execution, delivery and performance by the Buyer of this Agreement, and the consummation by the Buyer of the transactions contemplated hereby, will not, with or without the giving of notice or the passage of time or both, (i) violate in any material respect any provision of any law, rule or regulation applicable to the Buyer; (ii) violate any provision of the articles or by-laws of the Buyer; (iii) violate any judgment, decree, order or award of any arbitrator, court or other governmental entity; or (iv) conflict with or result in the breach or termination of any term or provision of, or constitute a default under, or cause any acceleration under, or cause the creation of any Encumbrance, other than Buyer Permitted Encumbrances, upon the properties or assets of the Buyer pursuant to, any indenture, mortgage, deed of trust or other instrument or agreement to which the Buyer is a party or by which the Buyer or any of its properties is or may be bound except, with respect to clauses (i) and (iii), for any violations that would not, individually or in the aggregate, reasonably be expected to be material to the business and assets of Buyer.

# ARTICLE 4 ADDITIONAL COVENANTS

#### 4.1 Confidentiality

From and after the Effective Date, all information to the extent that it relates solely to the Assets, including the Assigned Know-How, that has not, as of the Effective Date, been disclosed to the public shall constitute confidential and proprietary information of the Buyer, and shall be deemed not to be Seller's "Information" (as defined in each Confidentiality Agreement) under either Confidentiality Agreement. The Seller agrees not to, and to ensure that its Representatives do not, (a) use any such information for any purpose other than the Internal Research License or (b) disclose to any Third Party any such information; except that the obligations set forth in this Section 4.1 shall not apply to (i) any information that is or becomes, without any fault of the Seller or any of its Representatives, part of the public domain, (ii) any information that is lawfully provided, after the Effective Date, to Seller or any of its Representatives by any Third Party rightfully in possession of such information without a duty of confidentiality owed to Buyer or (iii) any information which Seller or its Affiliates develop after the Effective Date without the use or application of any Assets or (iv) any information which Seller or its Affiliates develop after the Effective Date in practicing the Internal Research License, other than information that relates solely to any enzyme replacement therapy, agonist, gene therapy, compound or other pharmaceutical preparation that is intended by Seller or any of its Affiliates to constitute, replace or increase ENPP1 or is intended by Seller or any of its Affiliates to be directed against ENPP1. Neither Party shall disclose, and each Party shall ensure that its Representatives do not disclose, the terms of this Agreement to any Third Party, except as permitted in Section 4.2 or under the Confidentiality Agreements.

#### 4.2 Publicity

The Buyer may issue the press release attached as <u>Exhibit C</u>. Except with respect to the press release attached as <u>Exhibit C</u>, neither Party shall originate any publicity, news release or other public announcement, written or oral, relating to this Agreement without the prior written consent of the other Party (whether such other Party is named in such publicity, news release or

other public announcement or not), which consent shall not be unreasonably withheld, conditioned or delayed, except where such publicity, news release or other public announcement is required by law or any listing or trading agreement concerning its publicly traded securities, provided that, in such event, the Party issuing the same shall still be required to consult with the other Party (whether such other Party is named in such publicity, news release or public announcement or not) at least [\*\*] (or, in respect of Buyer's Form S-1 filed with the SEC on July 2, 2020 or any Form S-1/A thereto, at least [\*\*]) prior to its release to allow the other Party to comment thereon and, after its release, shall provide the other Party with a copy thereof. If Buyer, based on the advice of its counsel, determines that this Agreement must be filed with the United States Securities and Exchange Commission ("SEC") or any other similar governmental entity, then Buyer, at least [\*\*] prior to making any such filing, shall provide Seller and its counsel with a redacted version of this Agreement which it intends to file and any draft correspondence with the SEC requesting the confidential treatment by the SEC of those redacted sections of the Agreement, and will give due consideration to any timely, reasonable comments provided by Seller or its counsel and use commercially reasonable efforts to ensure the confidential treatment by the SEC of those sections specified by Seller or its counsel. Notwithstanding anything to the contrary herein, each Party may, without the prior written consent of, or notice to, the other Party, disclose in such Party's periodic filings with the SEC the existence and amount of Seller's equity interests held in Buyer.

#### 4.3 Condition of the Assets

- Buyer and its Representatives have made all inspections and investigations relating to the Assets deemed necessary or desirable by Buyer. Buyer acknowledges and agrees that (i) it is purchasing the Assets based on the results of such inspections and investigations and the representations and warranties set forth in Section 3.1, and not on any representation or warranty of Seller or any of its Affiliates not expressly set forth in Section 3.1, and (ii) subject to Section 3.1, the Assets are sold "as is, where is" and Buyer accepts the Assets in the condition they are in on the Effective Date. In light of such inspections and investigations, and the representations and warranties expressly made to Buyer by Seller in this Section 3.1, BUYER AGREES THAT SUCH REPRESENTATIONS AND WARRANTIES ARE IN LIEU OF, AND BUYER HEREBY EXPRESSLY WAIVES ALL RIGHTS TO, ANY IMPLIED WARRANTIES THAT MAY OTHERWISE BE APPLICABLE BECAUSE OF THE PROVISIONS OF THE UNIFORM COMMERCIAL CODE OR ANY OTHER LAWS, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.
- (b) Any claims Buyer may have for breach of representation or warranty under this Agreement will be based solely on the representations and warranties of Seller expressly set forth in Section 3.1.

- (c) Buyer further acknowledges and agrees that neither Seller nor any of its Affiliates has made any representation, warranty or statement, express or implied, regarding Seller, any of its Affiliates or the Assets not expressly set forth in Section 3.1 upon which Buyer has relied in executing this Agreement, and neither Seller nor any of its Affiliates will have, or be subject to, any liability to Buyer resulting from the distribution to Buyer or its Representatives, or Buyer's use of, any such representation, warranty or statement.
- (d) Without limiting the foregoing or any representation or warranty set forth in Section 3.1, Buyer acknowledges and agrees that (i) it may have received from Seller various estimates, assumptions, projections, forecasts and plans regarding the Assets (collectively, the "Forward-Looking Statements") in connection with Buyer's investigation of the Assets; (ii) there are uncertainties inherent in attempting to make such Forward-Looking Statements; (iii) Buyer is familiar with such uncertainties; (iv) Buyer is taking full responsibility for making its own investigation, examination and valuation of the Assets, and has employed outside professionals to assist with such investigation, examination and valuation; (v) Buyer is taking full responsibility for making its own evaluation of the adequacy and accuracy of all Forward-Looking Statements; and (vi) Buyer is not relying on any Forward-Looking Statement in any manner whatsoever; and (vii) Buyer has no claim against Seller or any of its Affiliates with respect to the foregoing. Buyer further acknowledges and agrees that Seller makes no representation or warranty hereunder with respect to (A) the reasonableness of the assumptions underlying any Forward-Looking Statement; or (B) any Forward-Looking Statement made in any materials or any supplemental due diligence information provided or made available to Buyer, any of Buyer's discussions with management regarding the Assets, any negotiations leading to this Agreement, or any other circumstance. Notwithstanding anything to the contrary in this Section 4.3, this Section 4.3 does not limit in any way the representations and warranties of Seller set forth in Section 3.1.

#### 4.4 Grant of License

All rights and licenses granted under or pursuant to any section of this Agreement are, for purposes of 11 U.S.C. § 365(n) or any analogous provisions in any other country or jurisdiction (the "Bankruptcy Code"), licenses of rights to "intellectual property" as defined in Section 101(56) of the Bankruptcy Code (and any equivalent provisions under the bankruptcy or insolvency laws of any other relevant jurisdiction). The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code. The non-bankrupt Party shall further be entitled to a complete duplicate of, or complete access to, any such intellectual property and all embodiments of such intellectual property, which, if not already in its possession, shall be promptly delivered to the non-bankrupt Party (a) upon the commencement of a bankruptcy proceeding upon the non-bankrupt Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-bankrupt Party.

# ARTICLE 5 INDEMNIFICATION

#### 5.1 Seller's Indemnity

The Seller shall indemnify and defend the Buyer and its Affiliates from and against any and all Losses suffered or incurred by the Buyer or any of its Affiliates to the extent as a result of or arising, directly or indirectly, out of or in connection with:

- (a) any breach by the Seller of, or any inaccuracy in, any representation or warranty of the Seller contained in Section 3.1 of this Agreement;
- (b) any breach or non-performance by the Seller of any covenant to be performed by it contained in this Agreement;
- (c) any Retained Liability; or
- (d) any Fraud or intentional misrepresentation by the Seller.

#### 5.2 Buyer's Indemnity

The Buyer shall indemnify and defend the Seller and its Affiliates from and against any and all Losses suffered or incurred by the Seller or any of its Affiliates to the extent as a result of or arising, directly or indirectly, out of or in connection with:

- (a) any breach by the Buyer of, or any inaccuracy in, any representation or warranty of the Buyer contained in Section 3.2 of this Agreement;
- (b) any breach or non-performance by the Buyer of any covenant to be performed by it which is contained in this Agreement;
- (c) any Assumed Liability;
- (d) except with respect to any Retained Liability, any event occurring on or after the Effective Date in connection with use, ownership, possession, operation, management, business integration, or transfer of any Asset by or on behalf of Buyer on or after the Effective Date (including infringement of any Third Party intellectual property rights by or on behalf of Buyer on or after the Effective Date and all Liability associated with any product that Buyer may develop, manufacture, use, commercialize or otherwise exploit using any of the Assets); or
- (e) any Fraud or intentional misrepresentation by the Buyer.

#### 5.3 Certain Limitations

- (a) All representations, warranties, covenants and obligations contained in this Agreement shall survive from and after the Effective Date; provided, however, that (i) the Fundamental Representations, the representations and warranties set forth in Section 3.2(a) and 3.2(b) or claims based on Fraud shall terminate on the earlier of (x) the expiration of any statute of limitations applicable thereto or (y) the date that is six (6) years after the Effective Date, and (ii) the other representations and warranties contained in this Agreement shall terminate on the date that is twelve (12) months after the Effective Date; provided, further, such covenants and agreements of the Parties shall survive until they are fully performed or fulfilled, except as otherwise expressly set forth in the terms of such covenants and agreements.
- (b) Notwithstanding anything to the contrary herein, Buyer shall not be entitled to be indemnified pursuant to Section 5.1(a) unless and until the aggregate of all Losses for which Buyer would, but for this Section 5.3(b), be entitled to indemnification hereunder exceeds on a cumulative basis \$[\*\*], at which point Buyer shall be entitled to be indemnified and held harmless by Seller for and against the full amount of such Losses; provided, however, that the foregoing provisions of this Section 5.3(b) shall not apply to any breach of the Fundamental Representations or claims based on Fraud.
- (c) In no event shall the aggregate amount for which Buyer shall be indemnified and held harmless under Section 5.1(a) with respect to breaches or inaccuracies of any of the representations and warranties of Seller set forth in Section 3.1, other than the Fundamental Representations or claims based on Fraud, exceed \$[\*\*]. The aggregate Liability of Seller for any Losses with respect to matters set forth in Section 5.1 shall not exceed \$[\*\*].
- (d) Each Party shall take all commercially reasonable steps to mitigate any Loss upon becoming aware of any event that would reasonably be expected to, or does, give rise to a claim for indemnification under Section 5.1 or Section 5.2, as applicable. The amount of any Loss for which indemnification is provided under Section 5.1 or Section 5.2 shall be net of any amounts actually recovered by the Indemnified Party pursuant to any indemnification by or indemnification agreement with any nonaffiliated Third Party. If the amount to be netted hereunder from any payment required under Section 5.1 or Section 5.2 is determined after payment by the Indemnifying Party of any amount otherwise required to be paid to the Indemnified Party pursuant to this Article 5, the Indemnified Party shall repay to the Indemnifying Party, promptly after such determination, any amount that the Indemnifying Party would not have had to pay pursuant to this Article 5 had such determination been made at the time of such payment. The Indemnifying Party may require, as a condition to the provision of any indemnification hereunder, that the Indemnified Party execute an undertaking consistent with its obligations set forth in this Section 5.3(d).

#### 5.4 Notice of Claim

If a Party (the "**Indemnified Party**") wishes to be indemnified with respect to any claim, demand, dispute, action, suit, examination, audit, proceeding, investigation, inquiry or other similar matter that may give rise to an indemnification obligation hereunder (each, a "**Claim**") against the other Party (the "**Indemnifying Party**") pursuant to Section 5.1 or 5.2, such Party shall deliver promptly to the other Party a written notice setting forth in reasonable particularity:

- (a) the factual basis for the Claim, and any provisions of this Agreement, or of any applicable laws, rules or regulations, relied upon; and
- (b) the amount of the Claim or, if an amount is not then determinable, an approximate and reasonable estimate of the potential amount of the

### 5.5 Defense of Third Party Actions

If the Indemnified Party receives notice or otherwise obtains knowledge of the commencement or threat of any Claim instituted by a Third Party (a "Third Party Claim") for which the Indemnified Party desires to seek indemnification from the Indemnifying Party hereunder, then the Indemnified Party shall promptly deliver to the Indemnifying Party a written notice describing such Claim, but any failure to so notify the Indemnifying Party shall relieve the Indemnifying Party from liability under this Agreement with respect to such Claim only if, and only to the extent that, such failure to notify the Indemnifying Party results in the forfeiture by the Indemnifying Party of rights and defenses otherwise available to the Indemnifying Party with respect to such Claim, or the opportunity to defend or participate in the defense of such Claim, or otherwise actually prejudices the Indemnifying Party with respect to such Claim. The Indemnifying Party shall have the right, upon written notice delivered to the Indemnified Party within [\*\*] after receipt of any such notice of a Claim, to assume the defense and control of such Claim, including the employment of counsel reasonably satisfactory to the Indemnified Party and the payment of the fees and disbursements of such counsel. In the event that the Indemnifying Party assumes, and continues to pursue in good faith, the defense and control of such Claim using counsel reasonably satisfactory to the Indemnified Party, then the Indemnified Party shall be entitled to participate in (but not control) the defense of such Claim, with its counsel and at its own expense. In the event that the Indemnifying Party declines or fails to assume and control, or ceases to pursue in good faith, the defense of the Claim or to employ counsel reasonably satisfactory to the Indemnified Party, then the Indemnified Party may employ counsel, reasonably acceptable to the Indemnifying Party, to represent or defend the Indemnified Party in any such Claim, and the Indemnifying Party shall pay the reasonable fees and disbursements of such counsel as incurred, subject to the monetary limitations set forth in this Article 5; except that the Indemnifying Party shall not be required to pay the fees and disbursements of more than one (1) counsel in any jurisdiction in any single Claim and the Indemnifying Party nevertheless shall have the right to participate in the defense of any Third Party Claim and, at its own expense, to employ counsel of its own choosing for such purpose. The Indemnified Party may not settle or compromise any claim or consent to the entry of any judgment with respect to which indemnification is sought hereunder without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld, conditioned or delayed. The Indemnifying Party shall not settle any claim or assertion in any manner that would impose any obligation on the

Indemnified Party (other than solely financial obligations against which Indemnifying Party fully indemnifies the Indemnified Party in accordance with this Article 5), unless the Indemnified Party consents in writing to such settlement, which consent shall not be unreasonably withheld, conditioned or delayed.

#### 5.6 Effect of Knowledge

Buyer shall not be entitled to any indemnification hereunder with respect to any breach of any representation or warranty with respect to which Buyer had actual knowledge of such breach as of the Effective Date.

#### 5.7 No Consequential Damages

NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED HEREIN, WITH THE EXCEPTION (I) OF RELIEF MANDATED BY STATUTE AND (II) A PARTY'S INDEMNIFICATION OBLIGATIONS FOR ANY LOSS INCURRED OR SUFFERED AS A RESULT OF ANY THIRD PARTY CLAIM, NO PARTY TO THIS AGREEMENT SHALL BE LIABLE TO OR OTHERWISE RESPONSIBLE TO THE OTHER PARTY OR ANY AFFILIATE OF THE OTHER PARTY FOR LOST REVENUES OR PROFITS DAMAGES OR INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE, EXEMPLARY OR MULTIPLIED DAMAGES OR ATTORNEYS FEES, COSTS OR PREJUDGMENT INTEREST THAT ARISE OUT OF OR RELATE TO THIS AGREEMENT OR THE PERFORMANCE OR BREACH HEREOF OR ANY LIABILITY RETAINED OR ASSUMED HEREUNDER.

#### 5.8 Exclusive Remedy

Except as set forth in Section 6.6, this Article 5 provides the sole and exclusive means by which a Party may assert and remedy any claims arising under this Agreement. Except as set forth in Section 6.6, each Party hereby waives and releases any other remedies or claims that it may have against the other Party (or any of its Affiliates) with respect to the matters arising out of or in connection with this Agreement, except that nothing herein shall limit the liability of any Party hereto for Fraud. With respect to any Losses arising under this Agreement, the Parties agree that they shall only seek such Losses from the other Party and hereby waive the right to seek Losses from or equitable remedies, such as injunctive relief, against any Affiliate of the other Party or any Representative thereof (or any of its Affiliates).

# ARTICLE 6 GENERAL

#### 6.1 Notices

Any notices or other communications required or permitted hereunder shall be in writing and shall be sufficiently given if delivered personally or sent by facsimile, internationally recognized overnight courier or registered or certified mail, postage prepaid, addressed as follows (or such other address for a Party as may be specified in a notice provided pursuant to this Section 6.1):

(a) To the Seller: Alexion Pharmaceuticals, Inc.

121 Seaport Boulevard Boston, MA 02210 Attention: [\*\*] Email: [\*\*]

with a copy (which shall not constitute notice) to: Ropes & Gray LLP Prudential Tower 800 Boylston Street Boston, MA 02199

Attention: Mark Bellomy

Bradford Flint

Email: Mark.Bellomy@ropesgray.com

Bradford.Flint@ropesgray.com

(b) To the Buyer: Inozyme Pharma, Inc.

321 Summer Street, Floor 4

Boston, MA 02210 Attention: Axel Bolte Damon Banks

with a copy (which shall not constitute notice) to: WilmerHale LLP 60 State Street Boston, MA 02109

Attention: Brian A. Johnson

Steven D. Barrett

Email: brian.johnson@wilmerhale.com

steven.barrett@wilmerhale.com

Unless otherwise specified herein, each such notice or other communication will be deemed received (a) on the date delivered, if delivered personally, (b) on the date the facsimile was successfully transmitted to the receiving Party or (c) on the date the registered, certified or overnight mail was received by the receiving Party.

#### 6.2 Assignment; Successors and Assigns; No Third Party Beneficiaries

Neither this Agreement nor any of the rights, interests or obligations hereunder shall be assigned or delegated by any Party (whether by operation of law or otherwise) without the prior written consent of the other Party. Notwithstanding the immediately preceding sentence, (a) either Party may, without the other Party's prior written consent, assign or delegate this Agreement or any of its rights, interests or obligations hereunder, in whole or in part, to an Affiliate and (b) either Party may, without the other Party's prior written consent, assign or delegate this Agreement or any of its rights or obligations hereunder, in whole or in part, to a Third Party that acquires, by or otherwise in connection with any merger, sale of assets or otherwise, all or substantially all of the business of such Party to which the subject matter of this Agreement relates; except that (x) in the case of an acquisition of less than all or substantially all of the entire business of Seller, neither Seller nor any of its Affiliates may assign the Internal Research License to any Third Party and, upon any such assignment of this Agreement in the case of an acquisition of less than all or substantially all of the entire business of Seller, the Internal Research License shall immediately terminate, (y) any Third Party assignee of Seller's rights under this Agreement must agree in writing to assume all of Seller's obligations under this Agreement, including Seller's obligations under Section 2.3, and (z) the assigning Party shall not be relieved of any of its obligations under this Agreement. All of the covenants and agreements in this Agreement shall be binding upon the Parties and their respective successors and permitted assigns and shall inure to the benefit of and be enforceable by the Parties and their respective successors and permitted assigns. Any purported assignment in violation of this Section 6.2 will be null and void *ab initio*. Other than in respect of Section 6.12, there are no express or implied Third Party beneficia

#### 6.3 Independent Contractors

Nothing contained in this Agreement is intended or shall be deemed or construed to create any relationship of employer and employee, agent and principal, partnership or joint venture between the Parties, including for all applicable tax purposes. Each Party is an independent contractor. No Party shall assume, either directly or indirectly, any liability of or for the other Party. No Party shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party, nor to bind the other Party to any contract or other agreement or undertaking with any Third Party.

#### 6.4 Governing Law

This Agreement shall be construed and enforced in accordance with, and the respective rights and obligations of the Parties shall be governed by, the laws of the State of Delaware, without reference to conflicts of laws principles.

#### 6.5 Dispute Resolution

Each Party irrevocably submits to the exclusive jurisdiction of (a) the Suffolk County Superior Court of the Commonwealth of Massachusetts and (b) the United States District Court for the District of Massachusetts ((a) and (b), collectively, the "Courts"), for the purposes of any suit, action or other proceeding arising out of this Agreement or out of any transaction contemplated hereby. Each Party agrees to commence any such action, suit or proceeding either in the United States District Court for the District of Massachusetts or, if such suit, action or other proceeding may not be brought in such court for jurisdictional reasons, in the Suffolk County Superior Court of the Commonwealth of Massachusetts. Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the transactions contemplated hereby in any Court, and hereby and thereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such Court that any such action, suit or proceeding brought in any such Court has been brought in an inconvenient forum. Each Party agrees that service of any court paper may be made in the manner provided for in Section 6.1 (excluding facsimile) or such other as may be provided under applicable laws or court rules governing service of process. Notwithstanding anything to the contrary in this Section 6.5, each Party shall have the right to bring any action, suit or proceeding in any court anywhere in the world to the extent necessary to enforce any judgment obtained in any action, suit or proceeding brought in any Court. THE PARTIES HERETO HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVE, AND AGREE TO CAUSE THEIR RESPECTIVE AFFILIATES TO WAIVE, THE RIGHT TO TRIAL BY JURY IN ANY ACTION DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS AGREEMENT OR ANY OF THE TRANSACTIONS CONTEMPLATED HEREBY, EACH PARTY CERTIFIES AND ACKNOWLEDGES THAT (I) NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER, (II) EACH PARTY UNDERSTANDS AND HAS CONSIDERED THE IMPLICATIONS OF THIS WAIVER, (III) EACH PARTY MAKES THIS WAIVER VOLUNTARILY, AND (IV) EACH PARTY HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 6.5.

#### 6.6 Specific Performance

Each Party acknowledges and agrees that the other Party would be damaged irreparably in the event that such Party's obligation to effect the transactions contemplated by this Agreement is not performed or is otherwise breached or violated. Accordingly, each Party agrees that, without posting bond or other undertaking, the non-breaching Party shall be entitled to an injunction or injunctions to prevent breaches or violations of the obligation of the breaching Party to enforce specifically this Agreement and the terms and provisions hereof in any action instituted in any court specified in Section 6.5 in addition to any other remedy to which the non-breaching Party may be entitled, at law or in equity. Each Party further agrees that, in the event of any action for an injunction or specific performance in respect of any such threatened or actual breach or violation, it shall not assert that a remedy at law would be adequate.

#### 6.7 Entire Agreement

This Agreement (including the Exhibits attached hereto) and the Confidentiality Agreements constitute the entire agreement between the Parties with respect to the subject matter hereof, and supersede all prior and contemporaneous agreements, understandings, negotiations and discussions, whether oral or written, with respect thereto between the Parties. In the event of any conflict between any term in any Confidentiality Agreement and any term in this Agreement, this Agreement shall govern. The Parties may amend or modify this Agreement, in such manner as may be agreed upon by the Parties, by a written instrument executed by the Buyer and the Seller.

#### 6.8 Severability

This Agreement should not be considered only as an indivisible whole. If any provision of this Agreement is invalid, illegal or unenforceable in any respect, all other provisions of this Agreement shall nevertheless remain in full force and effect so long as the economic and legal substance of the transactions contemplated hereby remains consistent with the original intent of the Parties as of the date of this Agreement.

#### 6.9 Waiver

No waiver of any of the provisions of this Agreement shall be binding on a Party unless consented to in writing by that Party; no waiver shall constitute or shall be deemed to constitute a waiver of any other provision (whether or not similar); nor shall any waiver constitute a continuing waiver unless otherwise expressed or provided in a writing signed by the waiving Party.

#### 6.10 Expenses

Except as otherwise expressly provided herein, the Buyer and the Seller shall each pay their own expenses in connection with this Agreement and the transactions contemplated hereby.

#### 6.11 Counterparts

This Agreement may be executed in counterparts, all of which taken together will be regarded as one and the same instrument. Counterparts may be delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal ESIGN Act of 2000, and any counterpart so delivered will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

#### 6.12 Waiver of Conflicts

Buyer acknowledges and agrees that Seller is a client of Ropes & Gray LLP (the "**Firm**"). Buyer agrees that Buyer and its Affiliates shall not disqualify the Firm from representing, and Buyer hereby agrees that the Firm may represent, Seller in connection with any dispute that may arise between the Parties or their respective Affiliates in connection with this Agreement or the transactions contemplated hereby. Buyer consents thereto, and waives any conflict of interest

arising therefrom. Buyer acknowledges that such consent and waiver is voluntary, that it has been carefully considered, and that Buyer has consulted with counsel or has been advised they should do so in this connection. Buyer hereby acknowledges that any attorney-client privilege or attorney work-product protection between the Firm and Seller solely in connection with the negotiation, documentation and consummation of the transactions contemplated by this Agreement prior to the Effective Date shall, on and after the Effective Date, belong to and be controlled by Seller and constitute Excluded Assets (the "Retained Privilege"). In connection with any such dispute that may arise between the Parties or their respective Affiliates in connection with this Agreement or the transactions contemplated hereby, Seller shall have the sole right to decide whether or not to waive the Retained Privilege. Notwithstanding any other provision herein, no term of this Section 6.12 may be amended, waived or modified, without the prior written consent of Seller and the Firm.

[Signature page follows]

**IN WITNESS WHEREOF** the Parties have executed this Intellectual Property Asset Purchase Agreement as of the date first above written.

#### INOZYME PHARMA, INC.

By: /s/ Axel Bolte

Name: Axel Bolte

Title: President and Chief Executive Officer

[Signature Page to Intellectual Property Asset Purchase Agreement]

**IN WITNESS WHEREOF** the Parties have executed this Intellectual Property Asset Purchase Agreement as of the date first above written.

#### ALEXION PHARMACEUTICALS, INC.

By: /s/ Aradhana Sarin

Name: Aradhana Sarin Title: Chief Financial Officer

[Signature Page to Intellectual Property Asset Purchase Agreement]

#### SECOND AMENDED AND RESTATED

#### CERTIFICATE OF INCORPORATION

**OF** 

#### INOZYME PHARMA, INC.

Pursuant to Sections 242 and 245 of the General Corporation Law of the State of Delaware

Inozyme Pharma, Inc, (the "*Corporation*"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the "*DGCL*"), does hereby certify as follows:

FIRST: The name of the Corporation is Inozyme Pharma, Inc.

**SECOND:** The Certificate of Incorporation of the Corporation initially was originally filed with the Secretary of State of the State of Delaware on January 12, 2017. The original Certificate of Incorporation was amended and restated on April 13, 2017, as amended January 19, 2017.

THIRD: The Certificate of Incorporation of the Corporation is hereby amended and restated in its entirety as follows:

#### CERTIFICATE OF INCORPORATION

OF

#### INOZYME PHARMA, INC.

#### ARTICLE I.

The name of this corporation is Inozyme Pharma, Inc. (the "Company").

#### ARTICLE II.

The address of the registered office of this Company in the State of Delaware is The Corporation Trust Center, 1209 Orange Street, in the city of Wilmington, county of New Castle, Zip Code 19801, and the name of the registered agent of this Company in the State of Delaware at such address is The Corporation Trust Company.

#### ARTICLE III.

The purpose of the Company is to engage in any lawful act or activity for which a corporation may be organized under the General Corporation Law of the State of Delaware, as the same exists or as may hereafter be amended from time to time ("*DGCL*"),

#### ARTICLE IV.

- **A.** The Company is authorized to issue two classes of stock to be designated, respectively, "Common Stock" and "Preferred Stock." The total number of shares that the Company is authorized to issue is One Hundred Eighty One Million Eight Hundred One Thousand Forty Four (181,801,044) shares, One Hundred Four Million (104,000,000) shares of which shall be Common Stock (the "*Common Stock*") and Seventy Seven Million Eight Hundred One Thousand Forty Four (77,801,044) shares of which shall be Preferred Stock (the "*Preferred Stock*"). The Common Stock shall have a par value of \$0.0001 per share and the Preferred Stock shall have a par value of \$0.0001 per share.
- **B.** The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares of Common Stock then outstanding) by the affirmative vote of the holders of a majority of the stock of the Company entitled to vote, voting together as a single class, with holders of shares of Series A Convertible Preferred Stock entitled to the number of votes per share provided in Section 2(a) of Article IV.D., and without a separate class vote by the holders of Common Stock, irrespective of the provisions of Section 242(b)(2) of the DGCL.
- **C.** Forty Eight Million Eight Hundred Fifty Thousand (48,850,000) of the authorized shares of Preferred Stock are hereby designated "*Series A Convertible Preferred Stock*" and Twenty Eight Million Nine Hundred Fifty One Thousand Forty Four (28,951,044) of the authorized shares of Preferred Stock are hereby designated "*Series A-2 Convertible Preferred Stock*". The Series A Convertible Preferred Stock and the Series A-2 Convertible Preferred Stock are collectively referred to herein as the "*Series A Preferred*."
  - D. The rights, preferences, privileges, restrictions and other matters relating to the Series A Preferred are as follows:

#### SERIES A PREFERRED

#### 1. DIVIDEND RIGHTS.

(a) The Company shall not declare, pay or set aside for payment any dividends on shares of any other class or series of capital stock of the Company (other than dividends on shares of Common Stock payable in shares of Common Stock) unless (in addition to the obtaining of any vote or approval required by Section 2(b)(viii) of Article IV.D.) prior to or simultaneous with such declaration, payment or setting aside the Company shall pay, or declare and set aside for payment to holders of the outstanding Series A Preferred, a dividend on each outstanding share of the applicable series of Series A Preferred in an amount equal to (i) in the case of a dividend on Common Stock, the product of the amount of such dividend per share of Common Stock times the number of shares of Common Stock into which one share of such series of Series A Preferred is convertible at the close of business on the record date for such dividend,

(ii) in the case of a dividend on any class or series of the Company's stock that is convertible into Common Stock, that dividend per share of the applicable series of Series A Preferred as would equal the product of (A) the quotient obtained by dividing the amount of the dividend payable on each share of such class or series on which a dividend is being declared, paid or set aside by the number of shares of Common Stock into which each share of such class or series is convertible at the close of business on the record date for such dividend, and (B) the number of shares of Common Stock issuable upon conversion of a share of such series of Series A Preferred, calculated at the close of business on the record date for determination of holders entitled to receive such dividend or (iii) in the case of a dividend on any class or series of stock of the Company that is not convertible into Common Stock, at a rate per share of the applicable series of Series A Preferred determined by (A) dividing the amount of the dividend payable on each share of such class or series of capital stock by the original issuance price of such class or series of capital stock (subject to proportionate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to shares of such class or series) and (B) multiplying such rate by an amount equal to the applicable Original Issue Price (as defined below),

- **(b)** The "*Original Issue Price*" of (i) the Series A Convertible Preferred Stock shall be \$1.00 (as proportionately adjusted for any stock dividends, combinations, splits, recapitalizations and the like with respect to such shares) and (ii) the Series A-2 Convertible Preferred Stock shall be \$1.43 (as proportionately adjusted for any stock dividends, combinations, splits, recapitalizations and the like with respect to such shares).
- (c) So long as any shares of Series A Preferred are outstanding, the Company shall not declare, pay, or set aside for payment, any dividends (whether in cash or property), or make any other distribution, on the Common Stock, or purchase, redeem or otherwise acquire for value any shares of any other class or series of capital stock of the Company, until all dividends as set forth in Section 1(a) above on each applicable series of Series A Preferred shall have been paid or declared and set aside for payment, except for:
- (i) acquisitions of Common Stock by the Company from employees or consultants pursuant to agreements that permit the Company to repurchase such shares at no more than cost upon termination of services to the Company or the occurrence of other events as may be specified in such agreements;
- (ii) acquisitions of Common Stock or Series A Preferred in exercise of the Company's right of first refusal to repurchase such shares; or
  - (iii) distributions to holders of Common Stock in accordance with Section 3.
- **(d)** The provisions of Sections 1(c) shall not apply to a dividend payable solely in Common Stock to which the provisions of Section 4(f) hereof are applicable, or any repurchase of any outstanding securities of the Company that is approved by (i) the Board of Directors of the Company (the "*Board*") and (ii) holders of the Series A Preferred as may be required by Section 2(b)(viii) of this Article IV.D.

#### 2. VOTING RIGHTS.

- (a) General Rights. On any matter presented to the stockholders of the Company for their action or consideration at any meeting of stockholders of the Company (or by written consent of stockholders in lieu of meeting) other than the election of directors pursuant to Section 2(d)(ii) of this Article IV.D., each holder of shares of Series A Preferred shall be entitled to cast the number of votes equal to the number of shares of Common Stock into which such holder's shares of Series A Preferred could be converted (pursuant to Section 4 hereof) (x) at the close of business on the record date fixed for such meeting or (y) on the effective date of such written consent and shall be entitled to notice of any stockholders' meeting in accordance with the By-laws of the Company. Except as otherwise provided herein or as required by law, the Series A Preferred shall vote together with the Common Stock at any annual or special meeting of the stockholders and not as a separate class, and on any matter to be acted upon by written consent in lieu of a meeting shall act together with the Common Stock and not as a separate class.
- **(b) Separate Vote of Series A Preferred.** For so long as at least 9,572,255 shares of Series A Preferred remain outstanding (as proportionately adjusted for any stock dividends, combinations, splits, recapitalizations and the like with respect to such shares), in addition to any other vote or consent of the stockholders or the Board required herein or by law or the By-laws of the Company, the Company shall not, either directly or indirectly by amendment, merger, recapitalization, consolidation or otherwise, do any of the following without the prior affirmative vote of, or written consent in lieu of a meeting by, the holders of at least 56% of the then outstanding shares of Series A Preferred (the "*Required Majority*"), voting or consenting (as the case may be) as a single class on an as-converted basis, and any such act or transaction entered into without such consent or vote, shall be null and void *ab initio*, and of no force or effect:
- (i) Amend, alter, or repeal any provision of the Certificate of Incorporation or the Bylaws of the Company (including any filing with the Secretary of State of a certificate designating the rights and preferences of any class or series of capital stock of the Company pursuant to Section 151(g) of the DGCL) that alters or changes the voting or other powers, preferences, or other special rights, privileges or restrictions of the Series A Preferred:
  - (ii) Increase the authorized number of shares of Common Stock or Preferred Stock:
  - (iii) Amend, alter, or repeal any provision of an employee stock or option plan;
- **(iv)** Approve, authorize, or undertake any new financing or other transaction in which the Company raises capital (inclusive of equity, bridge notes, warrants, or other financing vehicles or structures, including corporate partnerships for the purpose of researching, developing or commercializing any of the Company's products);
- (v) Approve, authorize, make, or issue any borrowings, loans or guarantees, if the aggregate amount of such borrowing, loan and/or guarantee outstanding at any one time would exceed \$500,000;
- (vi) Authorize, designate or issue, whether by reclassification or otherwise, any new class or series of stock or any other equity or debt securities convertible into

capital stock of the Company that would have rights to vote as a separate class or that would rank on parity with or senior to the Series A Preferred in right of redemption, liquidation preference, or dividend rights or increase the authorized number of shares of any such class or series;

- **(vii)** Terminate the employment of any officer of the Company, hire any new officer of the Company, make any change in the officer position held by any existing employee or appoint or elect any employee to an officer position with the Company;
- (viii) Make any redemption, repurchase, payment or declaration of cash dividends or other distributions with respect to Common Stock or Preferred Stock (except for acquisitions of Common Stock by the Company permitted by Section 1(c)(i), (ii) and (iii) of this Article IV.D.);
- (ix) Enter into any agreement by the Company regarding a Liquidation Event, an Asset Transfer or Acquisition (each as defined in Section 3 hereof) or a license of material intellectual property out of the ordinary course of business;
- **(x)** Dissolve, liquidate or wind-up the business and affairs of the Company or undertake any reclassification or recapitalization of the outstanding capital stock of the Company, or consent to any of the foregoing;
  - (xi) Increase or decrease the authorized number of, or method of selecting, members of the Board.
- (xii) Enter into any interested party transaction (which shall mean a transaction between the Company and any director, officer, consultant, employee or stockholder of the Company or any affiliate or "associate" (as defined in Rule 12b-2 promulgated under the Exchange Act) of any such persons), unless approved by the Board (including a majority of disinterested Directors);
- (xiii) Make any loan or advance, or enter into any agreement in contemplation of making any loan or advance, to any person or entity, including but not limited to employees, consultants or directors, except advances (a) in the ordinary course of business, (b) under the terms of an employee stock or option plan duly authorized and administered by the Board or (c) as approved by the affirmative vote of a majority of the directors elected by the holders of shares of Series A Preferred pursuant to Section 2(d)(i) of this Article IV.D. (the "*Preferred Directors*") and the affirmative vote of a majority of the Board; or
- (xiv) Make any change to the type of legal entity of the Company, unless approved by the affirmative vote of a majority of the Preferred Directors and the affirmative vote of a majority of the Board.
- (c) Separate Vote of Series A-2 Convertible Preferred Stock. For so long as at least 2,244,755 shares of Series A-2 Convertible Preferred Stock remain outstanding (as proportionately adjusted for any stock dividends, combinations, splits, recapitalizations and the like with respect to such shares), in addition to any other vote or consent of the stockholders or the Board required herein or by law or the By-laws of the Company, the Company shall not, either directly or indirectly by amendment, merger, recapitalization, consolidation or otherwise, do any

of the following without the prior affirmative vote of, or written consent in lieu of a meeting by, the holders of a majority of the then outstanding shares of Series A-2 Convertible Preferred Stock, voting or consenting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote, shall be null and void *ab initio*, and of no force or effect:

- (i) Amend, alter, or repeal any provision of the Certificate of Incorporation or the By-laws of the Company (including any filing with the Secretary of State of a certificate designating the rights and preferences of any class or series of capital stock of the Company pursuant to Section 151(g) of the DGCL) that materially and adversely affects the powers, preferences or rights of the Series A-2 Convertible Preferred Stock (it being understood that the creation or authorization of a class or series of stock that is senior to, pari passu with or junior to any other class or series of stock shall not be deemed to materially and adversely affect the powers, preferences or rights of the Series A-2 Convertible Preferred Stock), except to the extent that such alteration or change is simultaneously made to all series of Preferred Stock then outstanding so as to affect all such series adversely; or
  - (ii) Increase the authorized number of shares of Series A-2 Convertible Preferred Stock.

#### (d) Election of Board of Directors.

- (i) The holders of Series A Preferred, voting as a separate class, shall be entitled to elect four (4) members of the Board at each meeting of the Company's stockholders for the election of directors or action to elect directors by written consent in lieu of a meeting, and shall have the exclusive power to remove such directors from office in accordance with applicable law and to fill any vacancy caused by the resignation, death or removal of such directors; provided, however, the right of the holders of Series A Preferred to elect four (4) members of the Board pursuant to this subsection (i) shall be correspondingly reduced in the event one or more of the holders of shares of Series A Preferred entitled to designate a Preferred Director pursuant to Section 1.2(a) of that certain Voting Agreement, dated as of a date on or about the Original Issue Date (defined below), by and among the Company, holders of the Series A Preferred and certain holders of Common Stock, as such agreement may be amended from time to time (the "Voting Agreement"), is no longer entitled to designate a Preferred Director in accordance with the provisions set forth in Section 1.2(a) of the Voting Agreement.
- (ii) The holders of Common Stock, voting as a separate class, shall be entitled to elect two (2) members of the Board at each meeting of the Company's stockholders for the election of directors or action to elect directors by written consent in lieu of a meeting, and shall have the exclusive power to remove such directors from office in accordance with applicable law and to fill any vacancy caused by the resignation, death or removal of such directors.
- (iii) The holders of Common Stock and Series A Preferred, voting together as a single class, with holders of shares of Series A Preferred entitled to the number of votes per share provided in Section 2(a) of this Article IV.D., shall be entitled to elect the balance of the members of the Board at each meeting or pursuant to each consent of the Company's stockholders for the election of directors, and to remove from office such director in accordance

with applicable law and to fill any vacancy caused by the resignation, death or removal of such director; the director nominated for a vote of stockholders under this Section 2(d)(iii) shall be nominated as provided in the Voting Agreement.

(iv) At any meeting held for the purpose of electing a director, the presence in person or by proxy of the holders of a majority of the outstanding shares of the class or series entitled to elect such director shall constitute a quorum for the purpose of electing such director.

#### 3. LIQUIDATION RIGHTS.

- (a) Upon any liquidation, dissolution, or winding up of the Company, whether voluntary or involuntary (a "Liquidation Event"), before any distribution or payment shall be made to the holders of any Common Stock, the holders of Series A Preferred shall be entitled to be paid, on a pari passu basis, out of the assets of the Company legally available for distribution (or the consideration received by the Company or its stockholders in an Acquisition) for each share of Series A Preferred held by them, an amount per share of the applicable series of Series A Preferred equal to the applicable Original Issue Price plus all declared and unpaid dividends on each such series of Series A Preferred. If, upon any such Liquidation Event, the assets of the Company shall be insufficient to make payment in full to all holders of Series A Preferred of the liquidation preference set forth in this Section 3(a), then such assets (or consideration) shall be distributed among the holders of Series A Preferred at the time outstanding, ratably in proportion to the full amounts to which they would otherwise be respectively entitled.
- **(b)** After the payment of the full liquidation preference of the Series A Preferred as set forth in Section 3(a) above, the remaining assets of the Company legally available for distribution in such Liquidation Event (or the consideration received by the Company or its stockholders in an Acquisition), if any, shall be distributed ratably to the holders of the Common Stock and Series A Preferred, with each share of Series A Preferred being treated as if converted into the number of shares of Common Stock into which such share was convertible under Section 4(a) of this Article IV.D. on the date of the Liquidation Event.
  - (c) An Asset Transfer or Acquisition (each as defined below) shall be deemed a Liquidation Event for purposes of this Section 3.
- (i) For the purposes of this Section 3: (i) "Acquisition" shall mean (A) any consolidation or merger of the Company with or into any other corporation or other entity or person, or any other corporate reorganization, other than any such consolidation, merger or reorganization in which the shares of capital stock of the Company outstanding immediately prior to such consolidation, merger or reorganization, continue to represent a majority of the voting power of the surviving or resulting entity (or, if the surviving or resulting entity is a wholly owned subsidiary, its parent) immediately after such consolidation, merger or reorganization (provided that, for the purpose of this Section 3(c), all shares of Common Stock issuable upon exercise of options outstanding immediately prior to such consolidation or merger or upon conversion of Convertible Securities (as defined below) outstanding immediately prior to such merger or consolidation shall be deemed to be outstanding immediately prior to such merger or consolidation and, if applicable, converted or exchanged in such merger or consolidation on the same terms as

the actual outstanding shares of capital stock are converted or exchanged); or (B) any transaction or series of related transactions to which the Company is a party in which in excess of fifty percent (50%) of the voting power of the outstanding capital stock of the Company's is transferred by a transfer of outstanding shares of capital stock of the Company (but excluding the issuance of stock pursuant to bona fide financings by the Company); and (ii) "Asset Transfer" shall mean a sale, lease, exclusive license or other disposition of all or substantially all of the assets of the Company.

- (ii) In any Acquisition or Asset Transfer, if the consideration to be received is securities of a corporation or other property other than cash, its value will be deemed its fair market value as determined in good faith by the Board (including at least three of the Preferred Directors) on the date such determination is made.
- (iii) The Company shall not have the power to effect an Acquisition or Asset Transfer unless the definitive agreement for such transaction (the "Agreement") provides that the consideration payable to the stockholders of the Company in connection therewith shall be allocated among the holders of capital stock of the Company in accordance with this Section 3.
- (d) In the event of a Liquidation Event, if any portion of the consideration payable to the Company or the stockholders of the Company is placed into escrow and/or is payable to the Company or the stockholders of the Company subject to contingencies, the definitive agreement for such transaction shall provide that (x) the portion of such consideration that is not placed in escrow and not subject to any contingencies (the "Initial Consideration") shall be allocated among the holders of capital stock of the Company in accordance with Section(s) 3(a) and 3(b) as if the Initial Consideration were the only consideration payable in connection with such Acquisition or Asset Transfer and (y) any additional consideration that becomes payable to the stockholders of the Company upon release from escrow or satisfaction of contingencies shall be allocated among the holders of capital stock of the Company in accordance with Section(s) 3(a) and 3(b) after taking into account the previous payment of the Initial Consideration as part of the same transaction and, if applicable, any earlier release of consideration from escrow.

#### 4. CONVERSION RIGHTS.

The holders of the Series A Preferred shall have the following rights with respect to the conversion of the Series A Preferred into shares of Common Stock (the "Conversion Rights"):

(a) Optional Conversion. Subject to and in compliance with the provisions of this Section 4, any shares of Series A Preferred may, at the option of the holder, be converted at any time after the Conversion Trigger Date, into fully-paid and nonassessable shares of Common Stock. The "Conversion Trigger Date" means the earliest to occur of: (i) the business day immediately following the date of the Milestone Closing (as defined in the Series A-2 Convertible Preferred Stock Purchase Agreement, dated on or about the Original Issue Date, by and between the Company and the purchasers of the Series A-2 Convertible Preferred Stock (the "Stock Purchase Agreement")), (ii) the business day immediately following the date of the Qualified Closing (as defined in the Stock Purchase Agreement) with respect to the Series A

Preferred held by purchasers who participate in such Qualified Closing, (iii) September 30, 2021, (iv) the date upon which the Company and the Required Majority determine that the Milestone (as defined in the Stock Purchase Agreement) will not occur, (v) the day immediately following the date on which the Board or the Company's stockholders adopt a resolution to effect a Liquidation Event, Acquisition or Asset Transfer. The number of shares of Common Stock to which a holder of Series A Preferred shall be entitled upon conversion shall be the product obtained by multiplying the "Series A Preferred Conversion Rate" then in effect (determined as provided in Section 4(b)) by the number of shares of Series A Preferred being converted.

- **(b) Series A Preferred Conversion Rate.** The conversion rate in effect at any time for conversion of a series of Series A Preferred (the "Series A Preferred Conversion Rate") shall be the quotient obtained by dividing the applicable Original Issue Price of such series of Series A Preferred by the applicable "Series A Preferred Conversion Price," calculated as provided in Section 4(c).
- **(c) Series A Preferred Conversion Price.** The conversion price for a series of Series A Preferred shall initially be the applicable Original Issue Price of such series of Series A Preferred (as applicable, the "*Series A Preferred Conversion Price*). Such initial Series A Preferred Conversion Price shall be adjusted from time to time in accordance with this Section 4. All references to the Series A Preferred Conversion Price herein at any particular date shall mean the Series A Preferred Conversion Price as so adjusted at such date.
- (d) Mechanics of Optional Conversion. Each holder of Series A Preferred who desires to convert the same into shares of Common Stock pursuant to Section 4(a) shall surrender the certificate or certificates therefor, duly endorsed, at the office of the Company or any transfer agent for the Series A Preferred, and shall give written notice to the Company at such office that such holder elects to convert the same. Such notice shall state the number of shares of Series A Preferred being converted. Thereupon, the Company shall promptly issue and deliver at such office to such holder a certificate or certificates for the number of shares of Common Stock to which such holder is entitled and shall promptly pay (i) in cash or, to the extent sufficient funds are not then legally available therefor, in Common Stock (at the Common Stock's fair market value determined by the Board as of the date of such conversion), any declared and unpaid dividends on the shares of Series A Preferred being converted and (ii) in cash (at the Common Stock's fair market value as of the date of conversion, as determined by the Board and set forth in a duly adopted resolution) the value of any fractional share of Common Stock otherwise issuable to any holder of Series A Preferred. Such conversion shall be deemed to have been made at the close of business on the date of such surrender of the certificates representing the shares of Series A Preferred to be converted, and the person entitled to receive the shares of Common Stock issuable upon such conversion shall be treated for all purposes as the record holder of such shares of Common Stock at the close of business on such date. If the conversion is in connection with an underwritten offering of securities registered pursuant to the Securities Act of 1933, as amended (the "Securities Act"), the conversion may, at the option of any holder tendering shares of Series A Preferred for conversion, be conditioned upon the closing with the underwriters of the sale of securities pursuant to such offering, in which event the persons entitled to receive the Common Stock upon conversion of the Series A Preferred shall not be deemed to have converted such Series A Preferred until immediately prior to the closing of such sale of securities.

- **(e) Adjustment for Stock Splits and Combinations.** If at any time or from time to time on or after the date that the first share of Series A-2 Convertible Preferred Stock is issued (the "*Original Issue Date*") the Company effects a subdivision of the outstanding Common Stock, each Series A Preferred Conversion Price in effect immediately before that subdivision shall be proportionately decreased. Conversely, if at any time or from time to time after the Original Issue Date the Company combines the outstanding shares of Common Stock into a smaller number of shares, each Series A Preferred Conversion Price in effect immediately before the combination shall be proportionately increased. Any adjustment under this Section 4(e) shall become effective at the close of business on the date the subdivision or combination becomes effective.
- **(f)** Adjustment for Common Stock Dividends and Distributions. If at any time or from time to time on or after the Original Issue Date the Company pays to holders of Common Stock a dividend or other distribution in additional shares of Common Stock, each Series A Preferred Conversion Price then in effect shall be decreased as of the time of such payment, as provided below:
- (i) The Series A Preferred Conversion Price shall be adjusted by multiplying the applicable Series A Preferred Conversion Price in effect immediately prior to such payment by a fraction:
- (A) the numerator of which is the total number of shares of Common Stock issued and outstanding immediately prior to the time of such payment, and
- **(B)** the denominator of which is the total number of shares of Common Stock issued and outstanding immediately prior to the time of such payment plus the number of shares of Common Stock issued in payment of such dividend or distribution;
- (ii) If the Company fixes a record date to determine which holders of Common Stock are entitled to receive such dividend or other distribution, each Series A Preferred Conversion Price shall be adjusted as of the close of business on such record date and the number of shares of Common Stock shall be calculated immediately prior to the close of business on such record date; and
- (iii) If such record date is fixed and such dividend is not fully paid or if such distribution is not fully made on the payment date fixed therefor, each Series A Preferred Conversion Price shall be recomputed accordingly as of the close of business on such record date and thereafter each Series A Preferred Conversion Price shall be adjusted pursuant to this Section 4(f) to reflect the actual payment of such dividend or distribution.
- **(g) Adjustment for Reclassification, Exchange, Substitution, Reorganization, Merger or Consolidation.** If at any time or from time to time on or after the Original Issue Date the Common Stock issuable upon the conversion of the Series A Preferred is changed into the same or a different number of shares of any class or classes of stock, whether by recapitalization, reclassification, merger, consolidation or otherwise (other than an Acquisition as defined in Section 3 or a subdivision or combination of shares or stock dividend provided for elsewhere in this Section 4), in any such event each outstanding share of Series A Preferred shall

thereafter be convertible, in lieu of the Common Stock into which it was convertible prior to such event, into the kind and amount of securities, cash or other property that a holder of the number of shares of Common Stock of the Company issuable upon conversion of one share of the applicable series of Series A Preferred immediately prior to such recapitalization, reclassification, merger, consolidation or other transaction would have been entitled to receive pursuant to such transaction, all subject to further adjustment as provided herein or with respect to such other securities or property by the terms thereof. In any such case, appropriate adjustment shall be made in the application of the provisions of this Section 4 with respect to the rights of the holders of Series A Preferred after the capital reorganization to the end that the provisions of this Section 4 (including adjustment of the Series A Preferred Conversion Price then in effect and the number of shares issuable upon conversion of the Series A Preferred) shall be applicable after that event and be as nearly equivalent as practicable.

#### (h) Sale of Shares Below Series A Preferred Conversion Price.

(i) If at any time or from time to time on or after the Original Issue Date the Company issues or sells, or is deemed by the express provisions of this Section 4(h) to have issued or sold, Additional Shares of Common Stock (as defined below), other than as provided in Section 4(e), 4(f) or 4(g) above, for an Effective Price (as defined below) less than the Series A Preferred Conversion Price in effect for such series immediately prior to such issuance, sale or deemed issuance or sale (a "Qualifying Dilutive Issuance"), then and in each such case, the applicable Series A Preferred Conversion Price in effect immediately prior to such issuance, sale or deemed issuance or sale shall be reduced, as of the time of such issuance, sale or deemed issuance or sale, to a price determined by multiplying the Series A Preferred Conversion Price in effect immediately prior to such issuance, sale or deemed issuance or sale by a fraction:

(A) the numerator of which shall be (A) the number of shares of Common Stock deemed outstanding (as determined below) immediately prior to such issue or sale, plus (B) the number of shares of Common Stock that the Aggregate Consideration (as defined below) received or deemed received by the Company for the total number of Additional Shares of Common Stock so issued would purchase at such theneffective Series A Preferred Conversion Price for such series, and

**(B)** the denominator of which shall be the number of shares of Common Stock deemed outstanding (as determined below) immediately prior to such issue or sale plus the total number of Additional Shares of Common Stock so issued.

For the purposes of the immediately preceding sentence, the number of shares of Common Stock deemed to be outstanding as of any date of determination shall be the sum of (A) the number of shares of Common Stock outstanding on such date, (B) the number of shares of Common Stock into which the shares of Series A Preferred outstanding on such date could be converted if fully converted at the close of business on the day immediately preceding such date, and (C) the number of shares of Common Stock that are issuable upon the exercise, conversion or exchange of all other rights, options and convertible securities outstanding at the close of business on the day immediately preceding such date. Shares described in (A) through (C) immediately above shall be included whether vested or unvested, whether exercisable, convertible or exchangeable contingently or non-contingently and whether convertible, exercisable, or exchangeable at the close of business on such date or not yet convertible, exercisable or exchangeable.

- (ii) Except as provided in the second sentence of this subsection (ii), no adjustment shall be made to the Series A Preferred Conversion Price in an amount less than one percent (1%) of the Series A Preferred Conversion Price then in effect. Any adjustment otherwise required by this Section 4(h) that is not required to be made due to the first sentence of this subsection (ii) shall be included in any subsequent adjustment to the Series A Preferred Conversion Price and in any event upon actual conversion of the Series A Preferred into shares of Common Stock at the time of conversion. Any adjustment required by this Section 4(h) shall be calculated to the nearest one-hundredth of a cent.
- (iii) For the purpose of making any adjustment required under this Section 4(h), the aggregate consideration received by the Company for any issue or sale of securities (the "Aggregate Consideration") shall be defined as: (A) to the extent it consists of cash, the gross amount of cash received by the Company before deduction of any underwriting, placement, finder's adviser's or similar commissions, compensation or concessions paid or allowed by the Company in connection with such issue or sale and without deduction of any expenses payable by the Company, (B) to the extent it consists of property other than cash, the fair market value of that property as determined in good faith by the Board, and (C) if Additional Shares of Common Stock, Convertible Securities (as defined below) or Options (as defined below) are issued or sold together with other stock or securities or other assets of the Company for a consideration that the Company receives for both, the portion of the consideration so received that may be reasonably determined in good faith by the Board to be allocable to such Additional Shares of Common Stock, Convertible Securities or Options.
- (iv) For the purpose of the adjustment required under this Section 4(h), if the Company issues or sells (x) any evidences of indebtedness, shares or other securities directly or indirectly convertible into or exchangeable for Additional Shares of Common Stock, but excluding Options ("Convertible Securities") or (y) rights, options or warrants to subscribe for, purchase or otherwise acquire Additional Shares of Common Stock or Convertible Securities ("Options") and if the Effective Price of such Additional Shares of Common Stock is less than the Series A Preferred Conversion Price, in each case the Company shall be deemed to have issued at the time of the issuance of such Convertible Securities or Options the maximum number of Additional Shares of Common Stock issuable upon exercise or conversion thereof and to have received as consideration for the issuance of such shares an amount equal to the total amount of the consideration, if any, received by the Company for the issuance of such Convertible Securities or Options plus:
  - (A) in the case of Options, the minimum amounts of consideration, if any, payable to the Company upon the exercise

of such Options; and

**(B)** in the case of Convertible Securities, the minimum amounts of consideration, if any, payable to the Company upon the exercise or conversion thereof (other than by cancellation of liabilities or obligations evidenced by such Convertible Securities to the extent amounts the Company received in exchange for creating such liabilities and obligations were included in the Aggregate Consideration the Company is deemed to have received for

issuance of such Additional Shares of Common Stock); *provided* that if the minimum amounts of such consideration cannot be ascertained, but are a function of antidilution or similar protective clauses, the Company shall be deemed to have received the minimum amounts of consideration without reference to such clauses.

(C) If the minimum amount of consideration payable to the Company upon the exercise or conversion of Options or Convertible Securities is reduced over time or on the occurrence or non-occurrence of specified events other than by reason of antidilution adjustments, the Effective Price shall be recalculated using the figure to which such minimum amount of consideration is reduced; *provided further*, that if the minimum amount of consideration payable to the Company upon the exercise or conversion of such Options or Convertible Securities is subsequently increased, the Effective Price shall be again recalculated, effective on the date of each increase, using the increased minimum amount of consideration payable to the Company upon the exercise or conversion of such Options or Convertible Securities.

(D) No further adjustment of the Series A Preferred Conversion Price, as adjusted upon the issuance of such Options or Convertible Securities, shall be made as a result of the actual issuance of Additional Shares of Common Stock or the exercise of any such Options or the conversion or exchange of any such Convertible Securities. If any such Options or the exercise, conversion or exchange rights represented by any such Convertible Securities shall expire without having been exercised, converted or exchanged, as applicable, the Series A Preferred Conversion Price as adjusted upon the issuance of such Options or Convertible Securities shall be readjusted to the Series A Preferred Conversion Price that would have been in effect had an adjustment been made on the basis that the only Additional Shares of Common Stock so issued were the Additional Shares of Common Stock, if any, actually issued or sold on the exercise of such Options or rights of conversion or exchange of such Convertible Securities, and such Additional Shares of Common Stock, if any, were issued or sold for the consideration actually received by the Company upon such exercise, conversion or exchange, as applicable, plus the consideration, if any, actually received by the Company for the granting of all such Options, whether or not exercised, plus the consideration received for issuing or selling the Convertible Securities actually converted, plus the consideration, if any, actually received by the Company (other than by cancellation of liabilities or obligations evidenced by such Convertible Securities to the extent amounts the Company received in exchange for creating such liabilities and obligations were included in the Aggregate Consideration the Company is deemed to have received for issuance of such Additional Shares of Common Stock) on the conversion or exchange of such Convertible Securities, provided that such readjustment shall not apply to conversions of Series A Preferred that occurred prior to such readjustment.

(v) For the purpose of making any adjustment to the Conversion Price of the Series A Preferred required under this Section 4(h), "Additional Shares of Common Stock" shall mean all shares of Common Stock issued by the Company or, pursuant to this Section 4(h), deemed to be issued by the Company (including shares of Common Stock subsequently reacquired or retired by the Company), other than the following (collectively, the "Exempted Securities"):

(A) shares of Common Stock issued or deemed to be issued upon conversion of, or as a dividend on, the Series A

Preferred:

- **(B)** shares of Common Stock or Options issued after the Original Issue Date to employees, officers or directors of, or consultants or advisors to, the Company or any subsidiary pursuant to stock purchase or stock option plans or other arrangements, which plans or other arrangements are approved by the Board, including, for plans or arrangements approved after the Original Issue Date, at least three of the Preferred Directors;
- **(C)** shares of Common Stock or Convertible Securities issued pursuant to the exercise of Options or shares of Common Stock issued upon the conversion or exchange of Convertible Securities, in each case outstanding as of the Original Issue Date;
- **(D)** shares of Common Stock, Options or Convertible Securities issued pursuant to any equipment loan or leasing arrangement, real property leasing arrangement or debt financing from a bank or similar financial or lending institution approved by the Board, including at least three of the Preferred Directors;
- (E) shares of Common Stock, Options or Convertible Securities issued in connection with any strategic transactions involving the Company and another entity or any acquisition by the Company of another business (whether by merger, consolidation, purchase of stock or assets, lease, license or otherwise) which transaction has been approved by the Board, including at least three of the Preferred Directors, including, without limitation (i) joint ventures, (ii) development, joint development and co-development arrangements, (iii) strategic alliances, (iv) licensing transactions and (v) corporate partnering arrangements;
  - **(F)** shares of Common Stock issued in a Qualified Public Offering (as defined below);
- (G) shares of Common Stock or Convertible Securities issued on exercise of Options or shares of Common Stock issued upon conversion or exchange of Convertible Securities for which any adjustment to the Conversion Price under this Section 4(h) was made at the time of issuance of such Option or Convertible Security, in each case, provided such issuance is pursuant to the terms of such Option or Convertible Security; and
- **(H)** shares of Common Stock issued in a transaction or circumstance described in Section 4(e), 4(f) or 4(g) and for which adjustment, if any, is provided therein.
- The "Effective Price" of Additional Shares of Common Stock shall mean the quotient determined by dividing the total number of Additional Shares of Common Stock issued or sold, or deemed to have been issued or sold by the Company under this Section 4(h), into the Aggregate Consideration received, or deemed to have been received by the Company for such issue under this Section 4(h), for such Additional Shares of Common Stock. In the event that the number of Additional Shares of Common Stock or the Effective Price cannot be ascertained at the time of issuance, such Additional Shares of Common Stock shall be deemed issued immediately upon the occurrence of the first event that makes such number of shares or the Effective Price, as applicable, ascertainable.
- (vi) In the event that the Company issues or sells, or is deemed to have issued or sold, Additional Shares of Common Stock in a Qualifying Dilutive Issuance (the

"First Dilutive Issuance"), then in the event that the Company issues or sells, or is deemed to have issued or sold, Additional Shares of Common Stock in a Qualifying Dilutive Issuance other than the First Dilutive Issuance as a part of the same transaction or series of related transactions as the First Dilutive Issuance (a "Subsequent Dilutive Issuance"), then and in each such case upon a Subsequent Dilutive Issuance the Series A Preferred Conversion Price shall be reduced to the Series A Preferred Conversion Price that would have been in effect had the First Dilutive Issuance and each Subsequent Dilutive Issuance all occurred on the closing date of the First Dilutive Issuance.

(vii) No Adjustment of Conversion Price. No adjustment in the Series A Conversion Price of a series of Series A Preferred shall be made as the result of the issuance or deemed issuance of Additional Shares of Common Stock if the Corporation receives written notice from the holders of a majority of the outstanding shares of such series agreeing that no such adjustment shall be made as the result of the issuance or deemed issuance of such Additional Shares of Common Stock.

- (i) Certificate of Adjustment. In each case of an adjustment or readjustment of the Series A Preferred Conversion Price, the Company, at its expense, shall compute such adjustment or readjustment in accordance with the provisions hereof and shall, upon request, prepare a certificate showing such adjustment or readjustment, and shall mail such certificate, by first class mail, postage prepaid, to each holder of record of each applicable series of Series A Preferred so requesting at the holder's address as shown in the Company's stock ledger. The certificate shall state the adjusted or readjusted Series A Conversion Price and show in reasonable detail the facts upon which such adjustment or readjustment is based, including a statement of (i) the Aggregate Consideration received or deemed to be received by the Company for any Additional Shares of Common Stock issued or sold or deemed to have been issued or sold, (ii) the applicable Series A Preferred Conversion Price in effect immediately prior to such adjustment or readjustment, (iii) the number of Additional Shares of Common Stock issued, deemed issued or no longer issued or deemed issued and in respect of which such adjustment or readjustment has been made and (iv) the type and amount, if any, of other property that at the time would be received upon conversion of the Series A Preferred. Failure to request or provide such notice shall have no effect on any such adjustment or readjustment.
- (j) Notices of Record Date. Upon (i) any taking by the Company of a record of the holders of any class of securities for the purpose of determining the holders thereof who are entitled to receive any dividend or other distribution, or (ii) any Acquisition (as defined in Section 3) or other capital reorganization of the Company, any reclassification or recapitalization of the capital stock of the Company, any merger or consolidation of the Company with or into any other corporation, or any stockholder vote on any Asset Transfer (as defined in Section 3), or any voluntary or involuntary dissolution, liquidation or winding up of the Company, the Company shall mail to each holder of Series A Preferred at least ten days prior to (x) the record date, if any, specified therein; or (y) if no record date is specified, the date upon which such action is to take effect (or, in either case, such shorter period approved by the Required Majority) a notice specifying (A) the date on which any such record is to be taken for the purpose of such dividend or distribution and a description of such dividend or distribution, (B) the date on which any such Acquisition, reorganization, reclassification, transfer, consolidation, merger, Asset Transfer, dissolution, liquidation or winding up is expected to become effective, and (C) the date, if any,

that is to be fixed as to when the holders of record of Common Stock (or other securities) shall be entitled to exchange their shares of Common Stock (or other securities) for securities or other property deliverable upon such Acquisition, reorganization, reclassification, transfer, consolidation, merger, Asset Transfer, dissolution, liquidation or winding up.

#### (k) Automatic Conversion.

- (i) Each share of Series A Preferred shall automatically be converted into shares of Common Stock, at the Series A Preferred Conversion Price in effect at the time of such conversion, (A) at any time upon the written consent of the Required Majority or (B) immediately upon the closing of a firmly underwritten public offering pursuant to an effective registration statement under the Securities Act covering the offer and sale of Common Stock for the account of the Company in which (i) the per share price is at least \$3.00 (as proportionately adjusted for any stock dividends, combinations, splits, recapitalizations and the like with respect to the Common Stock after the Original Issue Date), and (ii) the gross cash proceeds to the Company (before underwriting discounts, commissions and fees) are at least \$50,000,000 (a "Qualified Public Offering"). Upon such automatic conversion, any declared and unpaid dividends shall be paid in accordance with the provisions of Section 4(d).
- (ii) Upon the occurrence of either of the events specified in Section 4(k)(i) above, the outstanding shares of Series A Preferred shall be converted automatically without any further action by the holders of such shares and whether or not the certificates representing such shares are surrendered to the Company or its transfer agent; *provided*, *however*, that the Company shall not be obligated to issue certificates evidencing the shares of Common Stock issuable upon such conversion unless the certificates evidencing such shares of Series A Preferred are either delivered to the Company or its transfer agent as provided below, or the holder notifies the Company or its transfer agent that such certificates have been lost, stolen or destroyed and executes an agreement satisfactory to the Company to indemnify the Company from any loss incurred by it in connection with such certificates and provides a bond. Upon the occurrence of such automatic conversion of the Series A Preferred, the holders of Series A Preferred shall surrender the certificates representing such shares at the office of the Company or any transfer agent for the Series A Preferred. Thereupon, there shall be issued and delivered to such holder promptly at such office and in its name as shown on such surrendered certificate or certificates, a certificate or certificates for the number of shares of Common Stock into which the shares of Series A Preferred surrendered were converted on the date on which such automatic conversion occurred, and any declared and unpaid dividends shall be paid in accordance with the provisions of Section 4(d).
- (I) Fractional Shares. No fractional shares of Common Stock shall be issued upon conversion of Series A Preferred. All shares of Common Stock (including fractions thereof) issuable upon conversion of more than one share of Series A Preferred by a holder thereof shall be aggregated for purposes of determining whether the conversion would result in the issuance of any fractional share. If after the aforementioned aggregation the conversion would result in the issuance of any fractional share, the Company shall, in lieu of issuing any fractional share, pay cash equal to the product of such fraction multiplied by the fair market value of one share of Common Stock (as determined by the Board) on the date of conversion.

- (m) Reservation of Stock Issuable Upon Conversion. The Company shall at all times reserve and keep available out of its authorized but unissued shares of Common Stock, solely for the purpose of effecting the conversion of the shares of the Series A Preferred, such number of its shares of Common Stock as shall from time to time be sufficient to effect the conversion of all outstanding shares of the Series A Preferred. If at any time the number of authorized but unissued shares of Common Stock shall not be sufficient to effect the conversion of all then outstanding shares of the Series A Preferred, the Company will take such corporate action as may be necessary to increase its authorized but unissued shares of Common Stock to such number of shares as shall be sufficient for such purpose.
- (n) Notices. Any notice required by the provisions of this Section 4 shall be in writing and shall be deemed effectively given; (i) upon personal delivery to the party to be notified, (ii) when sent by electronic transmission in compliance with the provisions of the DGCL if sent during normal business hours of the recipient; if not, then on the next business day, (iii) five days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (iv) one day after deposit with a nationally recognized overnight courier, specifying next day delivery, with verification of receipt. All notices shall be addressed to each holder of record at the address of such holder appearing on the books of the Company.
- **(o) Payment of Taxes.** The Company will pay all taxes (other than taxes based upon income) and other governmental charges that may be imposed with respect to the issue or delivery of shares of Common Stock upon conversion of shares of Series A Preferred, excluding any tax or other charge imposed in connection with any transfer involved in the issue and delivery of shares of Common Stock in a name other than that in which the shares of Series A Preferred so converted were registered.

#### (p) Special Mandatory Conversion.

- (i) Subject to clause (iv) below, if a holder of Series A-2 Convertible Preferred Stock does not either (i) participate in the Milestone Closing (as defined in the Stock Purchase Agreement) by purchasing at least the number of shares of Series A-2 Convertible Preferred Stock set forth opposite such holder's name on Exhibit A-2 to the Stock Purchase Agreement (the "Milestone Shares") (provided that, the Company has sent to such holder a Milestone-Based Notice (as defined in the Stock Purchase Agreement) within the time period specified by Section 2.4 of the Stock Purchase Agreement) or (ii) prior to the Milestone Closing, participate in a Qualified Closing (as defined in the Stock Purchase Agreement), then immediately upon completion of the Milestone Closing each share of Series A-2 Convertible Preferred Stock held by such holder or any of its Affiliates shall automatically, and without any further action on the part of such holder or Affiliate, be converted into shares of Common Stock at the conversion ratio determined by dividing (x) the applicable Original Issue Price by (y) the product of five (5) and the applicable Conversion Price in effect immediately prior to the consummation of such Milestone Closing (such conversion, a "Special Mandatory Conversion").
- (ii) Promptly after a Special Mandatory Conversion, the Company shall give notice of such Special Mandatory Conversion, in accordance with the Stock Purchase Agreement, to each holder of shares of Series A-2 Convertible Preferred Stock converted pursuant to Section 4(p)(i) (a "Special Mandatory Conversion Notice"). Upon receipt of a Special

Mandatory Conversion Notice, a holder of such shares of Series A-2 Convertible Preferred Stock in certificated form shall surrender his, her or its certificate or certificates for all such shares (or, if such holder alleges that any such certificate has been lost, stolen or destroyed, a lost certificate affidavit, an agreement, in the form specified by the Company, of such holder to indemnify the Company against any claim that may be made against the Company on account of the alleged loss, theft or destruction of such certificate and a bond if so required by the Company) to the Company at the place designated in the Special Mandatory Conversion Notice. If so required by the Company, any certificates surrendered for conversion shall be endorsed or accompanied by written instrument or instruments of transfer, in form satisfactory to the Company, duly executed by the registered holder or by his, her or its attorney duly authorized in writing. All rights as a holder of Series A-2 Convertible Preferred Stock in respect of the shares converted pursuant to Section 4(p)(i), including, without limitation, the rights, if any, to receive notices and vote such shares, will terminate at the time of the Special Mandatory Conversion (notwithstanding any delay or failure of the Company to give the Special Mandatory Conversion Notice or the failure of the holder or holders thereof to surrender any certificates for such shares when required hereby), except only the rights of the holders thereof, upon surrender of any certificate or certificates of such holders therefor (or lost certificate affidavit, indemnity agreement and bond), to receive the items provided for in Section 4(p)(iii).

- (iii) As soon as practicable after the Special Mandatory Conversion and, if applicable, the surrender of any certificate or certificates (or provision by the holder of a lost certificate affidavit, indemnity agreement and bond) for Series A-2 Convertible Preferred Stock so converted, the Company shall (a) issue and deliver to such holder, or to his, her or its nominees, a certificate or certificates for the number of full shares of Common Stock issuable on such conversion in accordance with the provisions hereof, (b) pay cash as provided in Section 4(1) in lieu of any fraction of a share of Common Stock otherwise issuable upon such conversion, and (c) pay any declared but unpaid dividends on the shares of Series A-2 Convertible Preferred Stock so converted. Such converted shares of Series A-2 Convertible Preferred Stock shall be retired and cancelled and may not be reissued as shares of such series, and the Company may thereafter take such action as may be appropriate to reduce the authorized number of shares of Series A-2 Convertible Preferred Stock accordingly.
- (iv) Notwithstanding the above, a Special Mandatory Conversion shall not apply until ten (10) business days after satisfaction of the CFIUS Condition (as defined in the Stock Purchase Agreement) in the event of the CFIUS Exception (as defined in the Stock Purchase Agreement).
- (v) As used herein, "Affiliate" means, with respect to any holder of Series A-2 Convertible Preferred Stock, any other person who, directly or indirectly, controls, is controlled by, or is under common control with such holder, including, without limitation, any general partner, managing member, officer or director of such holder or any investment fund or other person now or hereafter existing which is controlled by one or more general partners, managing members, or equity holders of, shares the same management company with, or is under common management with, such holder.
- 5. **REDEMPTION**. The Series A Preferred is not redeemable at the option of the holder thereof, and the Company shall not have any mandatory obligation to redeem the Series A Preferred. Any shares of Series A Preferred redeemed, purchased, converted or exchanged by the Company shall be cancelled and retired and shall not be reissued or transferred.

#### ARTICLE V.

- **A.** The liability of the directors of the Company for monetary damages shall be eliminated to the fullest extent not prohibited under applicable law.
- **B.** To the fullest extent not prohibited by applicable law, the Company is authorized to provide indemnification of (and advancement of expenses to) directors, officers and agents of the Company (and any other persons to which applicable law permits the Company to provide indemnification) through By-law provisions, agreements with such agents or other persons, vote of stockholders or disinterested directors or otherwise in excess of the indemnification and advancement otherwise permitted by such applicable law. If applicable law is amended after approval by the stockholders of this Article V to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director to the Company shall be eliminated or limited to the fullest extent permitted by applicable law as so amended.
- **C.** Any repeal or modification of this Article V shall be prospective only and shall not affect the rights or protections or increase the liability of any director under this Article V in effect at the time of the alleged occurrence of any act or omission to act giving rise to liability or indemnification.

#### ARTICLE VI.

The Company renounces any interest or expectancy of the Company in, or in being offered an opportunity to participate in, any Excluded Opportunity. An "Excluded Opportunity" is any matter, transaction or interest that is presented to, or acquired, created or developed by, or which otherwise comes into the possession of, (i) any director of the Company who is not an employee of the Company or any of its subsidiaries, or (ii) any holder of shares of Series A Preferred or Common Stock or any partner, member, director, stockholder, employee or agent of any such holder, other than someone who is an employee or consultant of the Company or any of its subsidiaries (collectively, "Covered Persons"), unless in either case such matter, transaction or interest is presented to, or acquired, created or developed by, or otherwise comes into the possession of, a Covered Person expressly and solely in such Covered Person's capacity as a director of the Company.

#### ARTICLE VII.

For the management of the business and for the conduct of the affairs of the Company, and in further definition, limitation and regulation of the powers of the Company, of its directors and of its stockholders or any class thereof, as the case may be, it is further *provided* that:

**A.** The management of the business and the conduct of the affairs of the Company shall be vested in its Board. The number of directors that shall constitute the whole Board shall be fixed by the Board in the manner provided in the By-laws of the Company, subject to any restrictions which may be set forth in this Certificate of Incorporation.

- **B.** The Board of Directors is expressly empowered to adopt, amend or repeal the By-laws of the Company, subject to any restrictions that may be set forth in this Certificate of Incorporation. The stockholders shall also have the power to adopt, amend or repeal the By-laws of the Company, subject to any restrictions that may be set forth in this Certificate of Incorporation.
  - **C.** The directors of the Company need not be elected by written ballot unless the By-laws of the Company so provide.

#### ARTICLE VIII.

Unless the Company consents in writing to the selection of an alternative forum, the Court of Chancery in the State of Delaware shall be the sole and exclusive forum for any stockholder (including a beneficial owner) to bring (i) any derivative action or proceeding brought on behalf of the Company, (ii) any action asserting a claim of breach of fiduciary duty owed by any director, officer or other employee of the Company to the Company or the Company's stockholders, (iii) any action asserting a claim against the Company, its directors, officers or employees arising pursuant to any provision of the Delaware General Company Law or the Company's certificate of incorporation or bylaws or (iv) any action asserting a claim against the Company, its directors, officers or employees governed by the internal affairs doctrine, except for, as to each of (i) through (iv) above, any claim as to which the Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, or for which the Court of Chancery does not have subject matter jurisdiction. If any provision or provisions of this Article VIII shall be held to be invalid, illegal or unenforceable as applied to any person or entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law, the validity, legality and enforceability of such provisions in any other circumstance and of the remaining provisions of this Article VIII (including, without limitation, each portion of any sentence of this Article VIII containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) and the application of such provision to other persons or entities and circumstances shall not in any

#### ARTICLE IX.

That the foregoing amendment and restatement of the Corporation's Certificate of Incorporation was duly authorized and adopted in accordance with the provisions of Section 242 of the DGCL, by the unanimous written consent of the Board of Directors of the Corporation, in accordance with the provisions of Section 141(f) of the DGCL.

#### ARTICLE X.

That the foregoing amendment and restatement the Corporation's Certificate of Incorporation has been duly approved, in accordance with the provisions of Section 242 of the DGCL, by the written consent of the holders of a majority of those shares entitled to vote thereon and written notice of such action has been or will be given to the holders of such shares who did not so consent, each in accordance with the provisions of Section 228 of the DGCL.

**IN WITNESS WHEREOF, INOZYME PHARMA, INC.** has caused this Amended and Restated Certificate of Incorporation to be signed by its duly authorized officer this 8th day of November, 2018.

INOZYME PHARMA, INC.

By: /s/ Axel Bolte

Axel Bolte Chief Executive Officer

## CERTIFICATE OF AMENDMENT OF SECOND AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF

#### INOZYME PHARMA, INC.

Pursuant to Section 242 of the General Corporation Law of the State of Delaware

Inozyme Pharma, Inc. (the "Corporation"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the "DGCL"), does hereby certify as follows:

Resolutions were duly adopted by the Board of Directors of the Corporation pursuant to Sections 141(f) and 242 of the DGCL setting forth amendments to the Second Amended and Restated Certificate of Incorporation of the Corporation (the "Certificate") and declaring such amendments to be advisable. The stockholders of the Corporation duly approved said proposed amendments by written consent in accordance with Sections 228 and 242 of the DGCL. The resolutions setting forth the amendments are as follows:

#### **RESOLVED:**

That the second sentence of ARTICLE IV.A. of the Certificate be and hereby is amended by deleting it in its entirety and substituting the following in lieu thereof:

"The total number of shares that the Company is authorized to issue is Two Hundred Twenty Four Million Nine Hundred Eighty Two Thousand Eight Hundred and Sixty Two (224,982,862) shares, One Hundred Twenty Nine Million (129,000,000) shares of which shall be Common Stock (the "Common Stock") and Ninety Five Million Nine Hundred Eighty-Two Thousand Eight Hundred and Sixty Two (95,982,862) shares of which shall be Preferred Stock (the "Preferred Stock")."

#### **FURTHER**

#### **RESOLVED**:

That the first sentence of ARTICLE IV.C. of the Certificate be and hereby is amended by deleting it in its entirety and substituting the following in lieu thereof:

"Forty Eight Million Eight Hundred Fifty Thousand (48,850,000) of the authorized shares of Preferred Stock are hereby designated "Series A Convertible Preferred Stock" and Forty Seven Million One Hundred Thirty Two Thousand Eight Hundred and Sixty Two (47,132,862) of the authorized shares of Preferred Stock are hereby designated "Series A-2 Convertible Preferred Stock"."

### FURTHER RESOLVED:

That the reference to "at least 56% of the then outstanding shares of Series A Preferred" in ARTICLE IV.D., Section 2(b) of the Certificate be and hereby is amended by deleting it in its entirety and substituting the following in lieu thereof:

"a majority of the then outstanding shares of Series A Preferred, including the vote or consent (as the case may be) of at least one of the Requisite Holders (as defined in the Stock Purchase Agreement (as defined below)) for so long as at least one of the Requisite Holders holds a majority of the shares of Series A-2 Convertible Preferred Stock purchased by such Requisite Holder from the Company prior to the Milestone Closing (as defined in the Stock Purchase Agreement) (subject to proportionate adjustment in the event of any stock dividend, stock split, combination or similar recapitalization with respect to such shares)".

## FURTHER RESOLVED:

That the first sentence of ARTICLE IV.D., Section 2(d)(i) of the Certificate be and hereby is amended by deleting it in its entirety and substituting the following in lieu thereof:

"The holders of Series A Preferred, voting as a separate class, shall be entitled to elect five (5) members of the Board at each meeting of the Company's stockholders for the election of directors or action to elect directors by written consent in lieu of a meeting, and shall have the exclusive power to remove such directors from office in accordance with applicable law and to fill any vacancy caused by the resignation, death or removal of such directors; provided, however, the right of the holders of Series A Preferred to elect five (5) members of the Board pursuant to this subsection (i) shall be correspondingly reduced in the event one or more of the holders of shares of Series A Preferred entitled to designate a Preferred Director pursuant to Section 1.2(a) of that certain Voting Agreement, dated November 9, 2018, by and among the Company, holders of the Series A Preferred and certain holders of Common Stock, as such agreement may be amended from time to time (the "Voting Agreement"), is no longer entitled to designate a Preferred Director in accordance with the provisions set forth in Section 1.2(a) of the Voting Agreement."

## FURTHER RESOLVED:

That the parenthetical that reads "(as defined in the Series A-2 Convertible Preferred Stock Purchase Agreement, dated on or about the Original Issue Date, by and between the Company and the purchasers of the Series A-2 Convertible Preferred Stock (the "*Stock Purchase Agreement*"))" in ARTICLE IV.D., Section 4(a) of the Certificate be and hereby is amended by deleting it in its entirety and substituting the following in lieu thereof:

"(as defined in the Series A-2 Convertible Preferred Stock Purchase Agreement, dated on or about the Original Issue Date, by and between the Company and the purchasers of the Series A-2 Convertible Preferred Stock, as such agreement may be amended from time to time (the "Stock Purchase Agreement"))".

## FURTHER RESOLVED:

That ARTICLE IV.D., Section 4(p)(i) of the Certificate be and hereby is amended by deleting it in its entirety and substituting the following in lieu thereof:

"Subject to clause (iv) below, if a holder of Series A-2 Convertible Preferred Stock does not either (i) participate in the Milestone Closing by purchasing at least the number of shares of Series A-2 Convertible Preferred Stock set forth opposite such holder's name on Exhibit A-2 to the Stock Purchase Agreement (the "*Milestone Shares*") (provided that, the Company has sent to such holder a Milestone-Based Notice (as defined in the Stock Purchase Agreement) within the time period specified by Section 2.4 of the Stock Purchase Agreement) or (ii) prior to the Milestone Closing, participate in a Qualified Closing (as defined in the Stock Purchase Agreement), then immediately upon, and conditioned on, completion of the Milestone Closing each share of Series A-2 Convertible Preferred Stock held by such holder or any of its Affiliates shall automatically, and without any further action on the part of such holder or Affiliate, be converted into shares of Common Stock at the conversion ratio determined by dividing (x) the applicable Original Issue Price by (y) the product of five (5) and the applicable Conversion Price in effect immediately prior to the consummation of such Milestone Closing (such conversion, a "*Special Mandatory Conversion*"). For the avoidance of doubt, all shares of Series A-2 Convertible Preferred Stock purchased by a holder at a Qualified Closing prior to a Milestone Closing (as defined in the Stock Purchase Agreement) shall be deemed to be "Milestone Shares" of such holder for the purposes of this Section 4(p)."

\*\*\*\*

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to be signed by its Chief Executive Officer this 22nd day of March, 2019

Inozyme Pharma, Inc.

By: /s/ Axel Bolte

Axel Bolte Chief Executive Officer

# CERTIFICATE OF AMENDMENT OF SECOND AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF INOZYME PHARMA, INC.

Pursuant to Section 242 of the General Corporation Law of the State of Delaware

Inozyme Pharma, Inc. (the "Corporation"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the "DGCL"), does hereby certify as follows:

Resolutions were duly adopted by the Board of Directors of the Corporation pursuant to Sections 141(f) and 242 of the DGCL setting forth amendments to the Second Amended and Restated Certificate of Incorporation of the Corporation, as amended (the "Certificate"), and declaring such amendments to be advisable. The stockholders of the Corporation duly approved said proposed amendments by written consent in accordance with Sections 228 and 242 of the DGCL. The resolutions setting forth the amendments are as follows:

#### **RESOLVED:**

That the second sentence of ARTICLE IV.A. of the Certificate be and hereby is amended by deleting it in its entirety and substituting the following in lieu thereof:

"The total number of shares that the Company is authorized to issue is Two Hundred Forty Two Million Two Hundred Seventy Seven Thousand Two Hundred Twenty Two (242,277,222) shares, One Hundred Thirty Eight Million (138,000,000) shares of which shall be Common Stock (the "Common Stock") and One Hundred Four Million Two Hundred Seventy Seven Thousand Two Hundred Twenty Two (104,277,222) shares of which shall be Preferred Stock (the "Preferred Stock")."

#### **FURTHER**

#### RESOLVED:

That the first sentence of the paragraph in ARTICLE IV.C. of the Certificate listing the authorized classes and shares of stock of the Corporation be and hereby is amended by deleting it in its entirety and substituting the following in lieu thereof:

"Forty Eight Million Eight Hundred Fifty Thousand (48,850,000) of the authorized shares of Preferred Stock are hereby designated "Series A Convertible Preferred Stock" and Fifty Five Million Four Hundred Twenty Seven Thousand Two Hundred Twenty Two (55,427,222) of the authorized shares of Preferred Stock are hereby designated "Series A-2 Convertible Preferred Stock"."

## FURTHER RESOLVED:

That ARTICLE IV.D., Section 4(p) of the Certificate be and hereby is amended by adding the following as a new subsection (vi) therein:

"(vi) For the avoidance of doubt, this Section 4(p) shall not be applicable to any holder of Series A-2 Convertible Preferred Stock who acquires such shares of Series A-2 Convertible Preferred Stock from the Company after the Milestone Closing."

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IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to be signed by its Chief Executive Officer this  $17^{th}$  day of July, 2020.

Inozyme Pharma, Inc.

By: /s/ Axel Bolte

Axel Bolte Chief Executive Officer

#### CERTIFICATE OF AMENDMENT

OF

#### SECOND AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

OF

#### INOZYME PHARMA, INC.

Pursuant to Section 242 of the General Corporation Law of the State of Delaware

Inozyme Pharma, Inc. (the "Corporation"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the "DGCL"), does hereby certify as follows:

Resolutions were duly adopted by the Board of Directors of the Corporation pursuant to Sections 141(f) and 242 of the DGCL setting forth amendments to the Second Amended and Restated Certificate of Incorporation of the Corporation, as amended (the "Charter"), and declaring such amendments to be advisable. The stockholders of the Corporation duly approved said proposed amendments by written consent in accordance with Sections 228 and 242 of the DGCL. The resolutions setting forth the amendments are as follows:

#### **RESOLVED:**

That a new first paragraph of Article IV.A. of the Charter be and hereby is inserted immediately preceding the existing first paragraph (listing the authorized classes and shares of stock of the Corporation) as follows:

"That, effective on the filing of this Certificate of Amendment of Second Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware (the "Effective Time"), a one-for-7.4730 reverse stock split of the Common Stock (as defined below) shall become effective, pursuant to which each 7.4730 shares of Common Stock outstanding and held of record by each stockholder of the Company (including treasury shares) immediately prior to the Effective Time shall be reclassified and combined into one (1) validly issued, fully paid and nonassessable share of Common Stock automatically and without any action by the holder thereof upon the Effective Time and shall represent one (1) share of Common Stock from and after the Effective Time (such reclassification and combination of shares, the "Reverse Stock Split"). The par value of the Common Stock following the Reverse Stock Split shall remain at \$0.0001 per share. No fractional shares of Common Stock shall be issued as a result of the Reverse Stock Split and, in lieu thereof, upon surrender after the Effective Time of a certificate which formerly represented shares of Common Stock that were issued and outstanding immediately prior to the Effective Time, any person who would otherwise be entitled to a fractional share of Common Stock as a result of the Reverse Stock Split, following the Effective Time, shall be entitled to receive a cash payment equal to the fraction of a share of Common Stock to which such holder would otherwise be entitled multiplied by the fair value per share of

the Common Stock immediately prior to the Effective Time as determined by the Board of Directors of the Company. Each stock certificate that, immediately prior to the Effective Time, represented shares of Common Stock that were issued and outstanding immediately prior to the Effective Time shall, from and after the Effective Time, automatically and without the necessity of presenting the same for exchange, represent that number of whole shares of Common Stock after the Effective Time into which the shares formerly represented by such certificate have been reclassified (as well as the right to receive cash in lieu of fractional shares of Common Stock after the Effective Time); provided, however, that each person of record holding a certificate that represented shares of Common Stock that were issued and outstanding immediately prior to the Effective Time shall receive, upon surrender of such certificate, a new certificate evidencing and representing the number of whole shares of Common Stock after the Effective Time into which the shares of Common Stock formerly represented by such certificate shall have been reclassified."

# FURTHER RESOLVED:

That the first sentence of Article IV.D., Section 4(k)(i) of the Charter be and hereby is amended by deleting it in its entirety and substituting the following in lieu thereof:

"Each share of Series A Preferred shall automatically be converted into shares of Common Stock, at the Series A Preferred Conversion Price in effect at the time of such conversion, (A) at any time upon the written consent of the Required Majority or (B) immediately upon the closing of a firmly underwritten public offering pursuant to an effective registration statement under the Securities Act covering the offer and sale of Common Stock for the account of the Company (a "Qualified Public Offering")."

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, this Certificate of Amendment has been executed by a duly authorized officer of the Corporation on this  $17^{th}$  day of July, 2020.

## INOZYME PHARMA, INC.

By: /s/ Axel Bolte
Name: Axel Bolte

Title: President and Chief Executive Officer

#### RESTATED CERTIFICATE OF INCORPORATION

OF

#### INOZYME PHARMA, INC.

Inozyme Pharma, Inc., a corporation organized and existing under the General Corporation Law of the State of Delaware, does hereby certify that the name of the corporation is Inozyme Pharma, Inc. and the original certificate of incorporation of the corporation was filed with the Secretary of State of the State of Delaware on January 12, 2017. This Restated Certificate of Incorporation, having been duly adopted in accordance with Sections 228, 242 and 245 of the General Corporation Law of the State of Delaware, restates, integrates and amends the certificate of incorporation of the Corporation as follows:

FIRST: The name of the Corporation is Inozyme Pharma, Inc.

SECOND: The address of the Corporation's registered office in the State of Delaware is Corporation Trust Center, 1209 Orange Street, in the City of Wilmington, County of New Castle, 19801. The name of its registered agent at that address is The Corporation Trust Company.

THIRD: The nature of the business or purposes to be conducted or promoted by the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware.

FOURTH: The total number of shares of all classes of stock that the Corporation shall have authority to issue is 205,000,000 shares, consisting of (i) 200,000,000 shares of Common Stock, \$0.0001 par value per share ("Common Stock"), and (ii) 5,000,000 shares of Preferred Stock, \$0.0001 par value per share ("Preferred Stock").

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.

#### A COMMON STOCK.

- 1. <u>General</u>. The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights of the holders of the Preferred Stock of any series as may be designated by the Board of Directors upon any issuance of the Preferred Stock of any series.
- 2. <u>Voting</u>. The holders of the Common Stock shall have voting rights at all meetings of stockholders, each such holder being entitled to one vote for each share thereof held by such holder; <u>provided</u>, <u>however</u>, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Certificate of

Incorporation (which, as used herein, shall mean the certificate of incorporation of the Corporation, as amended from time to time, including the terms of any certificate of designations of any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon pursuant to this Certificate of Incorporation or the General Corporation Law of the State of Delaware. There shall be no cumulative voting.

The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law of the State of Delaware.

- 3. <u>Dividends</u>. Dividends may be declared and paid on the Common Stock from funds lawfully available therefor if, as and when determined by the Board of Directors and subject to any preferential dividend or other rights of any then outstanding Preferred Stock.
- 4. <u>Liquidation</u>. Upon the dissolution, liquidation or winding up of the Corporation, whether voluntary or involuntary, holders of Common Stock will be entitled to receive all assets of the Corporation available for distribution to its stockholders, subject to any preferential or other rights of any then outstanding Preferred Stock.

### B PREFERRED STOCK.

Preferred Stock may be issued from time to time in one or more series, each of such series to have such terms as stated or expressed herein and in the resolution or resolutions providing for the issue of such series adopted by the Board of Directors of the Corporation as hereinafter provided. Any shares of Preferred Stock that may be redeemed, purchased or acquired by the Corporation may be reissued except as otherwise provided by law.

Authority is hereby expressly granted to the Board of Directors from time to time to issue the Preferred Stock in one or more series, and in connection with the creation of any such series, by adopting a resolution or resolutions providing for the issuance of the shares thereof and by filing a certificate of designations relating thereto in accordance with the General Corporation Law of the State of Delaware, to determine and fix the number of shares of such series and such voting powers, full or limited, or no voting powers, and such designations, preferences and relative, participating, optional or other special rights, and qualifications, limitations or restrictions thereof, including dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be stated and expressed in such resolutions, all to the full extent now or hereafter permitted by the General Corporation Law of the State of Delaware. Without limiting the generality of the foregoing, the resolutions providing for issuance of any series of Preferred Stock may provide that such series shall be superior or rank equally or be junior to any other series of Preferred Stock to the extent permitted by law. The powers, preferences and relative, participating, optional and other special rights of each series of Preferred Stock, and the qualifications, limitations or restrictions thereof, if any, may differ from those of any and all other series at any time outstanding.

The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares then outstanding) by the affirmative vote of the holders of a majority of the voting power of the capital stock of the Corporation entitled to vote thereon, voting as a single class, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law of the State of Delaware.

FIFTH: Except as otherwise provided herein, the Corporation reserves the right to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by statute and this Certificate of Incorporation, and all rights conferred upon stockholders herein are granted subject to this reservation.

SIXTH: In furtherance and not in limitation of the powers conferred upon it by the General Corporation Law of the State of Delaware, and subject to the terms of any series of Preferred Stock, the Board of Directors shall have the power to adopt, amend, alter or repeal the Bylaws of the Corporation by the affirmative vote of a majority of the directors present at any regular or special meeting of the Board of Directors at which a quorum is present. The stockholders may not adopt, amend, alter or repeal the Bylaws of the Corporation, or adopt any provision inconsistent therewith, unless such action is approved, in addition to any other vote required by this Certificate of Incorporation, by the affirmative vote of the holders of at least seventy-five percent (75%) of the votes that all the stockholders would be entitled to cast in an election of directors or class of directors. Notwithstanding any other provisions of law, this Certificate of Incorporation or the Bylaws of the Corporation, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least seventy-five percent (75%) of the votes that all the stockholders would be entitled to cast in an election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article SIXTH.

SEVENTH: Except to the extent that the General Corporation Law of the State of Delaware prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty, no director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability. No amendment to or repeal of this provision shall apply to or have any effect on the liability or alleged liability of any director of the Corporation for or with respect to any acts or omissions of such director occurring prior to such amendment or repeal. If the General Corporation Law of the State of Delaware is amended to permit further elimination or limitation of the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law of the State of Delaware as so amended.

EIGHTH: The Corporation shall provide indemnification and advancement of expenses as follows:

1. Actions, Suits and Proceedings Other than by or in the Right of the Corporation. The Corporation shall indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the Corporation) by reason of the fact that he or she is or was, or has agreed to become, a director or officer of the

Corporation, or is or was serving, or has agreed to serve, at the request of the Corporation, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan) (all such persons being referred to hereafter as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974), and amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with such action, suit or proceeding and any appeal therefrom, if Indemnitee acted in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that Indemnitee did not act in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that his or her conduct was unlawful.

- 2. Actions or Suits by or in the Right of the Corporation. The Corporation shall indemnify any Indemnitee who was or is a party to or threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the Corporation to procure a judgment in its favor by reason of the fact that Indemnitee is or was, or has agreed to become, a director or officer of the Corporation, or is or was serving, or has agreed to serve, at the request of the Corporation, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with such action, suit or proceeding and any appeal therefrom, if Indemnitee acted in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, except that no indemnification shall be made under this Section 2 in respect of any claim, issue or matter as to which Indemnitee shall have been adjudged to be liable to the Corporation, unless, and only to the extent, that the Court of Chancery of Delaware or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of such liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnity for such expenses (including attorneys' fees) which the Court of Chancery of Delaware or such other court shall deem proper.
- 3. <u>Indemnification for Expenses of Successful Party.</u> Notwithstanding any other provisions of this Article EIGHTH, to the extent that an Indemnitee has been successful, on the merits or otherwise, in defense of any action, suit or proceeding referred to in Sections 1 and 2 of this Article EIGHTH, or in defense of any claim, issue or matter therein, or on appeal from any such action, suit or proceeding, Indemnitee shall be indemnified against all expenses (including attorneys' fees) actually and reasonably incurred by or on behalf of Indemnitee in connection therewith. Without limiting the foregoing, if any action, suit or proceeding is disposed of, on the merits or otherwise (including a disposition without prejudice), without (i) the disposition being adverse to Indemnitee, (ii) an adjudication that Indemnitee was liable to the Corporation, (iii) a

plea of guilty or <u>nolo contendere</u> by Indemnitee, (iv) an adjudication that Indemnitee did not act in good faith and in a manner he or she reasonably believed to be in or not\_opposed to the best interests of the Corporation, and (v) with respect to any criminal proceeding, an adjudication that Indemnitee had reasonable cause to believe his or her conduct was unlawful, Indemnitee shall be considered for the purposes hereof to have been wholly successful with respect thereto.

- 4. Notification and Defense of Claim. As a condition precedent to an Indemnitee's right to be indemnified, such Indemnitee must notify the Corporation in writing as soon as practicable of any action, suit, proceeding or investigation involving such Indemnitee for which indemnity will or could be sought. With respect to any action, suit, proceeding or investigation of which the Corporation is so notified, the Corporation will be entitled to participate therein at its own expense and/or to assume the defense thereof at its own expense, with legal counsel reasonably acceptable to Indemnitee. After notice from the Corporation to Indemnitee of its election so to assume such defense, the Corporation shall not be liable to Indemnitee for any legal or other expenses subsequently incurred by Indemnitee in connection with such action, suit, proceeding or investigation, other than as provided below in this Section 4. Indemnitee shall have the right to employ his or her own counsel in connection with such action, suit, proceeding or investigation, but the fees and expenses of such counsel incurred after notice from the Corporation of its assumption of the defense thereof shall be at the expense of Indemnitee unless (i) the employment of counsel by Indemnitee has been authorized by the Corporation, (ii) counsel to Indemnitee shall have reasonably concluded that there may be a conflict of interest or position on any significant issue between the Corporation and Indemnitee in the conduct of the defense of such action, suit, proceeding or investigation or (iii) the Corporation shall not in fact have employed counsel to assume the defense of such action, suit, proceeding or investigation, in each of which cases the fees and expenses of counsel for Indemnitee shall be at the expense of the Corporation, except as otherwise expressly provided by this Article EIGHTH. The Corporation shall not be entitled, without the consent of Indemnitee, to assume the defense of any claim brought by or in the right of the Corporation or as to which counsel for Indemnitee shall have reasonably made the conclusion provided for in clause (ii) above. The Corporation shall not be required to indemnify Indemnitee under this Article EIGHTH for any amounts paid in settlement of any action, suit, proceeding or investigation effected without its written consent. The Corporation shall not settle any action, suit, proceeding or investigation in any manner which would impose any penalty or limitation on Indemnitee without Indemnitee's written consent. Neither the Corporation nor Indemnitee will unreasonably withhold or delay its consent to any proposed settlement.
- 5. Advancement of Expenses. Subject to the provisions of Section 6 of this Article EIGHTH, in the event of any threatened or pending action, suit, proceeding or investigation of which the Corporation receives notice under this Article EIGHTH, any expenses (including attorneys' fees) incurred by or on behalf of Indemnitee in defending an action, suit, proceeding or investigation or any appeal therefrom shall be paid by the Corporation in advance of the final disposition of such matter; provided, however, that the payment of such expenses incurred by or on behalf of Indemnitee in advance of the final disposition of such matter shall be made only upon receipt of an undertaking by or on behalf of Indemnitee to repay all amounts so advanced in the event that it shall ultimately be determined by final judicial decision from which there is no further right to appeal that Indemnitee is not entitled to be indemnified by the Corporation as authorized in this Article EIGHTH; and provided further that no such advancement of expenses

shall be made under this Article EIGHTH if it is determined (in the manner described in Section 6) that (i) Indemnitee did not act in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the Corporation, or (ii) with respect to any criminal action or proceeding, Indemnitee had reasonable cause to believe his or her conduct was unlawful. Such undertaking shall be accepted without reference to the financial ability of Indemnitee to make such repayment.

6. Procedure for Indemnification and Advancement of Expenses. In order to obtain indemnification or advancement of expenses pursuant to Section 1, 2, 3 or 5 of this Article EIGHTH, an Indemnitee shall submit to the Corporation a written request. Any such advancement of expenses shall be made promptly, and in any event within 60 days after receipt by the Corporation of the written request of Indemnitee, unless (i) the Corporation has assumed the defense pursuant to Section 4 of this Article EIGHTH (and none of the circumstances described in Section 4 of this Article EIGHTH that would nonetheless entitle the Indemnitee to indemnification for the fees and expenses of separate counsel have occurred) or (ii) the Corporation determines within such 60-day period that Indemnitee did not meet the applicable standard of conduct set forth in Section 1, 2 or 5 of this Article EIGHTH, as the case may be. Any such indemnification, unless ordered by a court, shall be made with respect to requests under Section 1 or 2 only as authorized in the specific case upon a determination by the Corporation that the indemnification of Indemnitee is proper because Indemnitee has met the applicable standard of conduct set forth in Section 1 or 2, as the case may be. Such determination shall be made in each instance (a) by a majority vote of the directors of the Corporation consisting of persons who are not at that time parties to the action, suit or proceeding in question ("disinterested directors"), whether or not a quorum, (b) by a committee of disinterested directors designated by majority vote of disinterested directors, whether or not a quorum, (c) if there are no disinterested directors, or if the disinterested directors so direct, by independent legal counsel (who may, to the extent permitted by law, be regular legal counsel to the Corporation) in a written opinion, or (d) by the stockholders of the Corporation.

7. Remedies. Subject to Article TWELFTH, the right to indemnification or advancement of expenses as granted by this Article EIGHTH shall be enforceable by Indemnitee in any court of competent jurisdiction. Neither the failure of the Corporation to have made a determination prior to the commencement of such action that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Corporation pursuant to Section 6 of this Article EIGHTH that Indemnitee has not met such applicable standard of conduct. In any suit brought by Indemnitee to enforce a right to indemnification or advancement of expenses, or brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Corporation shall have the burden of proving that Indemnitee is not entitled to be indemnified, or to such advancement of expenses, under this Article EIGHTH. Indemnitee's expenses (including attorneys' fees) reasonably incurred in connection with successfully establishing Indemnitee's right to indemnification or advancement of expenses, in whole or in part, in any such proceeding shall also be indemnified by the Corporation to the fullest extent permitted by applicable law. Notwithstanding the foregoing, in any suit brought by Indemnitee to enforce a right to indemnification or advancement of expenses hereunder it shall be a defense that the Indemnitee has not met any applicable standard for indemnification set forth in the General Corporation Law of the State of Delaware.

- 8. <u>Limitations</u>. Notwithstanding anything to the contrary in this Article EIGHTH, except as set forth in Section 7 of this Article EIGHTH, the Corporation shall not indemnify, or advance expenses to, an Indemnitee pursuant to this Article EIGHTH in connection with a proceeding (or part thereof) initiated by such Indemnitee unless the initiation thereof was approved by the Board of Directors. Notwithstanding anything to the contrary in this Article EIGHTH, the Corporation shall not indemnify or advance expenses to an Indemnitee to the extent such Indemnitee is reimbursed from the proceeds of insurance, and in the event the Corporation makes any indemnification or advancement payments to an Indemnitee and such Indemnitee is subsequently reimbursed from the proceeds of insurance, such Indemnitee shall promptly refund indemnification or advancement payments to the Corporation to the extent of such insurance reimbursement.
- 9. <u>Subsequent Amendment</u>. No amendment, termination or repeal of this Article EIGHTH or of the relevant provisions of the General Corporation Law of the State of Delaware or any other applicable laws shall adversely affect or diminish in any way the rights of any Indemnitee to indemnification or advancement of expenses under the provisions hereof with respect to any action, suit, proceeding or investigation arising out of or relating to any actions, transactions or facts occurring prior to the final adoption of such amendment, termination or repeal.
- 10. Other Rights. The indemnification and advancement of expenses provided by this Article EIGHTH shall not be deemed exclusive of any other rights to which an Indemnitee seeking indemnification or advancement of expenses may be entitled under any law (common or statutory), agreement or vote of stockholders or disinterested directors or otherwise, both as to action in Indemnitee's official capacity and as to action in any other capacity while holding office for the Corporation, and shall continue as to an Indemnitee who has ceased to be a director or officer, and shall inure to the benefit of the estate, heirs, executors and administrators of Indemnitee. Nothing contained in this Article EIGHTH shall be deemed to prohibit, and the Corporation is specifically authorized to enter into, agreements with officers and directors providing indemnification and expense advancement rights and procedures different from those set forth in this Article EIGHTH. In addition, the Corporation may, to the extent authorized from time to time by its Board of Directors, grant indemnification and expense advancement rights to other employees or agents of the Corporation or other persons serving the Corporation and such rights may be equivalent to, or greater or less than, those set forth in this Article EIGHTH.
- 11. <u>Partial Indemnification</u>. If an Indemnitee is entitled under any provision of this Article EIGHTH to indemnification by the Corporation for some or a portion of the expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974) or amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with any action, suit, proceeding or investigation and any appeal therefrom but not, however, for the total amount thereof, the Corporation shall nevertheless indemnify Indemnitee for the portion of such expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974) or amounts paid in settlement to which Indemnitee is entitled.

- 12. <u>Insurance</u>. The Corporation may purchase and maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Corporation or another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan) against any expense, liability or loss incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the General Corporation Law of the State of Delaware.
- 13. <u>Savings Clause</u>. If this Article EIGHTH or any portion hereof shall be invalidated on any ground by any court of competent jurisdiction, then the Corporation shall nevertheless indemnify each Indemnitee as to any expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974) and amounts paid in settlement in connection with any action, suit, proceeding or investigation, whether civil, criminal or administrative, including an action by or in the right of the Corporation, to the fullest extent permitted by any applicable portion of this Article EIGHTH that shall not have been invalidated and to the fullest extent permitted by applicable law.
- 14. <u>Definitions</u>. Terms used herein and defined in Section 145(h) and Section 145(i) of the General Corporation Law of the State of Delaware shall have the respective meanings assigned to such terms in such Section 145(h) and Section 145(i).

NINTH: This Article NINTH is inserted for the management of the business and for the conduct of the affairs of the Corporation.

- 1. General Powers. The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors.
- 2. <u>Number of Directors</u>; <u>Election of Directors</u>. Subject to the rights of holders of any series of Preferred Stock to elect directors, the number of directors of the Corporation shall be established from time to time by the Board of Directors. Election of directors need not be by written ballot, except as and to the extent provided in the Bylaws of the Corporation.
- 3. <u>Classes of Directors</u>. Subject to the rights of holders of any series of Preferred Stock to elect directors, the Board of Directors shall be and is divided into three classes, designated Class I, Class II and Class III. Each class shall consist, as nearly as may be possible, of one-third of the total number of directors constituting the entire Board of Directors. The Board of Directors is authorized to assign members of the Board of Directors already in office to Class I, Class II or Class III at the time such classification becomes effective.
- 4. <u>Terms of Office</u>. Subject to the rights of holders of any series of Preferred Stock to elect directors, each director shall serve for a term ending on the date of the third annual meeting of stockholders following the annual meeting of stockholders at which such director was elected; <u>provided</u> that each director initially assigned to Class I shall serve for a term expiring at

the Corporation's first annual meeting of stockholders held after the effectiveness of this Restated Certificate of Incorporation; each director initially assigned to Class II shall serve for a term expiring at the Corporation's second annual meeting of stockholders held after the effectiveness of this Restated Certificate of Incorporation; and each director initially assigned to Class III shall serve for a term expiring at the Corporation's third annual meeting of stockholders held after the effectiveness of this Restated Certificate of Incorporation; provided further, that the term of each director shall continue until the election and qualification of his or her successor and be subject to his or her earlier death, resignation or removal.

- 5. <u>Quorum</u>. The greater of (a) a majority of the directors at any time in office and (b) one-third of the number of directors fixed pursuant to Section 2 of this Article NINTH shall constitute a quorum of the Board of Directors. If at any meeting of the Board of Directors there shall be less than such a quorum, a majority of the directors present may adjourn the meeting from time to time without further notice other than announcement at the meeting, until a quorum shall be present.
- 6. <u>Action at Meeting</u>. Every act or decision done or made by a majority of the directors present at a meeting duly held at which a quorum is present shall be regarded as the act of the Board of Directors unless a greater number is required by law or by this Certificate of Incorporation.
- 7. <u>Removal</u>. Subject to the rights of holders of any series of Preferred Stock, directors of the Corporation may be removed only for cause and only by the affirmative vote of the holders of at least seventy-five percent (75%) of the votes that all the stockholders would be entitled to cast in an election of directors or class of directors.
- 8. <u>Vacancies</u>. Subject to the rights of holders of any series of Preferred Stock, any vacancies or newly-created directorships on the Board of Directors, however occurring, shall be filled only by vote of a majority of the directors then in office, although less than a quorum, or by a sole remaining director and shall not be filled by the stockholders. A director elected to fill a vacancy or to fill a position resulting from a newly-created directorship shall hold office until the next election of the class for which such director shall have been chosen, subject to the election and qualification of a successor and to such director's earlier death, resignation or removal.
- 9. <u>Stockholder Nominations and Introduction of Business, Etc</u>. Advance notice of stockholder nominations for election of directors and other business to be brought by stockholders before a meeting of stockholders shall be given in the manner provided by the Bylaws of the Corporation.
- 10. <u>Amendments to Article</u>. Notwithstanding any other provisions of law, this Certificate of Incorporation or the Bylaws of the Corporation, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least seventy-five percent (75%) of the votes that all the stockholders would be entitled to cast in an election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article NINTH.

TENTH: Stockholders of the Corporation may not take any action by written consent in lieu of a meeting. Notwithstanding any other provisions of law, this Certificate of Incorporation or the Bylaws of the Corporation, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least seventy-five percent (75%) of the votes that all the stockholders would be entitled to cast in an election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article TENTH.

ELEVENTH: Special meetings of stockholders for any purpose or purposes may be called at any time only by the Board of Directors, and may not be called by any other person or persons. Business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of meeting. Notwithstanding any other provisions of law, this Certificate of Incorporation or the Bylaws of the Corporation, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least seventy-five percent (75%) of the votes that all the stockholders would be entitled to cast in an election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article ELEVENTH.

TWELFTH: (a) Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for: (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer, other employee or stockholder of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware or as to which the General Corporation Law of the State of Delaware, or (iv) any action asserting a claim arising pursuant to any provision of this Certificate of Incorporation or the Bylaws of the Corporation (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine. This paragraph (a) of Article TWELFTH does not apply to claims arising under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, or any other claim for which the federal courts have exclusive jurisdiction.

- (b) Unless the Corporation consents in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any claims arising under the Securities Act of 1933, as amended.
- (c) Any person or entity purchasing or otherwise acquiring or holding any interest in shares of capital stock of the Corporation shall be deemed to have notice of, and to have consented to, the provisions of this Article TWELFTH.

IN WITNESS WHEREOF, this Restated Certificate of Incorporation, which restates, integrates and amends the certificate of incorporation of the Corporation, and which has been duly adopted in accordance with Sections 228, 242 and 245 of the General Corporation Law of the State of Delaware, has been executed by its duly authorized officer this day of , 2020.

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Name: Axel Bolte

Title: President and Chief Executive Officer

## AMENDED AND RESTATED BYLAWS

OF

INOZYME PHARMA, INC.

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#### ARTICLE I

#### **STOCKHOLDERS**

- 1.1 <u>Place of Meetings</u>. All meetings of stockholders shall be held at such place, if any, as may be designated from time to time by the Board of Directors, the Chairman of the Board or the Chief Executive Officer or, if not so designated, at the principal executive office of the corporation. The Board of Directors may, in its sole discretion, determine that a meeting shall not be held at any place, but shall instead be held solely by means of remote communication in a manner consistent with the General Corporation Law of the State of Delaware.
- 1.2 <u>Annual Meeting</u>. The annual meeting of stockholders for the election of directors to succeed those whose terms expire and for the transaction of such other business as may properly be brought before the meeting shall be held on a date and at a time designated by the Board of Directors, the Chairman of the Board or the Chief Executive Officer. The Board of Directors may postpone, reschedule or cancel any previously scheduled annual meeting of stockholders.
- 1.3 <u>Special Meetings</u>. Special meetings of stockholders for any purpose or purposes may be called at any time only by the Board of Directors, and may not be called by any other person or persons. Business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of meeting. The Board of Directors may postpone, reschedule or cancel any previously scheduled special meeting of stockholders.
- 1.4 <u>Record Date for Stockholder Meetings</u>. In order that the corporation may determine the stockholders entitled to notice of any meeting of stockholders or any adjournment thereof, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which record date shall not be more than 60 nor less than 10 days before the date of such meeting. If the Board of Directors so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the Board of Directors

determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination. If no record date is fixed by the Board of Directors, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board of Directors may fix a new record date for determination of stockholders entitled to vote at the adjourned meeting, and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance herewith at the adjourned meeting.

1.5 Notice of Meetings. Except as otherwise provided by law, the Certificate of Incorporation or these bylaws, notice of each meeting of stockholders, whether annual or special, shall be given not less than 10 nor more than 60 days before the date of the meeting to each stockholder entitled to vote at such meeting as of the record date for determining the stockholders entitled to notice of the meeting. Without limiting the manner by which notice otherwise may be given to stockholders, any notice shall be effective if given in accordance with Section 232 of the General Corporation Law of the State of Delaware. The notices of all meetings shall state the place, if any, date and time of the meeting and the means of remote communications, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such meeting. The notice of a special meeting shall state, in addition, the purpose or purposes for which the meeting is called.

1.6 <u>Voting List</u>. The corporation shall prepare, at least 10 days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting (provided, however, if the record date for determining the stockholders entitled to vote is less than 10 days before the meeting date, the list shall reflect the stockholders entitled to vote as of the tenth day before the meeting), arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting for a period of at

least 10 days prior to the meeting: (a) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (b) during ordinary business hours, at the principal place of business of the corporation. If the meeting is to be held at a physical location (and not solely by means of remote communication), then the list shall be produced and kept at the time and place of the meeting during the whole time thereof, and may be examined by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting. Except as otherwise provided by law, such list shall be the only evidence as to who are the stockholders entitled to examine the list of stockholders required by this Section 1.6 or to vote in person or by proxy at any meeting of stockholders.

1.7 Quorum. Except as otherwise provided by law, the Certificate of Incorporation or these bylaws, the holders of a majority in voting power of the shares of the capital stock of the corporation issued and outstanding and entitled to vote at the meeting, present in person, present by means of remote communication in a manner, if any, authorized by the Board of Directors in its sole discretion, or represented by proxy, shall constitute a quorum for the transaction of business; provided, however, that where a separate vote by a class or classes or series of capital stock is required by law or the Certificate of Incorporation, the holders of a majority in voting power of the shares of such class or classes or series of the capital stock of the corporation issued and outstanding and entitled to vote on such matter, present in person, present by means of remote communication in a manner, if any, authorized by the Board of Directors in its sole discretion, or represented by proxy, shall constitute a quorum entitled to take action with respect to the vote on such matter. A quorum, once established at a meeting, shall not be broken by the withdrawal of enough votes to leave less than a quorum.

1.8 <u>Adjournments</u>. Any meeting of stockholders may be adjourned from time to time to reconvene at any other time and to any other place at which a meeting of stockholders may be held under these bylaws by the chairman of the meeting. It shall not be necessary to notify any stockholder of any adjournment of less than 30 days if the time and place, if any, of the adjourned meeting, and the means of remote communication, if any, by which stockholders and

proxyholders may be deemed to be present in person and vote at such adjourned meeting, are announced at the meeting at which adjournment is taken, unless after the adjournment a new record date is fixed for the adjourned meeting. At the adjourned meeting, the corporation may transact any business that might have been transacted at the original meeting. If the adjournment is for more than 30 days, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting. If after the adjournment a new record date for determination of stockholders entitled to vote is fixed for the adjourned meeting, the Board of Directors shall fix as the record date for determining stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote at the adjourned meeting, and shall give notice of the adjourned meeting to each stockholder of record as of the record date so fixed for notice of such adjourned meeting.

- 1.9 <u>Voting and Proxies</u>. Each stockholder shall have one vote upon the matter in question for each share of stock entitled to vote held of record by such stockholder and a proportionate vote for each fractional share so held, unless otherwise provided by law or the Certificate of Incorporation. Each stockholder of record entitled to vote at a meeting of stockholders may vote in person (including by means of remote communications, if any, by which stockholders may be deemed to be present in person and vote at such meeting) or may authorize another person or persons to vote for such stockholder by a proxy executed or transmitted in a manner permitted by the General Corporation Law of the State of Delaware by the stockholder or such stockholder's authorized agent and delivered (including by electronic transmission) to the Secretary of the corporation. No such proxy shall be voted upon after three years from the date of its execution, unless the proxy expressly provides for a longer period.
- 1.10 Action at Meeting. When a quorum is present at any meeting, any matter other than the election of directors to be voted upon by the stockholders at such meeting shall be decided by the vote of the holders of shares of stock having a majority in voting power of the votes cast by the holders of all of the shares of stock present or represented at the meeting and voting affirmatively or negatively on such matter (or if there are two or more classes or series of stock entitled to vote as separate classes, then in the case of each such class or series, the holders of a majority in voting power of the shares of stock of that class or series present or represented at the meeting and voting affirmatively or negatively on such matter), except when a different

vote is required by law, the Certificate of Incorporation or these bylaws. When a quorum is present at any meeting, any election by stockholders of directors shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election.

#### 1.11 Nomination of Directors.

- (a) Except for (1) any directors entitled to be elected by the holders of preferred stock, (2) any directors elected in accordance with Section 2.8 hereof by the Board of Directors to fill vacancies or newly-created directorships or (3) as otherwise required by applicable law or stock exchange regulation, at any meeting of stockholders, only persons who are nominated in accordance with the procedures in this Section 1.11 shall be eligible for election as directors. Nomination for election to the Board of Directors at a meeting of stockholders may be made (i) by or at the direction of the Board of Directors or (ii) by any stockholder of the corporation who (x) timely complies with the notice procedures in Section 1.11(b), (y) is a stockholder of record who is entitled to vote for the election of such nominee on the date of the giving of such notice and on the record date for the determination of stockholders entitled to vote at such meeting and (z) is entitled to vote at such meeting.
- (b) To be timely, a stockholder's notice must be received in writing by the Secretary at the principal executive office of the corporation as follows: (1) in the case of an election of directors at an annual meeting of stockholders, not less than 90 days nor more than 120 days prior to the first anniversary of the preceding year's annual meeting; provided, however, that (x) in the case of an annual meeting of stockholders of the corporation to be held in 2021 or (y) in the event that the date of the annual meeting in any other year is advanced by more than 30 days, or delayed by more than 60 days, from the first anniversary of the preceding year's annual meeting, or if no annual meeting was held in the preceding year, a stockholder's notice must be so received not earlier than the 120th day prior to such annual meeting and not later than the close of business on the later of (A) the 90th day prior to such annual meeting and (B) the tenth day following the day on which notice of the date of such annual meeting was mailed or public disclosure of the date of such annual meeting was made, whichever first occurs; or (2) in the case of an election of directors at a special meeting of stockholders, provided that the Board of Directors has determined, in accordance with Section 1.3, that

directors shall be elected at such special meeting and provided further that the nomination made by the stockholder is for one of the director positions that the Board of Directors has determined will be filled at such special meeting, not earlier than the 120th day prior to such special meeting and not later than the close of business on the later of (x) the 90th day prior to such special meeting and (y) the tenth day following the day on which notice of the date of such special meeting was mailed or public disclosure of the date of such special meeting was made, whichever first occurs. In no event shall the adjournment or postponement of a meeting (or the public disclosure thereof) commence a new time period (or extend any time period) for the giving of a stockholder's notice.

The stockholder's notice to the Secretary shall set forth: (A) as to each proposed nominee (1) such person's name, age, business address and, if known, residence address, (2) such person's principal occupation or employment, (3) the class and series and number of shares of stock of the corporation that are, directly or indirectly, owned, beneficially or of record, by such person, (4) a description of all direct and indirect compensation and other material monetary agreements, arrangements and understandings during the past three years, and any other material relationships, between or among (x) the stockholder, the beneficial owner, if any, on whose behalf the nomination is being made and the respective affiliates and associates of, or others acting in concert with, such stockholder and such beneficial owner, on the one hand, and (y) each proposed nominee, and his or her respective affiliates and associates, or others acting in concert with such nominee(s), on the other hand, including all information that would be required to be disclosed pursuant to Item 404 of Regulation S-K if the stockholder making the nomination and any beneficial owner on whose behalf the nomination is made or any affiliate or associate thereof or person acting in concert therewith were the "registrant" for purposes of such Item and the proposed nominee were a director or executive officer of such registrant, and (5) any other information concerning such person that must be disclosed as to nominees in proxy solicitations pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and (B) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination is being made (1) the name and address of such stockholder, as they appear on the corporation's books, and of such beneficial owner, (2) the class and series and number of shares of stock of the corporation that are, directly or indirectly, owned, beneficially or of record, by such stockholder and such benefic

description of any agreement, arrangement or understanding between or among such stockholder and/or such beneficial owner and each proposed nominee and any other person or persons (including their names) pursuant to which the nomination(s) are being made or who may participate in the solicitation of proxies or votes in favor of electing such nominee(s), (4) a description of any agreement, arrangement or understanding (including any derivative or short positions, swaps, profit interests, options, warrants, convertible securities, stock appreciation or similar rights, hedging transactions, and borrowed or loaned shares) that has been entered into by, or on behalf of, such stockholder or such beneficial owner, the effect or intent of which is to mitigate loss to, manage risk or benefit of share price changes for, or increase or decrease the voting power of, such stockholder or such beneficial owner with respect to shares of stock of the corporation, (5) any other information relating to such stockholder and such beneficial owner that would be required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for the election of directors in a contested election pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated thereunder, (6) a representation that such stockholder intends to appear in person or by proxy at the meeting to nominate the person(s) named in its notice and (7) a representation whether such stockholder and/or such beneficial owner intends or is part of a group that intends (x) to deliver a proxy statement and/or form of proxy to holders of at least the percentage of the corporation's outstanding capital stock reasonably believed by such stockholder or such beneficial owner to be sufficient to elect the nominee (and such representation shall be included in any such proxy statement and form of proxy) and/or (y) otherwise to solicit proxies or votes from stockholders in support of such nomination (and such representation shall be included in any such solicitation materials). Not later than 10 days after the record date for the meeting, the information required by Items (A)(1)-(5) and (B)(1)-(5) of the prior sentence shall be supplemented by the stockholder giving the notice to provide updated information as of the record date. In addition, to be effective, the stockholder's notice must be accompanied by the written consent of the proposed nominee to serve as a director if elected. The corporation may require any proposed nominee to furnish such other information as the corporation may reasonably require to determine the eligibility of such proposed nominee to serve as a director of the corporation or whether such nominee would be independent under applicable Securities and Exchange Commission and stock exchange rules and the corporation's publicly disclosed corporate governance guidelines. A

stockholder shall not have complied with this Section 1.11(b) if the stockholder (or beneficial owner, if any, on whose behalf the nomination is made) solicits or does not solicit, as the case may be, proxies or votes in support of such stockholder's nominee in contravention of the representations with respect thereto required by this Section 1.11.

- (c) The chairman of any meeting shall have the power and duty to determine whether a nomination was made in accordance with the provisions of this Section 1.11 (including whether the stockholder or beneficial owner, if any, on whose behalf the nomination is made solicited (or is part of a group that solicited) or did not so solicit, as the case may be, proxies or votes in support of such stockholder's nominee in compliance with the representations with respect thereto required by this Section 1.11), and if the chairman should determine that a nomination was not made in accordance with the provisions of this Section 1.11, the chairman shall so declare to the meeting and such nomination shall not be brought before the meeting.
- (d) Except as otherwise required by law, nothing in this Section 1.11 shall obligate the corporation or the Board of Directors to include in any proxy statement or other stockholder communication distributed on behalf of the corporation or the Board of Directors information with respect to any nominee for director submitted by a stockholder.
- (e) Notwithstanding the foregoing provisions of this Section 1.11, unless otherwise required by law, if the stockholder (or a qualified representative of the stockholder) does not appear at the meeting to present a nomination, such nomination shall not be brought before the meeting, notwithstanding that proxies in respect of such nominee may have been received by the corporation. For purposes of this Section 1.11, to be considered a "qualified representative of the stockholder", a person must be a duly authorized officer, manager or partner of such stockholder or must be authorized by a written instrument executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting of stockholders and such person must produce such written instrument or electronic transmission, or a reliable reproduction of the written instrument or electronic transmission, at the meeting of stockholders.

(f) For purposes of this Section 1.11, "public disclosure" shall include disclosure in a press release reported by the Dow Jones News Service, Associated Press or comparable national news service or in a document publicly filed by the corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the Exchange Act.

#### 1.12 Notice of Business at Annual Meetings.

- (a) At any annual meeting of the stockholders, only such business shall be conducted as shall have been properly brought before the meeting. To be properly brought before an annual meeting, business must be (1) specified in the notice of meeting (or any supplement thereto) given by or at the direction of the Board of Directors, (2) otherwise properly brought before the meeting by or at the direction of the Board of Directors, or (3) properly brought before the meeting by a stockholder. For business to be properly brought before an annual meeting by a stockholder, (i) if such business relates to the nomination of a person for election as a director of the corporation, the procedures in Section 1.11 must be complied with and (ii) if such business relates to any other matter, the business must constitute a proper matter under Delaware law for stockholder action and the stockholder must (x) have given timely notice thereof in writing to the Secretary in accordance with the procedures in Section 1.12(b), (y) be a stockholder of record who is entitled to vote on such business on the date of the giving of such notice and on the record date for the determination of stockholders entitled to vote at such annual meeting and (z) be entitled to vote at such annual meeting.
- (b) To be timely, a stockholder's notice must be received in writing by the Secretary at the principal executive office of the corporation not less than 90 days nor more than 120 days prior to the first anniversary of the preceding year's annual meeting; provided, however, that in the event that the date of the annual meeting is advanced by more than 30 days, or delayed by more than 60 days, from the first anniversary of the preceding year's annual meeting, or if no annual meeting was held in the preceding year, a stockholder's notice must be so received not earlier than the 120th day prior to such annual meeting and not later than the close of business on the later of (x) the 90th day prior to such annual meeting and (y) the tenth day following the day on which notice of the date of such annual meeting was mailed or public disclosure of the date of such annual meeting was made, whichever first occurs. In no event

shall the adjournment or postponement of an annual meeting (or the public disclosure thereof) commence a new time period (or extend any time period) for the giving of a stockholder's notice.

The stockholder's notice to the Secretary shall set forth: (A) as to each matter the stockholder proposes to bring before the annual meeting (1) a brief description of the business desired to be brought before the annual meeting, (2) the text of the proposal (including the exact text of any resolutions proposed for consideration and, in the event that such business includes a proposal to amend the bylaws, the exact text of the proposed amendment), and (3) the reasons for conducting such business at the annual meeting, and (B) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the proposal is being made (1) the name and address of such stockholder, as they appear on the corporation's books, and of such beneficial owner, (2) the class and series and number of shares of stock of the corporation that are, directly or indirectly, owned, beneficially or of record, by such stockholder and such beneficial owner, (3) a description of any material interest of such stockholder or such beneficial owner and the respective affiliates and associates of, or others acting in concert with, such stockholder or such beneficial owner in such business, (4) a description of any agreement, arrangement or understanding between or among such stockholder and/or such beneficial owner and any other person or persons (including their names) in connection with the proposal of such business or who may participate in the solicitation of proxies in favor of such proposal, (5) a description of any agreement, arrangement or understanding (including any derivative or short positions, swaps, profit interests, options, warrants, convertible securities, stock appreciation or similar rights, hedging transactions, and borrowed or loaned shares) that has been entered into by, or on behalf of, such stockholder or such beneficial owner, the effect or intent of which is to mitigate loss to, manage risk or benefit of share price changes for, or increase or decrease the voting power of, such stockholder or such beneficial owner with respect to shares of stock of the corporation, (6) any other information relating to such stockholder and such beneficial owner that would be required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for the business proposed pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated thereunder, (7) a representation that such stockholder intends to appear in person or by proxy at the annual meeting to bring such business before the meeting and (8) a representation whether such stockholder and/or such

beneficial owner intends or is part of a group that intends (x) to deliver a proxy statement and/or form of proxy to holders of at least the percentage of the corporation's outstanding capital stock required to approve or adopt the proposal (and such representation shall be included in any such proxy statement and form of proxy) and/or (y) otherwise to solicit proxies or votes from stockholders in support of such proposal (and such representation shall be included in any such solicitation materials). Not later than 10 days after the record date for the meeting, the information required by Items (A) (3) and (B)(1)-(6) of the prior sentence shall be supplemented by the stockholder giving the notice to provide updated information as of the record date. Notwithstanding anything in these bylaws to the contrary, no business shall be conducted at any annual meeting of stockholders except in accordance with the procedures in this Section 1.12; provided that any stockholder proposal that complies with Rule 14a-8 of the proxy rules (or any successor provision) promulgated under the Exchange Act and is to be included in the corporation's proxy statement for an annual meeting of stockholders shall be deemed to comply with the notice requirements of this Section 1.12. A stockholder shall not have complied with this Section 1.12(b) if the stockholder (or beneficial owner, if any, on whose behalf the proposal is made) solicits or does not solicit, as the case may be, proxies or votes in support of such stockholder's proposal in contravention of the representations with respect thereto required by this Section 1.12.

- (c) The chairman of any annual meeting shall have the power and duty to determine whether business was properly brought before the annual meeting in accordance with the provisions of this Section 1.12 (including whether the stockholder or beneficial owner, if any, on whose behalf the proposal is made solicited (or is part of a group that solicited) or did not so solicit, as the case may be, proxies or votes in support of such stockholder's proposal in compliance with the representation with respect thereto required by this Section 1.12), and if the chairman should determine that business was not properly brought before the annual meeting in accordance with the provisions of this Section 1.12, the chairman shall so declare to the meeting and such business shall not be brought before the annual meeting.
- (d) Except as otherwise required by law, nothing in this Section 1.12 shall obligate the corporation or the Board of Directors to include in any proxy statement or other stockholder communication distributed on behalf of the corporation or the Board of Directors information with respect to any proposal submitted by a stockholder.

- (e) Notwithstanding the foregoing provisions of this Section 1.12, unless otherwise required by law, if the stockholder (or a qualified representative of the stockholder) does not appear at the annual meeting to present business, such business shall not be considered, notwithstanding that proxies in respect of such business may have been received by the corporation.
- (f) For purposes of this Section 1.12, the terms "qualified representative of the stockholder" and "public disclosure" shall have the same meaning as in Section 1.11.

## 1.13 Conduct of Meetings.

- (a) Unless otherwise provided by the Board of Directors, meetings of stockholders shall be presided over by the Chairman of the Board, if any, or in the Chairman's absence by the Vice Chairman of the Board, if any, or in the Vice Chairman's absence by the Chief Executive Officer, or in the Chief Executive Officer's absence by the President, or in the President's absence by a Vice President, or in the absence of all of the foregoing persons by a chairman designated by the Board of Directors. The Secretary shall act as secretary of the meeting, but in the Secretary's absence the chairman of the meeting may appoint any person to act as secretary of the meeting.
- (b) The Board of Directors may adopt by resolution such rules, regulations and procedures for the conduct of any meeting of stockholders of the corporation as it shall deem appropriate including, without limitation, such guidelines and procedures as it may deem appropriate regarding the participation by means of remote communication of stockholders and proxyholders not physically present at a meeting. Except to the extent inconsistent with such rules, regulations and procedures as adopted by the Board of Directors, the chairman of any meeting of stockholders shall have the right and authority to convene and (for any or no reason) to recess and/or adjourn the meeting and prescribe such rules, regulations and procedures and to do all such acts as, in the judgment of such chairman, are appropriate for the proper conduct of the meeting. Such rules, regulations or procedures, whether adopted by the Board of Directors

or prescribed by the chairman of the meeting, may include, without limitation, the following: (i) the establishment of an agenda or order of business for the meeting; (ii) rules and procedures for maintaining order at the meeting and the safety of those present; (iii) limitations on attendance at or participation in the meeting to stockholders entitled to vote at the meeting, their duly authorized and constituted proxies or such other persons as shall be determined; (iv) restrictions on entry to the meeting after the time fixed for the commencement thereof; and (v) limitations on the time allotted to questions or comments by participants. Unless and to the extent determined by the Board of Directors or the chairman of the meeting, meetings of stockholders shall not be required to be held in accordance with the rules of parliamentary procedure.

- (c) The chairman of the meeting shall announce at the meeting when the polls for each matter to be voted upon at the meeting will be opened and closed. After the polls close, no ballots, proxies or votes or any revocations or changes thereto may be accepted.
- (d) In advance of any meeting of stockholders, the Board of Directors, the Chairman of the Board, the Chief Executive Officer or the President shall appoint one or more inspectors of election to act at the meeting and make a written report thereof. One or more other persons may be designated as alternate inspectors to replace any inspector who fails to act. If no inspector or alternate is present, ready and willing to act at a meeting of stockholders, the chairman of the meeting shall appoint one or more inspectors to act at the meeting. Unless otherwise required by law, inspectors may be officers, employees or agents of the corporation. Each inspector, before entering upon the discharge of such inspector's duties, shall take and sign an oath faithfully to execute the duties of inspector with strict impartiality and according to the best of such inspector's ability. The inspector shall have the duties prescribed by law and shall take charge of the polls and, when the vote is completed, shall make a certificate of the result of the vote taken and of such other facts as may be required by law. Every vote taken by ballots shall be counted by a duly appointed inspector or duly appointed inspectors.
- 1.14 No Action by Consent in Lieu of a Meeting. Stockholders of the corporation may not take any action by written consent in lieu of a meeting.

#### ARTICLE II

#### **DIRECTORS**

- 2.1 <u>General Powers</u>. The business and affairs of the corporation shall be managed by or under the direction of a Board of Directors, who may exercise all of the powers of the corporation except as otherwise provided by law or the Certificate of Incorporation.
- 2.2 <u>Number, Election and Qualification</u>. The number of directors of the corporation shall be the number fixed by, or determined in the manner provided in, the Certificate of Incorporation. Election of directors need not be by written ballot. Directors need not be stockholders of the corporation.
- 2.3 <u>Chairman of the Board</u>; <u>Vice Chairman of the Board</u>. The Board of Directors may appoint from its members a Chairman of the Board and a Vice Chairman of the Board, neither of whom need be an employee or officer of the corporation. If the Board of Directors appoints a Chairman of the Board, such Chairman shall perform such duties and possess such powers as are assigned by the Board of Directors and, if the Chairman of the Board is also designated as the corporation's Chief Executive Officer, shall have the powers and duties of the Chief Executive Officer prescribed in Section 3.7 of these bylaws. If the Board of Directors appoints a Vice Chairman of the Board, such Vice Chairman shall perform such duties and possess such powers as are assigned by the Board of Directors or the Chairman of the Board. Unless otherwise provided by the Board of Directors, the Chairman of the Board or, in the Chairman's absence, the Vice Chairman of the Board, if any, shall preside at all meetings of the Board of Directors.
- 2.4 <u>Terms of Office</u>. Directors shall be elected for such terms and in the manner provided by the Certificate of Incorporation and applicable law. The term of each director shall continue until the election and qualification of his or her successor and be subject to his or her earlier death, resignation or removal.
- 2.5 <u>Quorum</u>. The greater of (a) a majority of the directors at any time in office and (b) one-third of the number of directors established by the Board of Directors pursuant to the

Certificate of Incorporation shall constitute a quorum of the Board of Directors. If at any meeting of the Board of Directors there shall be less than such a quorum, a majority of the directors present may adjourn the meeting from time to time without further notice other than announcement at the meeting, until a quorum shall be present.

- 2.6 <u>Action at Meeting</u>. Every act or decision done or made by a majority of the directors present at a meeting duly held at which a quorum is present shall be regarded as the act of the Board of Directors, unless a greater number is required by law or by the Certificate of Incorporation.
  - 2.7 Removal. Directors of the corporation may be removed in the manner specified by the Certificate of Incorporation and applicable law.
- 2.8 <u>Vacancies</u>. Any vacancy or newly-created directorship on the Board of Directors, however occurring, shall be filled in the manner specified by the Certificate of Incorporation and applicable law.
- 2.9 <u>Resignation</u>. Any director may resign by delivering a resignation in writing or by electronic transmission to the corporation at its principal executive office or to the Chairman of the Board, the Chief Executive Officer, the President or the Secretary. Such resignation shall be effective upon receipt unless it is specified to be effective at some later time or upon the happening of some later event.
- 2.10 <u>Regular Meetings</u>. Regular meetings of the Board of Directors may be held without notice at such time and place as shall be determined from time to time by the Board of Directors; provided that any director who is absent when such a determination is made shall be given notice of the determination. A regular meeting of the Board of Directors may be held without notice immediately after and at the same place as the annual meeting of stockholders.
- 2.11 <u>Special Meetings</u>. Special meetings of the Board of Directors may be held at any time and place designated in a call by the Chairman of the Board, the Chief Executive Officer, the President, two or more directors, or by one director in the event that there is only a single director in office.

- 2.12 <u>Notice of Special Meetings</u>. Notice of the date, place and time of any special meeting of directors shall be given to each director by the Secretary or by the officer or one of the directors calling the meeting. Notice shall be duly given to each director (a) in person, by telephone or by electronic transmission at least 24 hours in advance of the meeting, (b) by delivering written notice by hand to such director's last known business or home address at least 48 hours in advance of the meeting, or (c) by sending written notice by first-class mail to such director's last known business or home address at least 72 hours in advance of the meeting. A notice or waiver of notice of a meeting of the Board of Directors need not specify the purposes of the meeting.
- 2.13 <u>Meetings by Conference Communications Equipment</u>. Directors may participate in meetings of the Board of Directors or any committee thereof by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and participation by such means shall constitute presence in person at such meeting.
- 2.14 Action by Consent. Any action required or permitted to be taken at any meeting of the Board of Directors or of any committee thereof may be taken without a meeting if all members of the Board of Directors or committee, as the case may be, consent to the action in writing or by electronic transmission. After an action is taken, the consent or consents relating thereto shall be filed with the minutes of proceedings of the Board of Directors or committee in the same paper or electronic form as the minutes are maintained.
- 2.15 <u>Committees</u>. The Board of Directors may designate one or more committees, each committee to consist of one or more of the directors of the corporation with such lawfully delegable powers and duties as the Board of Directors thereby confers, to serve at the pleasure of the Board of Directors. The Board of Directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members of the committee present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board of Directors to act at the meeting in the place of any such absent or disqualified

member. Any such committee, to the extent provided in the resolution of the Board of Directors and subject to the provisions of law, shall have and may exercise all the powers and authority of the Board of Directors in the management of the business and affairs of the corporation and may authorize the seal of the corporation to be affixed to all papers that may require it. Each such committee shall keep minutes and make such reports as the Board of Directors may from time to time request. Except as the Board of Directors may otherwise determine, any committee may make rules for the conduct of its business, but unless otherwise provided by the directors or in such rules, its business shall be conducted as nearly as possible in the same manner as is provided in these bylaws for the Board of Directors. Except as otherwise provided in the Certificate of Incorporation, these bylaws, or the resolution of the Board of Directors designating the committee, a committee may create one or more subcommittees, each subcommittee to consist of one or more members of the committee, and delegate to a subcommittee any or all of the powers and authority of the committee.

2.16 <u>Compensation of Directors</u>. Directors may be paid such compensation for their services and such reimbursement for expenses of attendance at meetings as the Board of Directors may from time to time determine. No such payment shall preclude any director from serving the corporation or any of its parent or subsidiary entities in any other capacity and receiving compensation for such service.

#### **ARTICLE III**

#### **OFFICERS**

- 3.1 <u>Titles</u>. The officers of the corporation shall consist of a Chief Executive Officer, a President, a Secretary, a Treasurer and such other officers with such other titles as the Board of Directors shall determine, including one or more Vice Presidents, Assistant Treasurers and Assistant Secretaries. The Board of Directors may appoint such other officers as it may deem appropriate.
- 3.2 <u>Election</u>. The Chief Executive Officer, President, Treasurer and Secretary shall be elected annually by the Board of Directors at its first meeting following the annual meeting of stockholders. Other officers may be appointed by the Board of Directors at such meeting or at any other meeting.

- 3.3 Qualification. No officer need be a stockholder. Any two or more offices may be held by the same person.
- 3.4 <u>Tenure</u>. Except as otherwise provided by law, by the Certificate of Incorporation or by these bylaws, each officer shall hold office until such officer's successor is elected and qualified, unless a different term is specified in the resolution electing or appointing such officer, or until such officer's earlier death, resignation or removal.
- 3.5 <u>Resignation and Removal</u>. Any officer may resign by delivering a resignation in writing or by electronic transmission to the corporation at its principal executive office or to the Chief Executive Officer, the President or the Secretary. Such resignation shall be effective upon receipt unless it is specified to be effective at some later time or upon the happening of some later event. Any officer may be removed at any time, with or without cause, by vote of a majority of the directors then in office. Except as the Board of Directors may otherwise determine, no officer who resigns or is removed shall have any right to any compensation as an officer for any period following such officer's resignation or removal, or any right to damages on account of such removal, whether such officer's compensation be by the month or by the year or otherwise, unless such compensation is expressly provided for in a duly authorized written agreement with the corporation.
- 3.6 <u>Vacancies</u>. The Board of Directors may fill any vacancy occurring in any office for any reason and may, in its discretion, leave unfilled for such period as it may determine any offices. Each such successor shall hold office for the unexpired term of such officer's predecessor and until a successor is elected and qualified, or until such officer's earlier death, resignation or removal.
- 3.7 <u>President; Chief Executive Officer</u>. Unless the Board of Directors has designated another person as the corporation's Chief Executive Officer, the President shall be the Chief Executive Officer of the corporation. The Chief Executive Officer shall have general charge and supervision of the business of the corporation subject to the direction of the Board of Directors,

and shall perform all duties and have all powers that are commonly incident to the office of the chief executive or that are delegated to such officer by the Board of Directors. The President shall perform such other duties and shall have such other powers as the Board of Directors or the Chief Executive Officer (if the President is not the Chief Executive Officer) may from time to time prescribe. In the event of the absence, inability or refusal to act of the Chief Executive Officer or the President (if the President is not the Chief Executive Officer), the Vice President (or if there shall be more than one, the Vice Presidents in the order determined by the Board of Directors) shall perform the duties of the Chief Executive Officer and when so performing such duties shall have all the powers of and be subject to all the restrictions upon the Chief Executive Officer.

3.8 <u>Vice Presidents</u>. Each Vice President shall perform such duties and possess such powers as the Board of Directors or the Chief Executive Officer may from time to time prescribe. The Board of Directors may assign to any Vice President the title of Executive Vice President, Senior Vice President or any other title selected by the Board of Directors.

3.9 <u>Secretary and Assistant Secretaries</u>. The Secretary shall perform such duties and shall have such powers as the Board of Directors or the Chief Executive Officer may from time to time prescribe. In addition, the Secretary shall perform such duties and have such powers as are incident to the office of the secretary, including without limitation the duty and power to give notices of all meetings of stockholders and special meetings of the Board of Directors, to attend all meetings of stockholders and the Board of Directors and keep a record of the proceedings, to maintain a stock ledger and prepare lists of stockholders and their addresses as required, to be custodian of corporate records and the corporate seal and to affix and attest to the same on documents.

Any Assistant Secretary shall perform such duties and possess such powers as the Board of Directors, the Chief Executive Officer or the Secretary may from time to time prescribe. In the event of the absence, inability or refusal to act of the Secretary, the Assistant Secretary (or if there shall be more than one, the Assistant Secretaries in the order determined by the Board of Directors) shall perform the duties and exercise the powers of the Secretary.

In the absence of the Secretary or any Assistant Secretary at any meeting of stockholders or directors, the chairman of the meeting shall designate a temporary secretary to keep a record of the meeting.

3.10 <u>Treasurer and Assistant Treasurers</u>. The Treasurer shall perform such duties and shall have such powers as may from time to time be assigned by the Board of Directors or the Chief Executive Officer. In addition, the Treasurer shall perform such duties and have such powers as are incident to the office of treasurer, including without limitation the duty and power to keep and be responsible for all funds and securities of the corporation, to deposit funds of the corporation in depositories selected in accordance with these bylaws, to disburse such funds as ordered by the Board of Directors, to make proper accounts of such funds, and to render as required by the Board of Directors statements of all such transactions and of the financial condition of the corporation.

The Assistant Treasurers shall perform such duties and possess such powers as the Board of Directors, the Chief Executive Officer or the Treasurer may from time to time prescribe. In the event of the absence, inability or refusal to act of the Treasurer, the Assistant Treasurer (or if there shall be more than one, the Assistant Treasurers in the order determined by the Board of Directors) shall perform the duties and exercise the powers of the Treasurer.

- 3.11 <u>Salaries</u>. Officers of the corporation shall be entitled to such salaries, compensation or reimbursement as shall be fixed or allowed from time to time by the Board of Directors.
- 3.12 <u>Delegation of Authority</u>. The Board of Directors may from time to time delegate the powers or duties of any officer to any other officer or agent, notwithstanding any provision hereof.

# ARTICLE IV

## **CAPITAL STOCK**

4.1 <u>Issuance of Stock</u>. Subject to the provisions of the Certificate of Incorporation, the whole or any part of any unissued balance of the authorized capital stock of the corporation

or the whole or any part of any shares of the authorized capital stock of the corporation held in the corporation's treasury may be issued, sold, transferred or otherwise disposed of by vote of the Board of Directors in such manner, for such lawful consideration and on such terms as the Board of Directors may determine.

4.2 <u>Stock Certificates</u>; <u>Uncertificated Shares</u>. The shares of the corporation shall be represented by certificates, provided that the Board of Directors may provide by resolution or resolutions that some or all of any or all classes or series of the corporation's stock shall be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the corporation. Every holder of stock of the corporation represented by certificates shall be entitled to have a certificate, in such form as may be prescribed by law and by the Board of Directors, representing the number of shares held by such holder registered in certificate form. Each such certificate shall be signed in a manner that complies with Section 158 of the General Corporation Law of the State of Delaware.

Each certificate for shares of stock that are subject to any restriction on transfer pursuant to the Certificate of Incorporation, these bylaws, applicable securities laws or any agreement among any number of stockholders or among such holders and the corporation shall have conspicuously noted on the face or back of the certificate either the full text of the restriction or a statement of the existence of such restriction.

If the corporation shall be authorized to issue more than one class of stock or more than one series of any class, the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of each certificate representing shares of such class or series of stock, provided that in lieu of the foregoing requirements there may be set forth on the face or back of each certificate representing shares of such class or series of stock a statement that the corporation will furnish without charge to each stockholder who so requests a copy of the full text of the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

Within a reasonable time after the issuance or transfer of uncertificated shares, the registered owner thereof shall be given a notice, in writing or by electronic transmission, containing the information required to be set forth or stated on certificates pursuant to Sections 151, 156, 202(a) or 218(a) of the General Corporation Law of the State of Delaware or, with respect to Section 151 of the General Corporation Law of the State of Delaware, a statement that the corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

4.3 <u>Transfers</u>. Shares of stock of the corporation shall be transferable in the manner prescribed by law and in these bylaws. Transfers of shares of stock of the corporation shall be made only on the books of the corporation or by transfer agents designated to transfer shares of stock of the corporation. Subject to applicable law, shares of stock represented by certificates shall be transferred only on the books of the corporation by the surrender to the corporation or its transfer agent of the certificate representing such shares properly endorsed or accompanied by a written assignment or power of attorney properly executed, and with such proof of authority or the authenticity of signature as the corporation or its transfer agent may reasonably require. Uncertificated shares may be transferred by delivery of a written assignment or power of attorney properly executed, and with such proof of authority or the authenticity of signature as the corporation or its transfer agent may reasonably require. Except as may be otherwise required by law, by the Certificate of Incorporation or by these bylaws, the corporation shall be entitled to treat the record holder of stock as shown on its books as the owner of such stock for all purposes, including the payment of dividends and the right to vote with respect to such stock, regardless of any transfer, pledge or other disposition of such stock until the shares have been transferred on the books of the corporation in accordance with the requirements of these bylaws.

4.4 <u>Lost, Stolen or Destroyed Certificates</u>. The corporation may issue a new certificate of stock in place of any previously issued certificate alleged to have been lost, stolen or destroyed, upon such terms and conditions as the corporation may prescribe, including the presentation of reasonable evidence of such loss, theft or destruction and the giving of such indemnity and posting of such bond as the corporation may require for the protection of the corporation or any transfer agent or registrar.

4.5 <u>Regulations</u>. The issue, transfer, conversion and registration of shares of stock of the corporation shall be governed by such other regulations as the Board of Directors may establish.

## ARTICLE V

# **GENERAL PROVISIONS**

- 5.1 <u>Fiscal Year</u>. Except as from time to time otherwise designated by the Board of Directors, the fiscal year of the corporation shall begin on the first day of January of each year and end on the last day of December in each year.
  - 5.2 Corporate Seal. The corporate seal shall be in such form as shall be approved by the Board of Directors.
- 5.3 Record Date for Purposes Other Than Stockholder Meetings. In order that the corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights, entitled to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action (other than with respect to determining stockholders entitled to notice of or to vote at a meeting of stockholders, which is addressed in Section 1.4 of these bylaws), the Board of Directors may fix a record date, which shall not precede the date upon which the resolution fixing the record date is adopted, and which record date shall not be more than 60 days prior to such action. If no such record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating thereto.
- 5.4 <u>Waiver of Notice</u>. Whenever notice is required to be given by law, by the Certificate of Incorporation or by these bylaws, a written waiver signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether provided before, at or after the time of the event for which notice is to be given, shall be deemed equivalent to notice required to be given to such person. Neither the business nor the purpose of

any meeting need be specified in any such waiver. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened.

- 5.5 <u>Voting of Securities</u>. Except as the Board of Directors may otherwise designate, the Chief Executive Officer, the President or the Treasurer may waive notice of, vote, or appoint any person or persons to vote, on behalf of the corporation at, and act as, or appoint any person or persons to act as, proxy or attorney-in-fact for this corporation (with or without power of substitution) at, any meeting of stockholders or securityholders of any other entity, the securities of which may be held by this corporation, or with respect to the execution of any written or electronic consent in the name of the corporation as a holder of such securities.
- 5.6 Evidence of Authority. A certificate by the Secretary, or an Assistant Secretary, or a temporary Secretary, as to any action taken by the stockholders, directors, a committee or any officer or representative of the corporation shall as to all persons who rely on the certificate in good faith be conclusive evidence of such action.
- 5.7 <u>Certificate of Incorporation</u>. All references in these bylaws to the Certificate of Incorporation shall be deemed to refer to the Certificate of Incorporation of the corporation, as amended and/or restated and in effect from time to time.
- 5.8 <u>Severability</u>. Any determination that any provision of these bylaws is for any reason inapplicable, illegal or ineffective shall not affect or invalidate any other provision of these bylaws.
- 5.9 <u>Pronouns</u>. All pronouns used in these bylaws shall be deemed to refer to the masculine, feminine or neuter, singular or plural, as the identity of the person or persons may require.

# ARTICLE VI

# **AMENDMENTS**

These bylaws may be altered, amended or repealed, in whole or in part, or new bylaws may be adopted by the Board of Directors or by the stockholders as provided in the Certificate of Incorporation.

ZQ|CERT#|COY|CLS|RGSTRY|ACCT#|TRANSTYPE|RUN#|TRANS# Exhibit 4.1 COMMON STOCK COMMON STOCK (\*)( inozyme Number ZQ00000000 INOZYME PHARMA, INC. ( THIS CERTIFIES THAT MR. SAMPLE & MRS. SAMPLE & CUSIP 45790W 10 8 MR. SAMPLE & MRS. SAMPLE (3) is the owner of \*\*\*ZERO HUNDRED THOUSAND ZERO HUNDRED AND ZERO\*\* FULLY-PAID AND NON-ASSESSABLE SHARES OF COMMON STOCK OF Inozyme Pharma, Inc. (hereinafter called the "Company"), transferable on the books of the Company in person or by duly authorized attorney, upon surrender of this Certificate properly endorsed. This Certificate and the shares represented hereby, are issued and shall be held subject to all of the provisions of the Certificate of Incorporation, as amended, and the By-Laws, as amended, of the Company (copies of which are on file with the Company and with the Transfer Agent), to all of which each holder, by acceptance hereof, assents. This Certificate is not valid unless countersigned and registered by the Transfer Agent and Registrar. Witness the facsimile seal of the Company and the facsimile signatures of its duly authorized officers. DATED DO-MIMM-YYYY COUNTERSIGNED AND REGISTERED: COMPUTERSHARE TRUST COMPANY, N.A. TRANSFER AGENT AND REGISTRAR, SEAL

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INOZYME PHARMA, INC.

THE COMPANY WILL FURNISH WITHOUT CHARGE TO EACH SHAREHOLDER WHO SO REQUESTS, A SUMMARY OF THE POWERS, DESIGNATIONS, PREFERENCES AND RELATIVE, PARTICIPATING, OPTIONAL, OR OTHER SPECIAL RIGHTS OF EACH CLASS OF ESTOCK OF THE COMPANY AND THE QUALIFICATIONS, LIMITATIONS OR RESTRICTIONS OF SUCH PREFERENCES AND RIGHTS, AND THE WARRATIONS IN RIGHTS, PREFERENCES AND LIMITATIONS DETERMINED FOR EACH SERIES, WHICH ARE FIXED BY THE CERTIFICATE OF INCORPORATION OF THE COMPANY, AS AMENDED, AND THE RESOLUTIONS OF THE BOARD OF DIRECTORS OF THE COMPANY, AND THE AUTHORITY OF THE BOARD OF DIRECTORS TO DETERMINE WARRATIONS FOR FUTURE SERIES, SUCH REQUEST MAY BE MADE TO THE OFFICE OF THE SECRETARY OF THE COMPANY OR TO THE TRANSFER AGENT. THE BOARD OF DIRECTORS MAY REQUIRE THE OWNER OF A LOST OR DESTROYED STOCK CERTIFICATE. OR HIS LEGAL REPRESENTATIVES, TO GIVE THE COMPANY AS BOAD TO INDENNIFY IT AND ITS TRANSFER AGENTS AND REGISTRARS AGAINST ANY CLAIM THAT MAY BE MADE AGAINST THEM ON ACCOUNT OF THE ALLEGED LOSS OR DESTRUCTION OF ANY SUCH CERTIFICATE.

	ulations:	tificate, shall be construed as though they were written out in full
TEN COM - as tenants in commo	n UNIF GIFT MIN	ACT - Custodian (Mnor)
TEN ENT - as tenants by the ent		under Uniform Gifts to Minors Act
JT TEN - as joint tenants with and not as tenants in	right of survivorship UNIF TRF MIN / n common	CT - Custodian (until age
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SECURITY INSTRUCTIONS



# WILMERHALE

+1 212 230 8800 (t) +1 212 230 8888 (f)

July 20, 2020

Inozyme Pharma, Inc. 321 Summer Street, Suite 400 Boston, Massachusetts 02210

#### Registration Statement on Form S-1

#### Ladies and Gentlemen:

This opinion is furnished to you in connection with a Registration Statement on Form S-1 (File No. 333-239648) (the "Registration Statement") filed with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended (the "Securities Act"), for the registration of 5,750,000 shares of Common Stock, par value \$0.0001 per share (the "Shares"), of Inozyme Pharma, Inc., a Delaware corporation (the "Company"), including 750,000 Shares issuable upon exercise of an option granted by the Company.

The Shares are to be sold by the Company pursuant to an underwriting agreement (the "Underwriting Agreement") to be entered into by and among the Company and BofA Securities, Inc., Cowen and Company, LLC and Piper Sandler & Co., as representatives of the several underwriters named in the Underwriting Agreement, the form of which has been filed as Exhibit 1.1 to the Registration Statement.

We are acting as counsel for the Company in connection with the issue and sale by the Company of the Shares. We have examined signed copies of the Registration Statement as filed with the Commission. We have also examined and relied upon the Underwriting Agreement, minutes of meetings and actions of the stockholders and the Board of Directors of the Company as provided to us by the Company, stock record books of the Company as provided to us by the Company, the Certificate of Incorporation and Bylaws of the Company, each as restated and/or amended to date, and such other documents as we have deemed necessary for purposes of rendering the opinions hereinafter set forth.

In our examination of the foregoing documents, we have assumed the genuineness of all signatures, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as copies, the authenticity of the originals of such latter documents and the legal competence of all signatories to such documents.

We express no opinion herein as to the laws of any state or jurisdiction other than the General Corporation Law of the State of Delaware and the federal laws of the United States of America.

Based upon and subject to the foregoing, we are of the opinion that the Shares have been duly authorized for issuance and, when the Shares are issued and paid for in accordance with the terms and conditions of the Underwriting Agreement, the Shares will be validly issued, fully paid and nonassessable.

Wilmer Cutler Pickering Hale and Dorr LLP, 7 World Trade center, 250 Greenwich Street, New York, New York 10007
Beijing Berlin Boston Brussels Denver Frankfurt London Los Angeles New York Palo Alto San Francisco Washington



July 20, 2020 Page 2

Please note that we are opining only as to the matters expressly set forth herein, and no opinion should be inferred as to any other matters. This opinion is based upon currently existing statutes, rules, regulations and judicial decisions, and we disclaim any obligation to advise you of any change in any of these sources of law or subsequent legal or factual developments which might affect any matters or opinions set forth herein.

We hereby consent to the filing of this opinion with the Commission as an exhibit to the Registration Statement in accordance with the requirements of Item 601(b)(5) of Regulation S-K under the Securities Act and to the use of our name therein and in the related Prospectus under the caption "Legal Matters." In giving such consent, we do not hereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission.

Very truly yours,

WILMER CUTLER PICKERING HALE AND DORR LLP

By: /s/ Brian A. Johnson

Brian A. Johnson, a Partner

#### INOZYME PHARMA, INC.

## SECOND AMENDED AND RESTATED INVESTOR RIGHTS AGREEMENT

THIS SECOND AMENDED AND RESTATED INVESTOR RIGHTS AGREEMENT (this "Agreement"), dated as of November 9, 2018, by and among INOZYME PHARMA, INC., a Delaware corporation (the "Company"), and the investors listed on Exhibit A hereto (referred to hereinafter as the "Investors" and each individually as an "Investor") amends and restates the Amended and Restated Investor Rights Agreement entered into as of April 13, 2017, by and among the Company and the Investors (defined therein) party thereto (the "Prior Agreement").

## RECITALS

- **A.** Certain of the Investors (the "*Existing Investors*") hold shares of the Company's Series A Convertible Preferred Stock, \$0.0001 par value per share (the "*Series A Preferred Stock*"), pursuant to that certain Amended and Restated Series A Convertible Preferred Stock Purchase Agreement and possess registration rights, information rights, rights of first offer, and other rights pursuant to the Prior Agreement.
- **B.** The Existing Investors are holders of a majority of the Registrable Securities of the Company (as defined in the Prior Agreement) and desire to amend and restate the Prior Agreement in its entirety and to accept the rights granted and obligations imposed pursuant to this Agreement in lieu of the rights granted and obligations imposed under the Prior Agreement.
- **C.** Certain of the Investors are parties to that certain Series A-2 Preferred Stock Purchase Agreement of even date herewith by and among the Company and such Investors (the "*Purchase Agreement*"), under which certain of the Company's and such Investors' obligations are conditioned upon the execution and delivery of this Agreement by such Investors, Existing Investors holding at least a majority of the Registrable Securities, and the Company.
  - **D.** The parties wish to amend and restate the Prior Agreement on the terms provided herein.

The parties hereto agree as follows:

# SECTION 1. GENERAL.

- **1.1 Definitions.** As used in this Agreement the following terms shall have the following respective meanings:
- (a) "Affiliate" means, with respect to any specified Person, any other Person who, directly or indirectly, controls, is controlled by, or is under common control with such Person, including, without limitation, any general partner, managing member, officer or director of such Person or any investment fund or other Person now or hereafter existing which is controlled by one or more general partners, managing members, or equity holders of, shares the same management company with, or is under common management with, such Person. Notwithstanding the above, with respect to Novo Holdings A/S, in lieu of the above definition, the term "Affiliate" shall mean Novo Ventures (US) Inc. (together with Novo Holdings A/S, "Novo"), any partner,

executive officer or director of Novo or any venture capital fund or other person now or hereafter existing formed for the purpose of making investments in other persons that is controlled by or under common control with Novo, and for the avoidance of doubt, shall not include any other affiliate of Novo.

- **(b)** "*Board*" shall mean the Company's Board of Directors.
- (c) "Business Day" means any day other than a Saturday, Sunday or other day on which commercial banks in The City of New York are authorized by law or executive order to remain closed.
  - (d) "Common Stock" shall mean the Common Stock, par value \$0.0001 per share, of the Company.
  - (e) "Exchange Act" means the Securities Exchange Act of 1934, as amended.
- **(f)** "*Form S-3*" means a Registration Statement on Form S-3 under the Securities Act, as such form is in effect on the date hereof or any successor or similar registration form under the Securities Act subsequently adopted by the SEC which permits inclusion or incorporation of substantial information by reference to other documents filed by the registrant thereunder with the SEC.
- **(g)** "Holder" means any person owning of record Registrable Securities that have not been sold to the public or any assignee of record of such Registrable Securities in accordance with Section 2.9 hereof.
- **(h)** "*Initial Public Offering*" means the closing of the Company's first bona fide, firm commitment underwritten public offering of the Common Stock registered under the Securities Act.
  - (i) "Major Investor" means any Investor who holds at least 3,139,860 shares of Preferred Stock.
  - (j) "Person" means any individual, corporation, partnership, trust, limited liability company, association or other entity.
  - (k) "Preferred Stock" means, collectively, the Series A Preferred Stock and the Series A-2 Preferred Stock.
- (I) "Qualified Public Offering" shall have the meaning prescribed in the Company's Amended and Restated Certificate of Incorporation of even date herewith, as the same may be amended from time to time (the "Charter").
- (m) "Register," "registered," and "registration" refer to a registration effected by preparing and filing with the SEC a registration statement in compliance with the Securities Act, and the declaration or ordering of effectiveness of such registration statement or document by the SEC.

- (n) "Registrable Securities" means (a) Common Stock of the Company issuable or issued upon conversion of Preferred Stock and (b) any Common Stock of the Company issued as (or issuable upon the conversion or exercise of any warrant, right or other security which is issued as) a dividend or other distribution with respect to, or in exchange for or in replacement of, any securities described in the immediately preceding clause (a) or this clause (b). Notwithstanding the foregoing, Registrable Securities shall not include any securities (i) sold by a person to the public either pursuant to a registration statement ordered effective by the SEC, Rule 144 under the Securities Act or another exemption from registration under the Securities Act, (ii) sold in a private transaction in which the transferor's rights under Section 2 of this Agreement are not assigned, or (iii) issued upon conversion of Preferred Stock pursuant to a Special Mandatory Conversion.
- **(o)** "Registrable Securities then outstanding" shall be the number of shares of the Common Stock that are Registrable Securities and either (a) are then issued and outstanding or (b) are issuable pursuant to then exercisable or convertible securities.
- **(p)** "*Registration Expenses*" shall mean all expenses incurred by the Company in complying with Sections 2.2, 2.3 and 2.4 hereof, including, without limitation, all registration, qualification and filing fees, FINRA fees and expenses, printing expenses, fees and disbursements of counsel for the Company, reasonable fees and disbursements not to exceed thirty-five thousand dollars (\$35,000) of a single counsel for the Holders, blue sky fees and expenses and the expense of any regular or special audits incident to or required by any such registration (but excluding the compensation of regular employees of the Company which shall be paid in any event by the Company).
  - (q) "SEC" means the Securities and Exchange Commission.
  - (r) "Securities Act" shall mean the Securities Act of 1933, as amended.
  - (s) "Selling Expenses" shall mean all underwriting discounts and selling commissions applicable to the sale of Registrable Securities.
- (t) "Series A-2 Preferred Stock" shall mean shares of the Company's Series A-2 Convertible Preferred Stock, \$0.0001 par value per share.
  - (u) "Special Mandatory Conversion" shall have the meaning provided in the Charter.
- (v) "Special Registration Statement" shall mean (i) a registration statement relating to any employee benefit plan or (ii) with respect to any corporate reorganization or transaction under Rule 145 under the Securities Act, any registration statements related to the issuance or resale of securities issued in such a transaction or (iii) a registration related to stock issued upon conversion of debt securities.

# SECTION 2. REGISTRATION; RESTRICTIONS ON TRANSFER.

# 2.1 Restrictions on Transfer.

- (a) Each Holder agrees not to make any disposition of all or any portion of the Preferred Stock or Registrable Securities unless and until:
- (i) there is then in effect a registration statement under the Securities Act covering such proposed disposition and such disposition is made in accordance with such registration statement; or
- (ii) (A) if such transfer is prior to the Company's Initial Public Offering, the transferee has agreed in writing to be bound by the terms of this Agreement, (B) such Holder shall have notified the Company of the proposed disposition, and (C) if reasonably requested by the Company, such Holder shall have furnished the Company, at its expense, with an opinion of counsel, reasonably satisfactory to the Company, or any other evidence that the Company may require (which may include a "no action" letter from the staff of the SEC) that such disposition will not require registration of such shares under the Securities Act. The Company will not require opinions of counsel for transactions made pursuant to Rule 144 under the Securities Act unless the Holder is an "affiliate" (as defined for purposes of Rule 144 under the Securities Act) of the Company or the Company believes in good faith that there is a substantial question about whether or not the Holder is such an affiliate.
- **(b)** Notwithstanding the provisions of subsection (a) above, no such restriction shall apply to a transfer by a Holder that is (A) a partnership transferring by means of distribution to its partners or former partners in accordance with partnership interests, (B) a corporation transferring to a wholly-owned subsidiary or a parent corporation that owns all of the capital stock of the Holder, (C) a limited liability company transferring by means of distribution to its members or former members in accordance with their interest in the limited liability company, (D) an individual transferring to the Holder's family member or a trust for the benefit of an individual Holder or members of such Holder's family or (E) a Holder transferring to an Affiliate of such Holder; *provided* that in each such case the transfere will agree in writing to be subject to the terms of this Agreement to the same extent as if he, she or it were an original Holder hereunder if such transfer is prior to the Company's Initial Public Offering.
- **(c)** Each certificate representing Preferred Stock or Registrable Securities shall be stamped or otherwise imprinted with legends substantially similar to the following (in addition to any legend required under applicable state securities laws):

THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 (THE "ACT") AND MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, ASSIGNED, PLEDGED OR HYPOTHECATED UNLESS AND UNTIL REGISTERED UNDER THE ACT OR UNLESS THE COMPANY HAS RECEIVED AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY AND ITS COUNSEL THAT SUCH REGISTRATION IS NOT REQUIRED.

THE SALE, PLEDGE, HYPOTHECATION OR TRANSFER OF THE SECURITIES REPRESENTED BY THIS CERTIFICATE IS SUBJECT TO THE TERMS AND CONDITIONS OF A CERTAIN INVESTOR

RIGHTS AGREEMENT BY AND BETWEEN THE STOCKHOLDER AND THE COMPANY. COPIES OF SUCH AGREEMENT MAY BE OBTAINED UPON WRITTEN REQUEST TO THE SECRETARY OF THE COMPANY.

- (d) The Company shall be obligated to reissue promptly unlegended certificates at the request of any Holder thereof if the Company has completed its Initial Public Offering and the Holder shall have obtained an opinion of counsel (which counsel may be counsel to the Company) reasonably acceptable to the Company to the effect that the securities proposed to be disposed of may lawfully be so disposed of without registration, qualification and legend and in circumstances in which the Holder would not be required to file a Form 144 with the SEC to claim the "safe harbor" exemption from registration under the Securities Act afforded by Rule 144 under the Securities Act, whether or not in fact such Holder is claiming such safe harbor exemption, *provided that* the second legend listed above shall be removed only at such time as the Holder of such certificate is no longer subject to any restrictions under this Agreement.
- **(e)** Any legend endorsed on an instrument pursuant to applicable state securities laws and the stop-transfer instructions with respect to such securities shall be removed upon receipt by the Company of an order of the appropriate blue sky authority authorizing such removal or advice of counsel to the Company that such legend may lawfully be removed.

# 2.2 Demand Registration.

- (a) Subject to the conditions of this Section 2.2, if the Company shall receive a written request from the Holders of 56% of the Registrable Securities (the "*Initiating Holders*") that the Company file a registration statement under the Securities Act covering the registration of all or a part of the Registrable Securities having (i) an anticipated aggregate offering price, net of underwriting discounts and commissions, of not less than \$50,000,000 (if the Company has not yet completed its Initial Public Offering) or (ii) an anticipated aggregate offering price, net of underwriting discounts and commissions, of not less than \$10,000,000 (after the Company completes its Initial Public Offering), then the Company shall, within 30 days of the receipt thereof, give written notice of such request to all Holders and, subject to the limitations of this Section 2.2, effect, as expeditiously as reasonably possible, the registration under the Securities Act of all Registrable Securities that the Initiating Holders requested to be registered and any additional Registrable Securities requested to be included in such registration by any other Holder or Holders joining in such request as specified by notice given by each such Holder to the Company within 20 days after receipt of such written notice from the Company.
- **(b)** If the Initiating Holders intend to distribute the Registrable Securities covered by their request by means of an underwriting, they shall so advise the Company as a part of their request made pursuant to this Section 2.2 or any request pursuant to Section 2.4 and the Company shall include such information in the written notice referred to in Section 2.2(a) or Section 2.4(a), as applicable. In such event, the right of any Holder to include its Registrable Securities in such registration shall be conditioned upon such Holder's participation in such underwriting and the inclusion of such Holder's Registrable Securities in the underwriting to the extent provided herein. All Holders proposing to distribute their securities through such underwriting shall enter into an underwriting agreement in customary form with the underwriter

or underwriters selected for such underwriting by the Holders of a majority of the Registrable Securities held by all Initiating Holders (which underwriter or underwriters shall be reasonably acceptable to the Company). Notwithstanding any other provision of this Section 2.2 or Section 2.4, if the underwriter advises the Company that marketing factors require a limitation of the number of securities to be underwritten (including Registrable Securities) then the Company shall so advise all Holders of Registrable Securities that would otherwise be underwritten pursuant hereto, and the number of shares of Common Stock that may be included in the underwriting shall be allocated to the Holders of such Registrable Securities on a *pro rata* basis based on the number of Registrable Securities held by all such Holders (including the Initiating Holders); *provided, however*, that the number of shares of Registrable Securities to be included in such underwriting and registration shall not be reduced unless all other securities of the Company and securities of any other selling stockholders proposed to be sold by the Company or such selling stockholders are first entirely excluded from the underwriting and registration. Any Registrable Securities excluded or withdrawn from such underwriting shall be withdrawn from the registration.

- **(c)** The Company shall not be required to effect a registration pursuant to this Section 2.2:
- (i) prior to the earlier of (A) the third anniversary of the date of this Agreement or (B) six months following the Initial Public Offering;
- (ii) after the Company has effected two (2) registrations pursuant to this Section 2.2, and such registrations have been declared or ordered effective by the SEC;
- (iii) during the period starting with the date of filing with the SEC of, and ending on the date 180 days following the effective date of the registration statement pertaining to the Initial Public Offering (or such longer period as may be determined pursuant to Section 2.11 hereof); provided that the Company makes reasonable good faith efforts to cause such registration statement to become effective;
- (iv) if within 30 days of receipt of a written request from Initiating Holders pursuant to Section 2.2(a), the Company, gives notice to the Holders of the company's intention to file a registration statement for its Initial Offering within 60 days;
- (v) if the Company shall furnish to Holders requesting a registration statement pursuant to this Section 2.2 a certificate signed by the Chairman of the Board or the Chief Executive Officer of the Company stating that in the good faith judgment of the Board, it would be seriously detrimental to the Company and its stockholders for such registration statement to be effected at such time, in which event the Company shall have the right to defer such filing for a period of not more than 90 days after receipt of the request of the Initiating Holders; *provided* that such right to delay a request shall be exercised by the Company not more than twice in any 12 month period;
- (vi) if the Initiating Holders propose to dispose of shares of Registrable Securities that may be immediately registered on Form S-3 pursuant to a request made pursuant to Section 2.4 below; or

- **(vii)** in any particular jurisdiction in which the Company would be required to qualify to do business, to execute a general consent to service of process or to subject itself to taxation in effecting such registration, qualification or compliance.
- 2.3 Piggyback Registrations. The Company shall notify all Holders of Registrable Securities in writing at least 20 days prior to the filing by the Company of any registration statement under the Securities Act for purposes of a public offering of securities of the Company (including, but not limited to, registration statements relating to secondary offerings of securities of the Company for stockholders other than the Holders, but excluding Special Registration Statements), and will afford each such Holder an opportunity to include in such registration statement all or part of such Registrable Securities held by such Holder. Each Holder desiring to include in any such registration statement all or any part of the Registrable Securities held by it shall, within 15 days after the above-described notice from the Company, so notify the Company in writing. Such notice shall state the intended method of disposition of the Registrable Securities by such Holder. If a Holder decides not to include all of its Registrable Securities in such registration statement filed by the Company, such Holder shall nevertheless continue to have the right to include any of its Registrable Securities in any subsequent registration statement or registration statements as may be filed by the Company with respect to offerings of its securities, all upon the terms and conditions set forth herein.
- (a) Underwriting. If the registration statement of which the Company gives notice under this Section 2.3 is for an underwritten offering, the Company shall so advise the Holders of Registrable Securities. In such event, the right of any such Holder to include Registrable Securities in a registration pursuant to this Section 2.3 shall be conditioned upon such Holder's participation in such underwriting and the inclusion of such Holder's Registrable Securities in the underwriting to the extent provided herein. All Holders proposing to distribute their Registrable Securities through such underwriting shall enter into an underwriting agreement in customary form with the underwriter or underwriters selected for such underwriting by the Company. Notwithstanding any other provision of this Agreement, if the underwriters determine in good faith that marketing factors require a limitation of the number of shares to be underwritten, the number of shares that may be included in the underwriting shall be allocated, first, to the Company; second, to the Holders on a pro rata basis based on the total number of Registrable Securities held by the Holders who propose to include their Registrable Securities in such underwriting; and third, to any stockholder of the Company (other than a Holder) on a pro rata basis; provided, however, that no such reduction shall reduce the amount of securities of the selling Holders included in the registration below twenty-five percent (25%) of the total amount of securities included in such registration, unless such offering is the Initial Public Offering and such registration does not include shares of any other selling stockholders, in which event any or all of the Registrable Securities of the Holders may be excluded in accordance with the immediately preceding clause. In no event will shares of any other selling stockholder be included in such registration that would reduce the number of shares that may be included by Holders without the written consent of Holders of a majority of the Registrable Securities proposed to be sold in the offering. If any Holder disapproves of the terms of any such underwriting, such Holder may elect to withdraw therefrom by written notice to the Company and the underwriter, delivered at least ten business days prior to the effective date of the registration statement. Any Registrable Securities excluded or withdrawn from such underwriting shall be excluded and withdrawn from the registration. For any Holder which is a partnership, limited liability company or corporation, the

partners, retired partners, members, retired members and stockholders of such Holder, or the estates and family members of any such partners, retired partners, members and retired members and any trusts for the benefit of any of the foregoing person shall be deemed to be a single "Holder," and any *pro rata* reduction with respect to such "Holder" shall be based upon the aggregate amount of shares carrying registration rights owned by all entities and individuals included in such "Holder," as defined in this sentence.

- **(b) Right to Terminate Registration.** The Company shall have the right to terminate or withdraw any registration initiated by it under this Section 2.3 whether or not any Holder has elected to include securities in such registration, and shall promptly notify any Holder that has elected to include Registrable Securities in such registration of such termination or withdrawal. The Registration Expenses of such withdrawn registration shall be borne by the Company in accordance with Section 2.5 hereof.
- **2.4 Form S-3 Registration.** In case the Company shall receive from any Holder or Holders of Registrable Securities a written request or requests that the Company effect a registration on Form S-3 and any related qualification or compliance with respect to all or a part of the Registrable Securities owned by such Holder or Holders, the Company will:
- (a) promptly give written notice of the proposed registration, and any related qualification or compliance, to all other Holders of Registrable Securities; and
- **(b)** as soon as practicable, effect such registration and all such qualifications and compliances as may be so requested and as would permit or facilitate the sale and distribution of all or such portion of such Holder's or Holders' Registrable Securities as are specified in such request, together with all or such portion of the Registrable Securities of any other Holder or Holders joining in such request as are specified in a written request given within 15 days after receipt of such written notice from the Company; *provided*, *however*, that the Company shall not be obligated to effect any such registration, qualification or compliance pursuant to this Section 2.4:
  - (i) if Form S-3 is unavailable for such offering by the Holders;
- (ii) if the Holders, together with the holders of any other securities of the Company entitled to include their securities in such registration, propose to sell Registrable Securities and such other securities (if any) at an aggregate price to the public of less than one million dollars (\$1,000,000);
- (iii) if within 30 days of receipt of a written request from any Holder or Holders pursuant to this Section 2.4, the Company gives notice to such Holder or Holders of the Company's intention to make a public offering of its securities within 90 days, other than pursuant to a Special Registration Statement;
- (iv) if the Company shall furnish to the Holders a certificate signed by the Chairman of the Board or the Chief Executive Officer of the Company stating that in the good faith judgment of the Board of the Company, it would be seriously detrimental to the Company and its stockholders for such Form S-3 registration to be effected at such time, in which event the Company shall have the right to defer the filing of the Form S-3 registration statement for a period

of not more than 90 days after receipt of the request of the Holder or Holders under this Section 2.4; *provided*, that such right to delay a request shall be exercised by the Company not more than twice in any 12 month period;

- (v) if the Company has, within the 12 month period preceding the date of such request, already effected two registrations on Form S-3 for the Holders pursuant to this Section 2.4; or
- (vi) in any particular jurisdiction in which the Company would be required to qualify to do business, to execute a general consent to service of process or to subject itself to taxation in effecting such registration, qualification or compliance.
- **(c)** Subject to the foregoing, the Company shall file a Form S-3 registration statement covering the Registrable Securities and other securities so requested to be registered as soon as practicable after receipt of the requests of the Holders. Registrations effected pursuant to this Section 2.4 shall not be counted as demands for registration or registrations effected pursuant to Section 2.2.
- **2.5 Expenses of Registration.** Except as specifically provided herein, all Registration Expenses incurred in connection with any registration, qualification or compliance pursuant to Section 2.2, 2.3 or 2.4 herein shall be borne by the Company. All Selling Expenses incurred in connection with any registrations hereunder, shall be borne by the holders of the securities so registered *pro rata* on the basis of the number of shares so registered. The Company shall not, however, be required to pay for expenses of any registration proceeding begun pursuant to Section 2.2 or 2.4, the request of which has been subsequently withdrawn by the Initiating Holders unless (a) the withdrawal is based upon material adverse information concerning the Company of which the Initiating Holders were unaware at the time of such request or (b) the Holders of a majority of Registrable Securities agree to deem such registration to have been effected as of the date of such withdrawal for purposes of determining whether the Company shall be obligated pursuant to Section 2.2(c)(ii) or 2.4(b)(v), as applicable, to undertake any subsequent registration, in which event such withdrawn registration shall be deemed to have been ordered effective by the SEC for purposes of determining whether the Company shall be obligated pursuant to Sections 2.2(c)(ii) and 2.4(b), as applicable, to undertake any subsequent registration in proportion to the number of shares for which registration was requested. If the Company is required to pay the Registration in proportion to the number of shares for which registration shall not be deemed to have been effected for purposes of determining whether the Company shall be obligated pursuant to Section 2.2(c)(ii) or 2.4(b)(v), as applicable, to undertake any subsequent registration.
- **2.6 Obligations of the Company.** Whenever required to effect the registration of any Registrable Securities, the Company shall, as expeditiously as reasonably possible:
- (a) prepare and file with the SEC a registration statement with respect to such Registrable Securities and use all reasonable efforts to cause such registration statement to become effective, and, upon the request of the Holders of a majority of the Registrable Securities registered thereunder, keep such registration statement effective for up to 30 days or, if earlier, until the

Holder or Holders have completed the distribution related thereto; provided, however, that at any time, upon written notice to the participating Holders and for a period not to exceed sixty (60) days thereafter (the "Suspension Period"), the Company may delay the filing or effectiveness of any registration statement or suspend the use of any registration statement (and the participating Holders hereby agree not to offer or sell any Registrable Securities pursuant to such registration statement during the Suspension Period) if the Company reasonably believes that there is or may be in existence material nonpublic information or events involving the Company, the failure of which to be disclosed in the prospectus included in the registration statement could result in a Violation (as defined below). In the event that the Company shall exercise its right to suspend the use of a registration statement and prospectus hereunder, the applicable time period during which the registration statement is to remain effective shall be extended by a period of time equal to the duration of the Suspension Period. The Company may extend the Suspension Period for an additional consecutive 60 days with the consent of the holders of a majority of the Registrable Securities registered under the applicable registration statement, which consent shall not be unreasonably withheld. If so directed by the Company, all Holders registering shares under such registration statement shall (i) not offer to sell any Registrable Securities pursuant to the registration statement during the Suspension Period after receiving notice of such delay or suspension; and (ii) use their reasonable efforts to deliver to the Company (at the Company's expense) all copies, other than permanent file copies then in such Holders' possession, of the prospectus relating to such Registrable Securities current at the time of receipt of such notice. Notwithstanding the foregoing, the Company shall not be required to file, cause to become effective or maintain the effectiv

- **(b)** Prepare and file with the SEC such amendments and supplements to such registration statement and the prospectus used in connection with such registration statement as may be necessary to comply with the provisions of the Securities Act with respect to the disposition of all securities covered by such registration statement for the period set forth in subsection (a) above.
- **(c)** Furnish to the Holders such number of copies of a prospectus, including a preliminary prospectus, in conformity with the requirements of the Securities Act, and such other documents as they may reasonably request in order to facilitate the disposition of Registrable Securities owned by them.
- **(d)** Use its reasonable efforts to register and qualify the securities covered by such registration statement under such other securities or Blue Sky laws of such jurisdictions as shall be reasonably requested by the Holders; *provided* that the Company shall not be required in connection therewith or as a condition thereto to qualify to do business, to file a general consent to service of process or to subject itself to taxation in any such states or jurisdictions.
- (e) In the event of any underwritten public offering, enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the managing underwriter(s) of such offering. Each Holder participating in such underwriting shall also enter into and perform its obligations under such an agreement.

- (f) Notify each Holder of Registrable Securities covered by such registration statement, at any time when a prospectus relating thereto is required to be delivered under the Securities Act, of the happening of any event as a result of which the prospectus included in such registration statement, as then in effect, includes an untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Company will use reasonable efforts to amend or supplement such prospectus in order to cause such prospectus not to include any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.
- (g) Use its reasonable efforts to furnish, on the date that such Registrable Securities are delivered to the underwriters for sale, if such securities are being sold through underwriters, (i) an opinion, dated as of such date, of the counsel representing the Company for the purposes of such registration, in form and substance as is customarily given to underwriters in an underwritten public offering, addressed to the underwriters, if any, and (ii) letters addressed to the underwriters, dated as of such date and as of the closing date for such offering, from the independent certified public accountants of the Company, in form and substance as is customarily given by independent certified public accountants to underwriters in an underwritten public offering.

# 2.7 Delay of Registration; Furnishing Information.

- (a) No Holder shall have any right to obtain or seek an injunction restraining or otherwise delaying any such registration as the result of any controversy that might arise with respect to the interpretation or implementation of this Section 2.
- **(b)** It shall be a condition precedent to the obligations of the Company to take any action pursuant to Section 2.2, 2.3 or 2.4 that the selling Holders shall furnish to the Company such information regarding themselves, the Registrable Securities held by them and the intended method of disposition of such securities as shall be required to effect the registration of their Registrable Securities.
- **(c)** The Company shall have no obligation with respect to any registration requested pursuant to Section 2.2 or Section 2.4 if the number of shares or the anticipated aggregate offering price of the Registrable Securities to be included in the registration does not equal or exceed the number of shares or the anticipated aggregate offering price required to originally trigger the Company's obligation to initiate such registration as specified in Section 2.2 or Section 2.4, whichever is applicable.
  - **2.8 Indemnification.** In the event any Registrable Securities are included in a registration statement under Sections 2.2, 2.3 or 2.4:
- (a) To the extent permitted by applicable law, the Company will indemnify and hold harmless each Holder, the partners, members, officers and directors of each Holder, any underwriter (as defined in the Securities Act) for such Holder and each person, if any, who controls such Holder or underwriter within the meaning of the Securities Act or the Exchange Act, against

any losses, claims, damages, or liabilities (joint or several) to which they may become subject under the Securities Act, the Exchange Act or other federal or state securities law, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any of the following statements, omissions or violations (collectively a "Violation") by the Company: (i) any untrue statement or alleged untrue statement of a material fact contained in such registration statement or incorporated reference therein, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto, (ii) the omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading, or (iii) any violation or alleged violation by the Company of the Securities Act, the Exchange Act, any state securities law or any rule or regulation promulgated under the Securities Act, the Exchange Act or any state securities law in connection with the offering covered by such registration statement; and the Company will reimburse each such Holder, partner, member, officer, director, underwriter or controlling person for any legal or other expenses reasonably incurred by them in connection with investigating or defending any such loss, claim, damage, liability or action; provided however, that the indemnity agreement contained in this Section 2.8(a) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability or action to the extent that it arises out of or is based upon a Violation which occurs in reliance upon and in conformity with written information furnished expressly for use in connection with such registration by such Holder, partner, member, officer, director, underwriter or controlling person of such Holder.

(b) To the extent permitted by applicable law, each Holder will, if Registrable Securities held by such Holder are included in the securities as to which such registration, qualifications or compliance is being effected, indemnify and hold harmless the Company, each of its directors and officers and each person, if any, who controls the Company within the meaning of the Securities Act or the Exchange Act, any underwriter and any other Holder selling securities under such registration statement or any of such other Holder's partners, directors or officers or any person who controls such underwriter or Holder, against any losses, claims, damages or liabilities (joint or several) to which the Company or any such director, officer, controlling person, underwriter or other such Holder, or partner, director, officer or controlling person of such other Holder may become subject under the Securities Act, the Exchange Act or other federal or state securities law, insofar as such losses, claims, damages or liabilities (or actions in respect thereto) arise out of or are based upon any of the following statements, omissions or violations: (i) any untrue statement or alleged untrue statement of a material fact contained in such registration statement or incorporated reference therein, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto, (ii) the omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading, or (iii) any violation or alleged violation by the Company of the Securities Act or Exchange Act (collectively, a "Holder Violation"), in each case to the extent (and only to the extent) that such Holder Violation occurs in reliance upon and in conformity with written information furnished by such Holder under an instrument duly executed by such Holder and stated to be specifically for use in connection with such registration; and each such Holder will reimburse any legal or other expenses reasonably incurred by the Company or any such director, officer, controlling person, underwriter or other Holder, or partner, officer, director or controlling person of such other Holder or any such underwriter in connection with investigating

or defending any such loss, claim, damage, liability or action if it is judicially determined that there was such a Holder Violation; *provided*, *however*, that the indemnity agreement contained in this Section 2.8(b) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability or action if such settlement is effected without the consent of the Holder, which consent shall not be unreasonably withheld; *provided further*, that in no event shall any indemnity under this Section 2.8 exceed the net proceeds from the offering received by such Holder.

- (c) Promptly after receipt by an indemnified party under this Section 2.8 of notice of the commencement of any action (including any governmental action), such indemnified party will, if a claim in respect thereof is to be made against any indemnifying party under this Section 2.8, deliver to the indemnifying party a written notice of the commencement thereof and the indemnifying party shall have the right to participate in, and, to the extent the indemnifying party so desires, jointly with any other indemnifying party similarly noticed, to assume the defense thereof with counsel mutually satisfactory to the parties; provided, however, that an indemnified party shall have the right to retain its own counsel, with the fees and expenses thereof to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such proceeding. The failure to deliver written notice to the indemnifying party within a reasonable time of the commencement of any such action shall relieve such indemnifying party of any liability to the indemnified party under this Section 2.8 to the extent, and only to the extent, prejudicial to its ability to defend such action, but the omission so to deliver written notice to the indemnifying party will not relieve it of any liability that it may have to any indemnified party otherwise than under this Section 2.8.
- (d) If the indemnification provided for in this Section 2.8 is held by a court of competent jurisdiction to be unavailable to an indemnified party with respect to any losses, claims, damages or liabilities referred to herein, the indemnifying party, in lieu of indemnifying such indemnified party thereunder, shall to the extent permitted by applicable law contribute to the amount paid or payable by such indemnified party as a result of such loss, claim, damage or liability in such proportion as is appropriate to reflect the relative fault of the indemnifying party on the one hand and of the indemnified party on the other in connection with the Violation(s) or Holder Violation(s) that resulted in such loss, claim, damage or liability, as well as any other relevant equitable considerations. The relative fault of the indemnifying party and of the indemnified party shall be determined by a court of law by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission to state a material fact relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission; *provided*, *that* in no event shall any contribution by a Holder hereunder exceed the net proceeds from the offering received by such Holder.
- **(e)** The obligations of the Company and Holders under this Section 2.8 shall survive completion of any offering of Registrable Securities in a registration statement and, with respect to liability arising from an offering to which this Section 2.8 would apply that is covered by a registration filed before termination of this Agreement, such termination. No indemnifying party, in the defense of any such claim or litigation, shall, except with the consent of each indemnified party, consent to entry of any judgment or enter into any settlement which does not include as an unconditional term thereof the giving by the claimant or plaintiff to such indemnified party of a release from all liability in respect to such claim or litigation.

- **2.9** Assignment of Registration Rights. The rights to cause the Company to register Registrable Securities pursuant to this Section 2 may be assigned by a Holder to a transferee or assignee of Registrable Securities (for so long as such shares remain Registrable Securities) that (a) is a subsidiary, parent, general partner, limited partner, retired partner, member or retired member, or stockholder of a Holder that is a corporation, partnership or limited liability company, (b) is a Holder's family member or trust for the benefit of an individual Holder, (c) acquires shares of Registrable Securities such that the transferee or assignee holds at least two percent (2%) of the Company's Registrable Securities (as adjusted for stock splits and combinations) as a result of such acquisition, or (d) is an Affiliate of a Holder; *provided*, *however*, (i) the transferor shall, within 20 days after such transfer, furnish to the Company written notice of the name and address of such transferee or assignee and the securities with respect to which such registration rights are being assigned, and (ii) such transferee shall execute a counterpart of this Agreement and thereby become a party to and bound by this Agreement with respect to the transferred Registrable Securities to the same extent as the transferring Holder was prior to such transfer; *provided further*, *however*, no such assignment shall be permitted if such assignment is not made in compliance with the Co-Sale Agreement (as defined in the Purchase Agreement).
- **2.10 Limitation on Subsequent Registration Rights.** After the date of this Agreement, the Company shall not enter into any agreement with any holder or prospective holder of any securities of the Company that would grant such holder rights to demand the registration of shares of the Company's capital stock, or to include such shares in a registration statement in either such case that would reduce the number of shares includable by the Holders.
- **2.11 Market Stand-Off Agreement.** Each Holder hereby agrees that such Holder shall not sell, dispose of, transfer, make any short sale of, grant any option for the purchase of, or enter into any hedging or similar transaction with the same economic effect as a sale, any shares of Common Stock (or other securities) of the Company held by such Holder (other than those included in the registration) during the 180-day period following the date of the final prospectus relating to the Initial Public Offering provided, that all officers and directors of the Company who beneficially own any shares of Common Stock and holders of at least one percent (1%) of the Company's voting securities are bound by and have entered into similar agreements on terms no more favorable than those applicable to the Holder. Any discretionary waiver or termination of the restrictions of any or all of such agreements by the Company or the underwriters shall apply pro rata to all Holders subject to such agreements, based on the number of shares subject to such agreements.
- **2.12 Agreement to Furnish Information.** Each Holder agrees to execute and deliver such other agreements as may be reasonably requested by the Company or the managing underwriters that are consistent with the Holder's obligations under Section 2.11 or that are necessary to give further effect thereto. In addition, if requested by the Company or the representative of the underwriters of Common Stock (or other securities) of the Company, each Holder shall provide, within ten days of such request, such information as may be required by the Company or such representative in connection with the completion of any public offering of the Company's securities pursuant to a registration statement filed under the Securities Act. The

obligations described in Section 2.11 and this Section 2.12 shall not apply to a Special Registration Statement. In order to enforce Section 2.11, Section 2.12 and any such other agreement requested by the Company or the managing underwriters, the Company may impose stop-transfer instructions with respect to such shares of Common Stock (or other securities) until the end of such period. Each Holder agrees that any transferee of any shares of Registrable Securities shall be bound by Section 2.11 and this Section 2.12. The underwriters of the Company's stock are intended third party beneficiaries of Section 2.11 and this Section 2.12 and shall have the right, power and authority to enforce the provisions hereof as though they were a party hereto.

- **2.13 Rule 144 Reporting.** With a view to making available to the Holders the benefits of certain rules and regulations of the SEC which may at any time permit a Holder to sell securities of the Company to the public without registration, the Company agrees to use its best efforts to:
- (a) Make and keep public information available, as those terms are understood and defined in SEC Rule 144 or any similar or analogous rule promulgated under the Securities Act, at all times after the effective date of the first registration filed by the Company under the Securities Act for an offering of its securities to the general public;
  - (b) File with the SEC, in a timely manner, all reports and other documents required of the Company under the Exchange Act; and
- (c) So long as a Holder owns any Registrable Securities, furnish to such Holder forthwith upon request: a written statement by the Company as to its compliance with the reporting requirements of Rule 144 under the Securities Act, and of the Exchange Act (at any time after it has become subject to such reporting requirements) if such compliance is required for such Holder to sell shares of Common Stock in reliance on Rule 144 under the Securities Act; a copy of the most recent annual or quarterly report of the Company filed with the SEC if the Company's making such filing is required for such Holder to sell shares of Common Stock in reliance on Rule 144 under the Securities Act; and such other reports and documents as a Holder may reasonably request in connection with availing itself of any rule or regulation of the SEC allowing it to sell any such securities without registration if the furnishing of any such report or document is necessary to enable such Holder to sell Common Stock in reliance on under Rule 144 under the Securities Act.
- **2.14 Termination of Registration Rights.** The right of any Holder to request registration or inclusion of Registrable Securities in any registration pursuant to Section 2.2, Section 2.3, or Section 2.4 hereof shall terminate upon the earlier of: (i) the date five (5) years following a Qualified Public Offering; or (ii) such time as such Holder beneficially owns less than 1% of the Company's outstanding Common Stock (treating all shares of Preferred Stock on an as-if-converted basis), and the Company has completed its Qualified Public Offering and all Registrable Securities of the Company issuable or issued upon conversion of the Preferred Stock held by and issuable to such Holder (and its Affiliates) may be sold pursuant to Rule 144 during any 90 day period. Upon such termination, such shares shall cease to be "Registrable Securities" hereunder for all purposes.
- **2.15 Amendment of Existing Registration Rights Agreements.** No amendment, waiver or modification of any provision of any other agreement relating to the registration of shares of the Company's capital stock in effect as of the Effective Date, including, without limitation,

that certain Registration Rights Agreement, dated as of June 1, 2016, by and among the Company and the holders of the Company's Common Stock party thereto (any such agreement a "*Prior Registration Rights Agreement*"), shall be effective unless such amendment, waiver or modification is approved by the vote or written consent of the holders of 56% of the then outstanding shares of Preferred Stock. In the event of any conflict between any Prior Registration Rights Agreement and this Agreement, the provisions of this Agreement shall control.

# SECTION 3. COVENANTS OF THE COMPANY.

# 3.1 Financial Information and Reporting.

- (a) The Company will maintain true books and records of account in which full and correct entries will be made of all its business transactions pursuant to a system of accounting established and administered in accordance with generally accepted accounting principles consistently applied (except as noted therein or as disclosed to the recipients thereof), and will set aside on its books all such proper accruals and reserves as shall be required under generally accepted accounting principles consistently applied.
- **(b)** The Company will furnish each Major Investor, as soon as practicable after the end of each fiscal year of the Company, and in any event within one hundred 120 days thereafter, an audited balance sheet of the Company, as at the end of such fiscal year, and an audited statement of income and a statement of cash flows of the Company, for such year, all prepared in accordance with generally accepted accounting principles consistently applied (except as noted therein or as disclosed to the recipients thereof) and setting forth in each case in comparative form the figures for the previous fiscal year, all in reasonable detail. Such financial statements shall be accompanied by a report and opinion thereon by independent public accountants selected by the Board.
- (c) The Company will furnish each Major Investor, as soon as practicable after the end of the first, second and third quarterly accounting periods in each fiscal year of the Company, and in any event within 45 days thereafter, an unaudited balance sheet of the Company as of the end of each such quarterly period, and an unaudited statement of income and a statement of cash flows of the Company for such period and for the current fiscal year to date, prepared in accordance with generally accepted accounting principles consistently applied (except as noted therein or as disclosed to the recipients thereof), with the exception that no notes need be attached to such statements and year-end audit adjustments may not have been made.
- (d) The Company will furnish each Major Investor: (i) at least 30 days prior to the beginning of each fiscal year an annual budget and operating plan for such fiscal year that has been approved by the holders of 56% of the then outstanding shares of Preferred Stock pursuant to Section 3.20 below (and as soon as available, any subsequent written revisions thereto); and (ii) as soon as practicable after the end of each month, and in any event within 20 days thereafter, a balance sheet of the Company as of the end of each such month, and a statement of income and a statement of cash flows of the Company for such month and for the current fiscal year to date, including a comparison to plan figures for such period, prepared in accordance with generally accepted accounting principles consistently applied (except as noted thereon), with the exception that no notes need be attached to such statements and year-end audit adjustments may not have been made.

- **3.2 Inspection Rights.** Each Major Investor shall have the right, exercisable on reasonable prior written notice to the Company, to visit and inspect any of the properties of the Company or any of its subsidiaries, and to discuss the affairs, finances and accounts of the Company or any of its subsidiaries with its officers, and to review such information as is reasonably requested all at such reasonable times during normal business hours and as often as may be reasonably requested; *provided*, *however*, that the Company shall not be obligated under this Section 3.2 to provide the rights hereunder to any Major Investor who is, or is associated or affiliated with, a competitor of the Company or with respect to information which the Company determines in good faith is confidential, attorney-client privileged or that the Company is prohibited by applicable law from disclosing to such Major Investor and should not, therefore, be disclosed (unless, in the case of confidential information, covered by an enforceable confidentiality agreement, in form acceptable to the Company).
- 3.3 Confidentiality of Records. Each Investor agrees to use the same degree of care as such Investor uses to protect its own confidential information to keep confidential any information furnished to such Investor pursuant to Section 3.1 and 3.2 hereof or pursuant to any Management Rights Letter (as defined in the Purchase Agreement) addressed to such Investor, in each case, that the Company identifies as being confidential or proprietary (so long as such information is not in the public domain) and not to use such information for any purpose other than monitoring its investment in the Company, except that such Investor may disclose such proprietary or confidential information (i) to any existing or prospective Affiliate, partner, subsidiary or parent of such Investor as long as such Affiliate, partner, subsidiary or parent is advised of and agrees or has agreed to be bound by the confidentiality and non-use provisions of this Section 3.3; (ii) at such time as it enters the public domain through no fault of such Investor; (iii) that the Company communicates to it free of any obligation of confidentiality and restriction on use; (iv) that is developed by Investor or its agents independently of and without reference to any confidential information communicated by the Company as shown by contemporaneous records; (v) with regard only to the confidentiality restriction, as required by applicable law or order of a court or tribunal; (vi) to its attorneys, accountants, consultants and other professionals to the extent necessary to obtain their services in connection with monitoring its investment in the Company, provided such persons agree to hold such information confidentially as provided herein and not to use it for any purpose other than providing such services to such Investor; or (vii) to any prospective purchaser of any Registrable Securities from such Holder, if prior to any such disclosure such prospective purchaser agrees in writing to be bound by the provisions of this Section 3.3.
- **3.4 Reservation of Common Stock.** The Company will at all times reserve and keep available, solely for issuance and delivery upon the conversion of the Preferred Stock, such number of shares of Common Stock as are issuable from time to time upon such conversion.
- **3.5 Stock Vesting.** Unless otherwise approved by the Board, all stock options and other stock equivalents issued after the date of this Agreement to employees, directors, consultants and other service providers shall be subject to vesting as follows: (a) twenty-five percent (25%) of such stock shall vest one year following the date of the grant, and (b) seventy-five percent (75%) of such stock shall vest in equal monthly installments over the next three years thereafter.

**3.6 Director and Officer Insurance.** The Company will use its commercially reasonable best efforts to maintain in full force and effect director and officer liability insurance for no less than the amount of three million dollars (\$3,000,000) in coverage, or such other amount as approved by the Board (including the affirmative vote of one of the representatives elected by the holders of Preferred Stock), with terms and policy limits approved by the Board.

# 3.7 Observer Rights.

(a) So long as the Company shall not be a company required to file reports with the SEC pursuant to Section 13 or Section 15(d) of the Exchange Act, the Company shall allow (1) two representatives designated by Longitude Venture Partners III, L.P. ("Longitude"), who are reasonably acceptable to the Company and who shall initially be Sandip Agarwala and Oren Isacoff, so long as Longitude shall hold any shares of Preferred Stock, (2) one representative designated by New Enterprise Associates 15, L.P. ("NEA"), who is reasonably acceptable to the Company and who shall initially be Jason Fuller, so long as NEA shall hold any shares of Preferred Stock, (3) one representative designated by Novo, who is reasonably acceptable to the Company and who shall initially be Jennifer Lee, so long as Novo shall hold any shares of Preferred Stock, (4), one representative designated by Sanofi US ("Sanofi"), who is reasonably acceptable to the Company and who shall initially be Ruchita Sinha, so long as Sanofi shall hold any shares of Preferred Stock, (5) Dr. Demetrios Braddock ("Braddock") so long as he shall own at least 25% of the shares of Common Stock that he owned on April 13, 2017, subject to appropriate adjustment for any stock splits, stock dividends, combinations, recapitalizations and the like, and (6) one representative designated by Pivotal bioVenture Partners LLC ("Pivotal"), who is reasonably acceptable to the Company and who shall initially be Jim Trenkle, so long as Pivotal shall hold any shares of Preferred Stock, to attend all meetings of the Board as observers, but without any right to make any motion or to vote (the "Observers"), and in connection therewith, the Company shall give the Observers copies of all notices, minutes, written consents of the Board to action taken without a meeting and other materials, financial or otherwise, which the Company provides to the Board; provided, however, that the observation rights (including the right to receive notices, minutes, consents and other materials) provided hereby shall be temporarily suspended, and any one or more Observers shall be excluded from access to any material or meeting or portion thereof, if (i) the Company believes, upon the advice of counsel, that such exclusion is necessary or appropriate to preserve the attorney-client privilege or to protect confidential or proprietary information of the Company or a third party; or (ii) with respect to Braddock, there exists, with respect to any meeting of the Board or any portion thereof or any deliberation by the Board or consent or material being furnished to the Board, an actual or potential conflict of interest between Braddock and the Company.

The rights of observation provided hereby shall not extend to any meeting of any committee of the Board; *provided, however,* that the Company will furnish to the Observer copies of minutes of committee meetings and actions taken by each committee by written consent, subject to the foregoing limits.

- **(b)** Before an initial Observer named in this Section or any subsequent designee as an Observer shall attend any meeting or receive any information or materials, such Observer each shall execute and deliver to the Company an agreement requiring such Observer to maintain the confidentiality of information and restricting the use thereof, such agreement to be in the form specified by the Company.
- **(c)** The Holders agree that any action duly taken by the Board shall not be invalidated by virtue of the fact that an Observer was not properly notified of, or was not in attendance at, the meeting at which such action was taken or that the Company may have breached this Section 3.7.
- (d) If a Special Mandatory Conversion occurs with respect to any Investor entitled to designate one or more Observers pursuant to this Section 3.7 or with respect to any Affiliate of such Investor, then such Investor's right to designate one or more Observers under this Section 3.7 shall immediately terminate and the observation rights of all Observers designated by such Investor shall immediately terminate.
- **3.8 Board Matters.** Unless otherwise determined by the Board (with the consent of at least a majority of the directors designated by the holders of Preferred Stock), the Board will meet at least quarterly. The Company shall reimburse the nonemployee directors and Observers for all reasonable out-of-pocket travel expenses incurred in connection with attending the meetings of the Board (or committees thereof) or any other activities such as meetings or trade shows which the Company requests such director or Observer to attend. The directors designated by the holders of Preferred Stock shall each be entitled in his or her discretion to be a member of any committee of the Board.
- **3.9 Proprietary Information and Inventions Agreement.** The Company shall require all employees and consultants to execute and deliver a Proprietary Information and Inventions Agreement substantially in a form attached as Exhibit F to the Purchase Agreement (except as otherwise stated in the Schedule of Exceptions for the Initial Closing under the Purchase Agreement) or in such other form as shall be approved by the Company's counsel or the Board.
- **3.10 CEO Relocation**. By January 17, 2020, the Company's Chief Executive Officer shall be located or relocate to within a reasonable daily commuting distance from the Company's corporate headquarters in the greater Boston, Massachusetts area.
- **3.11 Affiliate Transactions**. The Company shall not, after the date hereof, enter into or be a party to any transaction with an Affiliate, any director, officer, consultant or employee of the Company or any Affiliate or "associate" (as defined in Rule 12b-2 promulgated under the Exchange Act) of any such Persons, except for (i) transactions contemplated by the Related Agreements (as defined in the Purchase Agreement), or (ii) transactions made in the ordinary course of business and pursuant to reasonable requirements of the Company's business and upon fair and reasonable terms that are approved by the Board (including the affirmative vote of one of the representatives designated by the holders of Preferred Stock).
- **3.12 Compliance with Laws.** The Company shall observe and remain in compliance in all material respects with all applicable laws, including the Employee Retirement Income Security

Act of 1974, as amended, and maintain in full force and effect all approvals necessary to the conduct of its business, and the failure of which to maintain would have a material adverse effect on the Company.

- **3.13 Maintenance of Insurance.** The Company shall maintain insurance, including directors' and officers' liability insurance, with responsible insurance companies against such risks and in such amounts as are customarily maintained by similar businesses in similar industries.
- **3.14 Maintenance of Property**. The Company shall protect and preserve all properties necessary and material to its business, including all intellectual property and tangible and intangible assets; maintain in good working order and condition (ordinary wear and tear excepted) all buildings, equipment and other tangible real and personal property necessary and material to its business; and from time to time make or cause to be made all renewals, replacements and additions to such property necessary for the conduct of its business so that the business carried on in connection therewith may be properly conducted at all times.
- **3.15 Payment of Taxes.** The Company shall pay all material taxes, assessments and other governmental charges that may be levied or assessed upon it or any of its property (including, without limitation, withholding, social security, payroll and similar employment related taxes on the dates such taxes are due); provided, that the Company may contest such taxes, assessments and other governmental charges in good faith so long as adequate reserves are maintained with respect thereto.
- **3.16 Certain Notifications.** The Company shall notify the Investors with respect to (i) all material defaults by the Company and, to the extent known by the Company, by a counterparty under any material agreement or contract to which the Company is a party, (ii) any material litigation to which the Company becomes involved and (iii) other corporate events which, individually or in the aggregate, has had or would be reasonably likely to have a material adverse effect on the Company.
- **3.17 Real Property Holding Corporation.** The Company shall provide prompt notice to the Investors following any "determination date" (as defined in Treasury Regulation Section 1.897-2(c)(1)) on which the Company becomes a United States real property holding corporation. In addition, upon a written request by any Investor, the Company shall provide such Investor with a written statement informing such Investor whether such Investor's interest in the Company constitutes a United States real property interest. The Company's determination shall comply with the requirements of Treasury Regulation Section 1.897-2(h)(1) or any successor regulation, and the Company shall provide timely notice to the Internal Revenue Service, in accordance with and to the extent required by Treasury Regulation Section 1.897-2(h)(2) or any successor regulation, that such statement has been made. The Company's written statement to such Investor shall be delivered to such Investor within 10 days of such Investor's written request therefor. The Company's obligation to furnish such written statement shall continue notwithstanding the fact that a class of the Company's stock may be regularly traded on an established securities market or the fact that there is no preferred stock then outstanding.
- **3.18 Qualified Small Business Stock.** The Company shall use commercially reasonable efforts to cause the shares of Preferred Stock, as well as any shares into which such

shares are converted, within the meaning of Section 1202(f) of the Internal Revenue Code (the "Code"), to constitute "qualified small business stock" as defined in Section 1202(c) of the Code; provided, however, that such requirement shall not be applicable if the Board of the Company determines, in its good-faith business judgment, that such qualification is inconsistent with the best interests of the Company. The Company shall submit to its stockholders (including the Investors) and to the Internal Revenue Service any reports that may be required under Section 1202(d)(1)(C) of the Code and the regulations promulgated thereunder. In addition, within twenty (20) business days after any Investor's written request therefor, the Company shall, at its option, either (i) deliver to such Investor a written statement indicating whether (and what portion of) such Investor's interest in the Company constitutes "qualified small business stock" as defined in Section 1202(c) of the Code or (ii) deliver to such Investor such Investor's interest in the Company constitutes "qualified small business stock" as defined in Section 1202(c) of the Code.

- **3.19 Right to Conduct Activities.** The Company hereby acknowledges that Longitude and its Affiliates, NEA and its Affiliates, Novo and its Affiliates, Pivotal and its Affiliates and Sanofi and its Affiliates (collectively, "*Funds*") may invest in entities that operate in markets that may be competitive with the markets in which the Company operates. Neither any Fund nor its partners, directors, officers employees, Affiliates, advisors or affiliated investment funds shall be liable to the Company for any claim arising out of, or based upon, (i) the investment by such Fund or any affiliated investment fund in any entity, or activities of such Affiliates, that may be competitive to the Company or (ii) actions taken by any partner, officer, advisor or other representative of such Fund in his, her or its capacity as such to assist any such competitive company; provided, however, that nothing herein shall relieve any Fund or any other party from breach or violation of Section 3.3 above or any breach or violation by an Observer of the agreement between the Company and such Observer that is provided for in Section 3.7(b).
- **3.20 Approval of Company Annual Budget.** The adoption of any annual Company budget and any amendment or alteration to such budget shall require the approval of the holders of 56% of the then outstanding shares of Preferred Stock.
- **3.21 Defense Production Act of 1950.** To the extent that (i) any pre-existing products or services provided by the Company (a) are re-categorized by the U.S. government as critical technologies within the meaning of the Defense Production Act of 1950, as amended (the "*DPA*"), or (b) would reasonably be considered to constitute the design, fabrication, development, testing, production or manufacture of critical technologies after a re-categorization of selected technologies by the U.S. government, or (ii) after execution of the Purchase Agreement, the Company engages in any activities that would reasonably be considered to constitute the design, fabrication, development, testing, production or manufacture of critical technologies within the meaning of the DPA, the Company shall provide at least 60 days' notice to the Investors in advance of the Milestone Closing and/or any other financing or investment of a type contemplated by the DPA in the Company by the Investors or any other party.
- **3.22 CFIUS Filing Cooperation.** If and only if (i) the Committee on Foreign Investment in the United States ("*CFIUS*") requests or requires that any Investor or the Company file a notice or declaration (either, a "*Filing*") with CFIUS pursuant to the Defense Production Act of 1950, as

amended, including all implementing regulations thereof (the "*DPA*") with respect to such Investor's purchase of shares of Series A-2 Preferred Stock pursuant to the Purchase Agreement (the "*Transactions*") or (ii) either of (a) any Investor or (b) the Company determine a Filing with CFIUS with respect to the Transactions is required by or advisable in order to comply with applicable law, then each of the Company and the applicable Investor(s) (together, the "*CFIUS Parties*") shall (i) cooperate and undertake their reasonable best efforts to promptly make such a Filing and promptly respond to any CFIUS request for information and/or documents with respect to such Filing and/or the Transactions; and (ii) use commercially reasonable efforts to satisfy the CFIUS Condition, including without limitation agreeing to reasonable mitigation terms required by CFIUS to satisfy the CFIUS Condition, provided that agreement to any mitigation terms shall be at the reasonable discretion of the affected party.

**3.23 Termination of Covenants.** All covenants of the Company contained in Section 3 of this Agreement (other than the provisions of Section 3.3, 3.6, 3.17 and 3.19) shall expire and terminate as to each Investor upon the earlier of (i) the effective date of the registration statement pertaining to a Qualified Public Offering or (ii) upon an "*Acquisition*" as defined in the Charter.

# SECTION 4. COVENANT OF THE INVESTORS.

- **4.1 Commerce Department Compliance.** The Company may be required to file reports with the Bureau of Economic Analysis (the "*BEA*") of the U.S. Commerce Department when a U.S. Affiliate of a foreign Investor if such foreign Investor, together with its Affiliates, directly or indirectly controls ten percent (10%) or more of the voting securities of the Company. Such foreign Investor that is a foreign individual or entity or a U.S. subsidiary or Affiliate of a foreign parent covenants to provide information necessary for the Company to comply with BEA filings required under the International Investment and Trade in Services Act.
- **4.2 Voluntary Conversion.** Each Investor hereby covenants and agrees that it shall not exercise, and shall not permit any of its Affiliates to exercise, any right that such Investor or such Affiliate, as the case may be, may have under the Charter voluntarily to convert any shares of Preferred Stock owned or held by such Investor or such Affiliate, as the case may be, into shares of Common Stock at any time during the period commencing on the date of this Agreement and ending on the earliest of (i) the Business Day immediately following the date of the Milestone Closing (as defined in the Purchase Agreement), (ii) September 30, 2021, (iii) the date upon which the Company and the holders of 56% of outstanding Preferred Stock determine that the Milestone (as defined in the Purchase Agreement) will not occur, and (iv) the day immediately following the date on which the Board or the Company's stockholders adopt a resolution to effect (A) a liquidation, dissolution or a winding up of the Company, or (B) a Liquidation Event, Acquisition or Asset Transfer (each as defined in the Charter). The Company shall give notice to the Investors of the adoption of any such resolution within five (5) Business Days after the adoption of such resolution and in any case at least five (5) Business Days before effecting such liquidation, dissolution, winding up or Liquidation Event, Acquisition or Asset Transfer.

# SECTION 5. RIGHTS OF FIRST REFUSAL.

**5.1 Subsequent Offerings.** Subject to applicable securities laws, each Major Investor shall have a right of first refusal to purchase its *pro rata* share of all Equity Securities, as defined

below, that the Company may, from time to time, propose to sell and issue after the date of this Agreement, other than the Equity Securities excluded by Section 5.6 hereof. Each Major Investor's *pro rata* share is equal to the ratio of (a) the number of shares of Common Stock (including all shares of Common Stock issuable or issued upon conversion of Preferred Stock or upon the exercise of outstanding warrants or options) which such Major Investor holds immediately prior to the issuance of such Equity Securities to (b) the total number of outstanding shares of Common Stock (including all shares of Common Stock issued or issuable upon conversion of Preferred Stock or upon the exercise of any outstanding warrants or options) immediately prior to the issuance of the Equity Securities. The term "Equity Securities" shall mean (i) any Common Stock or preferred stock that is convertible into shares of Common Stock or the holders of which are entitled to participate with the Common Stock in the distribution of proceeds of a liquidation or sale of the Company, (ii) any security convertible into or exercisable or exchangeable for, with or without consideration, any Common Stock or such preferred stock (including any option to purchase such a convertible security), (iii) any security carrying any warrant or right to subscribe to or purchase any Common Stock or such preferred stock or other security.

- **5.2 Exercise of Rights.** If the Company proposes to issue any Equity Securities, it shall give each Major Investor notice of its intention, describing the Equity Securities, the price and the terms and conditions upon which the Company proposes to issue the same. Each Major Investor shall have 20 days from the giving of such notice to agree to purchase its *pro rata* share of the Equity Securities for the price and upon the terms and conditions specified in the Company's notice by giving notice of such agreement to the Company and stating therein the quantity of Equity Securities to be purchased. Notwithstanding the foregoing, the Company shall not be required to offer or sell such Equity Securities to any Major Investor who would cause the Company to be in violation of applicable federal securities laws by virtue of such offer or sale.
- 5.3 **Issuance of Equity Securities to Other Persons**. If not all of the Major Investors elect to purchase their *pro rata* share of the Equity Securities, then the Company shall promptly notify the Major Investors who do so elect and shall offer such Major Investors the right to acquire such unsubscribed shares on a *pro rata* basis. Each Major Investor shall have five days after receipt of such notice to notify the Company of its election to purchase all or a portion of the unsubscribed shares. The Company shall have 90 days thereafter to sell the Equity Securities in respect of which the Major Investor's rights were not exercised, at a price and upon general terms and conditions not materially more favorable to the purchasers thereof than specified in the Company's notice to the Major Investors pursuant to Section 5.2 hereof. If the Company has not sold such Equity Securities within 90 days of the notice provided pursuant to Section 5.2, the Company shall not thereafter issue or sell any Equity Securities, without first offering such securities to the Major Investors in the manner provided above.
- **5.4 Termination and Waiver of Rights of First Refusal.** The rights of first refusal established by this Section 5 shall not apply to, and shall terminate upon the earlier of, (i) the effective date of the registration statement pertaining to the Company's Qualified Public Offering or (ii) an Acquisition. Notwithstanding Section 6.5 hereof, the rights of first refusal established by this Section 5 may be amended, or any provision waived only by a written instrument duly executed by the Company and Major Investors holding a majority of the shares of Common Stock issued or issuable upon conversion of Preferred Stock held by all Major Investors, or as permitted by Section 6.5.

- 5.5 **Assignment of Rights of First Refusal.** The rights of first refusal of each Major Investor under this Section 5 may be assigned to the same parties, subject to the same restrictions as any transfer of registration rights pursuant to Section 2.9 but only to persons who are "accredited investors", as defined in Regulation D under the Securities Act and only if that such an assignment is permitted by the Securities Act and other applicable securities laws
- **5.6 Excluded Securities.** The rights of first refusal established by this Section 5 shall have no application to Exempted Securities (as defined in the Charter) and (i) shares of Common Stock issued in the Initial Public Offering; (ii) any Equity Securities issued by the Company pursuant to Sections 2.1, 2.2 or 2.4 of the Purchase Agreement; (iii) any Equity Securities issued by the Company upon conversion of any Equity Securities defined in Section 5.6(i); or (iv) any Equity Securities issued pursuant to the Special Mandatory Conversion terms in Article IV.D. Section 4(p) of the Charter.

## SECTION 6. MISCELLANEOUS.

- **6.1 Governing Law.** This Agreement shall be governed by and construed under the laws of the State of Delaware in all respects as such laws are applied to agreements among Delaware residents entered into and to be performed entirely within Delaware, without reference to conflicts of laws or principles thereof. The parties agree that any action brought by either party under or in relation to this Agreement, including without limitation to interpret or enforce any provision of this Agreement, shall be brought in, and each party agrees to and does hereby submit to the jurisdiction and venue of, any state or federal court located in the State of Delaware.
- **6.2 Successors and Assigns.** Except as otherwise expressly provided herein, the provisions hereof shall inure to the benefit of, and be binding upon, the parties hereto and their respective successors, assigns, heirs, executors, and administrators and shall inure to the benefit of and be enforceable by each person who shall be a holder of Equity Securities from time to time; *provided*, *however*, that prior to the receipt by the Company of adequate written notice of the transfer of any Equity Securities specifying the full name and address of the transferee, the Company may deem and treat the person listed as the holder of such shares in its records as the absolute owner and holder of such shares for all purposes, including the payment of dividends or any redemption price.
- **6.3 Entire Agreement.** Upon the effectiveness of this Agreement, the Prior Agreement shall be deemed amended and restated to read in its entirety as set forth in this Agreement. This Agreement and the Exhibits hereto, along with the Purchase Agreement and the other documents executed and delivered pursuant thereto constitute the full and entire understanding and agreement among the parties with regard to the subjects hereof and thereof and no party shall be liable or bound to any other in any manner by any oral or written representations, warranties, covenants and agreements except as specifically set forth herein and therein. Each party expressly represents and warrants that it is not relying on any oral or written representations, warranties, covenants or agreements outside of this Agreement and the other agreements and instruments referred to in this Section 6.3. The recitals to this Agreement form part of this Agreement.

**6.4 Severability.** In the event one or more of the provisions of this Agreement should, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provisions of this Agreement, and this Agreement shall be construed as if such invalid, illegal or unenforceable provision had never been contained herein.

## 6.5 Amendment and Waiver.

- (a) Except as otherwise expressly provided, this Agreement may be amended or modified, and the obligations of the Company and the rights of the Holders under this Agreement may be waived, only by a written instrument duly executed by the Company and the holders of 56% of the Registrable Securities then outstanding; provided, however, that any such instrument that amends (i) Section 3.7 and Section 3.19 in a manner adverse to Longitude shall become effective only if duly executed and delivered by Longitude, (ii) Section 3.7 and Section 3.19 in a manner adverse to NEA shall become effective only if duly executed by NEA, (iii) Section 3.7 and Section 3.19 in a manner adverse to Novo, or Section 6.6 in any manner, shall become effective only if duly executed by Novo, (iv) Section 3.7 and Section 3.19 in a manner adverse to Sanofi shall become effective only if duly executed and delivered by Sanofi, (v) Section 3.7 and Section 3.19 in a manner adverse to Pivotal shall become effective only if duly executed and delivered by Pivotal; and (vi) Sections 3.21 and 3.22 and this Section 6.5(vi), shall become effective only if duly executed by Novo and Pivotal; and provided further that any party may waive its rights under any provision hereof on such party's own behalf by an instrument in writing duly executed by such party without any action, instrument or concurrence of any other party. Notwithstanding the foregoing, this Agreement may not be amended or terminated and the observance of any term hereof may not be waived with respect to any Investor without the written consent of such Investor, unless such amendment, termination, or waiver applies to all Investors in the same fashion (it being agreed that a waiver of the provisions of Section 5 with respect to a particular transaction will be deemed to apply to all Investors in the same fashion if such waiver does so by its terms, notwithstanding the fact that certain Investors may nonetheless, by agreement with the Company, purchase securities in such transaction). The Company will give prompt notice of any amendment or termination hereof or waiver hereunder to any party hereto that did not execute and deliver an instrument making such amendment, termination, or waiver. Any amendment, termination, or waiver effected in accordance with this Section 6.5 will be binding on all parties hereto, regardless of whether any such party has agreed or consented thereto. No waivers of or exceptions to any term, condition, or provision of this Agreement, in any one or more instances, will be deemed to be or construed as a further or continuing waiver of any such term, condition, or provision.
- **(b)** For the purposes of determining the number of Holders or Investors entitled to vote or exercise any rights hereunder, the Company shall be entitled to rely solely on the list of record holders of its stock as maintained by or on behalf of the Company.
- **6.6 Purchasers' Liability.** The total liability, in the aggregate, of any Purchaser (as defined in the Purchase Agreement) its officers, directors, employees and agents, for any and all

claims, losses, costs or damages, including attorneys' and accountants' fees and expenses and costs of any nature whatsoever or claims or expenses resulting from or in any way related to such Purchaser's breach of this Agreement shall be several and not joint with the other stockholders and shall not exceed the total purchase price paid to the Company by such Purchaser for its Preferred Stock under the Purchase Agreement. Nothing in this Agreement or the Related Agreements (as defined in the Purchase Agreement) shall restrict an Investor's freedom to operate any of its Affiliates (including any such Affiliate that is a potential competitor of the Company).

- **6.7 Delays or Omissions.** It is agreed that no delay or omission to exercise any right, power, or remedy accruing to any party, upon any breach, default or noncompliance by another party under this Agreement shall impair any such right, power, or remedy, nor shall it be construed to be a waiver of any such breach, default or noncompliance, or any acquiescence therein, or of any similar breach, default or noncompliance thereafter occurring. It is further agreed that any waiver, permit, consent, or approval of any kind or character on any party's part of any breach, default or noncompliance under the Agreement or any waiver on such party's part of any provisions or conditions of this Agreement must be in writing and shall be effective only to the extent specifically set forth in such writing. All remedies, either under this Agreement, by law, or otherwise afforded to any party, shall be cumulative and not alternative.
- **6.8 Notices.** All notices required or permitted hereunder shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by confirmed electronic mail or facsimile if sent during normal business hours of the recipient; if not, then on the next business day, (c) five days after having been sent by certified mail, return receipt requested, postage prepaid, or (d) one day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All notices shall be sent to the party to be notified at the address as set forth on the signature pages hereof or **Exhibit A** hereto or at such other address or electronic mail address as such party may designate by ten (10) days' written notice to the other parties hereto.
- **6.9 Attorneys' Fees.** In the event that any suit or action is instituted to enforce any provision in this Agreement, the prevailing party in such dispute shall be entitled to recover from the non-prevailing party all out-of-pocket costs and expenses of enforcing any right of such prevailing party under this Agreement, including without limitation, such reasonable fees and expenses of attorneys and accountants, which shall include, without limitation, all reasonable out-of-pocket costs and expenses of appeals.
- **6.10 Titles and Subtitles.** The titles of the sections and subsections of this Agreement are for convenience of reference only and are not to be considered in construing this Agreement.
- **6.11 Additional Investors.** Notwithstanding anything to the contrary contained herein, if the Company shall issue additional shares of its Series A-2 Preferred Stock pursuant to the Purchase Agreement, any purchaser of such shares of Series A-2 Preferred Stock shall become a party to this Agreement by executing and delivering an additional counterpart signature page to this Agreement and shall be deemed an "*Investor*," a "*Holder*" and a party hereunder. Notwithstanding anything to the contrary contained herein, if the Company shall issue Equity Securities in accordance with Section 5.6(ii) of this Agreement, any purchaser of such Equity Securities may become a party to this Agreement by executing and delivering an additional counterpart signature page to this Agreement and shall be deemed an "*Investor*," a "*Holder*" and a party hereunder.

- **6.12 Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Any or all parties may execute this Agreement by telephone line facsimile transmission bearing its signature or by electronic transmission of its signature image in Portable Document Format ("**PDF**"), and any such signature sent by facsimile transmission or a PDF signature image, if identified, legible and complete, shall be deemed an original signature and each of the other parties is hereby authorized to rely thereon.
- **6.13 Aggregation of Stock.** All shares of Registrable Securities held or acquired by affiliated entities or persons or persons or entities under common management or control shall be aggregated together for the purpose of determining the availability of any rights under this Agreement.
- **6.14 Pronouns.** All pronouns contained herein, and any variations thereof, shall be deemed to refer to the masculine, feminine or neutral, singular or plural, as to the identity of the parties hereto may require.
- **6.15 Special Mandatory Conversion.** In the event that the Preferred Stock held by an Investor is converted into Common Stock pursuant to a Special Mandatory Conversion, such person shall cease to be an Investor under this Agreement and shall cease to be entitled to any of the rights and privileges granted to an Investor pursuant to this Agreement.

[Signature Pages Immediately Follow]

The parties hereto have duly executed this **SECOND AMENDED AND RESTATED INVESTOR RIGHTS AGREEMENT** by their respective officers thereunto duly authorized as of the date set forth in the first paragraph hereof.

# **COMPANY:**

# INOZYME PHARMA, INC.

By: /s/ Axel Bolte

Name: Axel Bolte

Title: Chief Executive Officer

Address: 280 Summer Street

5th Floor

Boston, Massachusetts 02210

## **INVESTORS:**

Pivotal bioVenture Partners Fund I, L.P.

By: Pivotal bioVenture Partners Fund I G.P., L.P., its general partner

By: Pivotal bioVenture Partners Fund I U.G.P. Ltd, its general partner

By: /s/ Robert Hopfner
Name: Robert Hopfner
Title: Managing Partner

Notice provisions:

# **INVESTORS:**

# LONGITUDE VENTURE PARTNERS III, L.P.

By: Longitude Capital Partners III, LLC

Its: General Partner

Signatures: /s/ Patrick Enright
Print Name: Patrick Enright
Title: Managing Member

## **INVESTORS:**

NEW ENTERPRISE ASSOCIATES 15, L.P.

By: NEA Partners 15, L.P. Its: General Partner

By: NEA 15 GP, LLC Its: General Partner

Signature: /s/ Louis Citron
Print Name: Louis Citron
Title: Chief Legal Officer

# NEA VENTURES 2016, LIMITED PARTNERSHIP

Signature: /s/ Louis Citron
Print Name: Louis Citron
Title: Chief Legal Officer

# **INVESTORS:**

# NOVO HOLDINGS A/S

Signature: /s/ Thomas Dyrberg

Print Name: Thomas Dyrberg, under specific power of

ttorney

Title: Managing Partner

**INVESTORS:** 

**AVENTIS INC.** 

Signature: /s/ Chan H. Lee

Print Name: Chan H. Lee
Print Title: Vice President

# **INVESTORS:**

Signature: /s/ Joseph Schlessinger

Print Name: Joseph Schlessinger

# **INVESTORS:**

STEVEN JUNGLES TRUST DATED NOV. 12, 2014

Signature: /s/ Steven Jungles
Print Name: Steven Jungles

Title: Trustee

### Counterpart Signature Page

By executing and delivering this signature page, the undersigned (the "**Investor**") hereby joins in, becomes a party to and agrees to be bound by the terms and conditions of:

- (i) that certain Second Amended and Restated Investor Rights Agreement, dated as of November 9, 2018, by and among the Company and the parties named therein, as amended from time to time (the "**Investor Rights Agreement**"), as an "Investor" thereunder;
- (ii) that certain Amended and Restated Right of First Refusal and Co-Sale Agreement, dated as of November 9, 2018, by and among the Company and the parties named therein, as amended from time to time (the "ROFR Agreement"), as an "Investor" thereunder; and
- (iii) that certain Amended and Restated Voting Agreement, dated as of November 9, 2018, by and among the Company and the parties named therein, as amended from time to time (the "**Voting Agreement**"), as an "Investor" thereunder.

The undersigned hereby authorizes this signature page to be attached to the Investor Rights Agreement, the ROFR Agreement and the Voting Agreement or counterparts thereof.

Investor: AGREED TO AND ACCEPTED:

BLACKWELL PARTNERS LLC – SERIES A INOZYME PHARMA, INC.

By: /s/ Abayomi A. Adigun

By: /s/ Axel Bolte

Name: Abayomi A. Adigun

Name: Axel Bolte

Title: Investment Manager Title: Chief Executive Officer and President

By: /s/ Jannine M. Lall

Name: Jannine M. Lall

Title: Head of Finance & Controller

DUMAC, Inc. Authorized Signatory

DUMAC, Inc. Authorized Signatory

Date: March 22, 2019 Date: March 22, 2019

Address:

### Counterpart Signature Page

By executing and delivering this signature page, the undersigned (the "**Investor**") hereby joins in, becomes a party to and agrees to be bound by the terms and conditions of:

- (i) that certain Second Amended and Restated Investor Rights Agreement, dated as of November 9, 2018, by and among the Company and the parties named therein, as amended from time to time (the "**Investor Rights Agreement**"), as an "Investor" thereunder;
- (ii) that certain Amended and Restated Right of First Refusal and Co-Sale Agreement, dated as of November 9, 2018, by and among the Company and the parties named therein, as amended from time to time (the "ROFR Agreement"), as an "Investor" thereunder; and
- (iii) that certain Amended and Restated Voting Agreement, dated as of November 9, 2018, by and among the Company and the parties named therein, as amended from time to time (the "**Voting Agreement**"), as an "Investor" thereunder.

The undersigned hereby authorizes this signature page to be attached to the Investor Rights Agreement, the ROFR Agreement and the Voting Agreement or counterparts thereof.

Investor:

AGREED TO AND ACCEPTED:

CHI EF II LP

INOZYME PHARMA, INC.

By: Cowen Healthcare Investments II GP LLC,

its General Partner

By: /s/ Axel Bolte

By: /s/ Michael Benwitt

Name: Axel Bolte

Name: Michael Benwitt
Title: Authorized Signatory

Title: Chief Executive Officer and President

Date: March 22, 2019

Date: March 22, 2019

Address:

### Counterpart Signature Page

By executing and delivering this signature page, the undersigned (the "**Investor**") hereby joins in, becomes a party to and agrees to be bound by the terms and conditions of:

- (i) that certain Second Amended and Restated Investor Rights Agreement, dated as of November 9, 2018, by and among the Company and the parties named therein, as amended from time to time (the "**Investor Rights Agreement**"), as an "Investor" thereunder;
- (ii) that certain Amended and Restated Right of First Refusal and Co-Sale Agreement, dated as of November 9, 2018, by and among the Company and the parties named therein, as amended from time to time (the "ROFR Agreement"), as an "Investor" thereunder; and
- (iii) that certain Amended and Restated Voting Agreement, dated as of November 9, 2018, by and among the Company and the parties named therein, as amended from time to time (the "**Voting Agreement**"), as an "Investor" thereunder.

The undersigned hereby authorizes this signature page to be attached to the Investor Rights Agreement, the ROFR Agreement and the Voting Agreement or counterparts thereof.

Investor:

COWEN HEALTHCARE INVESTMENTS II LP

By: Cowen Healthcare Investments II GP LLC,

its General Partner

By: /s/ Michael Benwitt

Name: Michael Benwitt
Title: Authorized Signatory

Date: March 22, 2019

Address:

[\*\*]

AGREED TO AND ACCEPTED:

INOZYME PHARMA, INC.

By: /s/ Axel Bolte

Name: Axel Bolte

Title: Chief Executive Officer and President

Date: March 22 2019

### Counterpart Signature Page

By executing and delivering this signature page, the undersigned (the "**Investor**") hereby joins in, becomes a party to and agrees to be bound by the terms and conditions of:

- (i) that certain Second Amended and Restated Investor Rights Agreement, dated as of November 9, 2018, by and among the Company and the parties named therein, as amended from time to time (the "**Investor Rights Agreement**"), as an "Investor" thereunder;
- (ii) that certain Amended and Restated Right of First Refusal and Co-Sale Agreement, dated as of November 9, 2018, by and among the Company and the parties named therein, as amended from time to time (the "ROFR Agreement"), as an "Investor" thereunder; and
- (iii) that certain Amended and Restated Voting Agreement, dated as of November 9, 2018, by and among the Company and the parties named therein, as amended from time to time (the "**Voting Agreement**"), as an "Investor" thereunder.

The undersigned hereby authorizes this signature page to be attached to the Investor Rights Agreement, the ROFR Agreement and the Voting Agreement or counterparts thereof.

/s/ Axel Bolte

Chief Executive Officer and President

Axel Bolte

By: Name:

Title:

Investor: AGREED TO AND ACCEPTED:

RA CAPITAL HEALTHCARE FUND, L.P. INOZYME PHARMA, INC.

By: RA Capital Management, LLC

Its: General Partner

Ry: /c/ James Schneider

By: /s/ James Schneider

Name: James Schneider Title: Authorized Signatory

Date: March 22, 2019 Date: March 22, 2019

Address:

### Counterpart Signature Page

By executing and delivering this signature page, the undersigned (the "**Investor**") hereby joins in, becomes a party to and agrees to be bound by the terms and conditions of:

- (i) that certain Second Amended and Restated Investor Rights Agreement, dated as of November 9, 2018, by and among the Company and the parties named therein, as amended from time to time (the "**Investor Rights Agreement**"), as an "Investor" thereunder;
- (ii) that certain Amended and Restated Right of First Refusal and Co-Sale Agreement, dated as of November 9, 2018, by and among the Company and the parties named therein, as amended from time to time (the "ROFR Agreement"), as an "Investor" thereunder; and
- (iii) that certain Amended and Restated Voting Agreement, dated as of November 9, 2018, by and among the Company and the parties named therein, as amended from time to time (the "**Voting Agreement**"), as an "Investor" thereunder.

The undersigned hereby authorizes this signature page to be attached to the Investor Rights Agreement, the ROFR Agreement and the Voting Agreement or counterparts thereof.

INOZYME PHARMA, INC.

/s/ Axel Bolte

Chief Executive Officer and President

Axel Bolte

By: Name:

Title:

Investor: AGREED TO AND ACCEPTED:

ROCK SPRINGS CAPITAL MASTER FUND

LP

By: Rock Springs General Partner LLC,

its general partner

By: /s/ Kris Jenner

Name: Kris Jenner
Title: Member

Date: March 22, 2019 Date: March 22, 2019

Address:

### Counterpart Signature Page

By executing and delivering this signature page, the undersigned (the "**Investor**") hereby joins in, becomes a party to and agrees to be bound by the terms and conditions of:

- (i) that certain Second Amended and Restated Investor Rights Agreement, dated as of November 9, 2018, by and among the Company and the parties named therein, as amended from time to time (the "**Investor Rights Agreement**"), as an "Investor" thereunder;
- (ii) that certain Amended and Restated Right of First Refusal and Co-Sale Agreement, dated as of November 9, 2018, by and among the Company and the parties named therein, as amended from time to time (the "ROFR Agreement"), as an "Investor" thereunder; and
- (iii) that certain Amended and Restated Voting Agreement, dated as of November 9, 2018, by and among the Company and the parties named therein, as amended from time to time (the "**Voting Agreement**"), as an "Investor" thereunder.

The undersigned hereby authorizes this signature page to be attached to the Investor Rights Agreement, the ROFR Agreement and the Voting Agreement or counterparts thereof.

Investor: AGREED TO AND ACCEPTED:

SOFINNOVA VENTURE PARTNERS X, L.P. INOZYME PHARMA, INC.

By: Sofinnova Management X, L.L.C.

its General Partner

By: /s/ James Healy By: /s/ Axel Bolte

Name: Name: Axel Bolte

Title: Chief Executive Officer and President

Date: March 22, 2019 Date: March 22, 2019

Address:

### AMENDMENT NO. 1 TO

### SECOND AMENDED AND RESTATED INVESTOR RIGHTS AGREEMENT

THIS AMENDMENT NO. 1 TO SECOND AMENDED AND RESTATED INVESTOR RIGHTS AGREEMENT (this "Amendment"), dated as of March 22, 2019, amends that certain Second Amended and Restated Investor Rights Agreement, dated as of November 9, 2018, by and among Inozyme Pharma, Inc. (the "Company") and the Investors identified therein (the "IRA"). Capitalized terms used and not defined herein shall have the meanings set forth in the IRA.

WHEREAS, the Company and the Investors desire to amend the Series A-2 Convertible Preferred Stock Purchase Agreement, dated as of November 9, 2018, by and among the Company and the parties named on the signature pages thereto, to provide for the issuance of additional shares of Series A-2 Preferred Stock to one or more purchasers in one or more additional closings;

WHEREAS, the Company and the Investors desire to revise the IRA to reflect the foregoing; and

WHEREAS, Section 6.5 of the IRA provides in part that the IRA may be amended or modified only by a written instrument duly executed by the Company and the holders of 56% of the Registrable Securities then outstanding;

NOW, THEREFORE, in consideration of the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and the undersigned, who constitute the Investors required to amend the IRA, hereby agree as follows:

1. <u>Amendment to Recital C</u>. The parenthetical in Recital C which currently reads "(the "*Purchase Agreement*")" is hereby deleted in its entirety, and the following is inserted in lieu thereof:

"(as the same may be amended and/or restated from time to time, the "Purchase Agreement")".

- 2. Amendment to Section 1.1(i). Section 1.1(i) of the IRA is hereby deleted in its entirety, and the following is inserted in lieu thereof:
- **"(i)** "*Major Investor*" means any Investor who individually or together with such Investor's Affiliates holds at least 3,139,860 shares of Preferred Stock, subject to appropriate adjustment for any stock splits, stock dividends, combinations, recapitalizations and the like. Notwithstanding the foregoing, (i) Rock Springs Capital Master Fund LP ("*Rock Springs*") shall be deemed a "Major Investor" for purposes of Section 3.1, Section 3.2 and Section 5 at all times prior to the Milestone Closing (as defined in the Purchase Agreement) so long as Rock Springs, individually or together

with its Affiliates, continues to hold at least 1,748,252 shares of Preferred Stock, subject to appropriate adjustment for any stock splits, stock dividends, combinations, recapitalizations and the like, and (ii) Blackwell Partners LLC – Series A ("Blackwell") shall be deemed a "Major Investor" for purposes of Section 3.1, Section 3.2 and Section 5 (a) at all times prior to the Milestone Closing so long as Blackwell, individually or together with its Affiliates, continues to hold at least 796,154 shares of Preferred Stock and (b) at all times after the Milestone Closing so long as Blackwell, individually or together with its Affiliates, continues to hold at least 1,592,308 shares of Preferred Stock, in each case subject to appropriate adjustment for any stock splits, stock dividends, combinations, recapitalizations and the like."

### 3. Amendment to Section 1.1.

- 1.1 Section 1.1 of the IRA is hereby amended to insert the following in a new Section 1.1(q) after Section 1.1(p):
- "(q) "Requisite Holders" means Pivotal bioVenture Partners LLC ("Pivotal"), Sofinnova Venture Partners X, L.P. ("Sofinnova"), and RA Capital Healthcare Fund, L.P. ("RA Capital")."
- **1.2** Current Sections 1.1(q) through 1.1(v) of the IRA are hereby amended to be renamed Sections 1.1(r) through a new Section 1.1(w).
- 4. <u>Amendments to Section 2.2(a)</u>. The reference to "56% of the Registrable Securities" in Section 2.2(a), is hereby deleted in its entirety, and the following inserted in lieu thereof:
  - "a majority of the Registrable Securities, including at least one of the Requisite Holders for so long as at least one of the Requisite Holders holds a majority of the shares of Series A-2 Preferred Stock purchased by such Requisite Holder from the Company prior to the Milestone Closing (subject to appropriate adjustment for any stock splits, stock dividends, combinations, recapitalizations and the like)".
- 5. <u>Amendments to Section 2.15 and Section 3.20</u>. The references to "56% of the then outstanding shares of Preferred Stock" in Section 2.15, Section 3.1(d) and Section 3.20 are hereby deleted in their entirety, and the following inserted in lieu thereof:
  - "a majority of the then outstanding shares of Preferred Stock, including at least one of the Requisite Holders for so long as at least one of the Requisite Holders holds a majority of the shares of Series A-2 Preferred Stock purchased by such Requisite Holder from the Company prior to the Milestone Closing (subject to appropriate adjustment for any stock splits, stock dividends, combinations, recapitalizations and the like)".
- 6. <u>Amendment to Section 2.11</u>. The first sentence of Section 2.11 of the IRA is hereby deleted in its entirety, and the following is inserted in lieu thereof:

"Each Holder hereby agrees that such Holder shall not sell, dispose of, transfer, make any short sale of, grant any option for the purchase of, or enter into any hedging or similar

transaction with the same economic effect as a sale, any shares of Common Stock (or other securities) of the Company held by such Holder immediately before the effective date of the final prospectus in such offering (other than those included in the registration) during the 180-day period following the date of the final prospectus relating to the Initial Public Offering provided, that all officers and directors of the Company who beneficially own any shares of Common Stock and holders of at least one percent (1%) of the Company's voting securities are bound by and have entered into similar agreements on terms no more favorable than those applicable to the Holder."

- 7. <u>Amendments to Section 3.1(d)</u>. The reference to "56% of the then outstanding shares of Preferred Stock" in Section 3.1(d) is hereby deleted in is entirety, and the following inserted in lieu thereof:
- "a majority of the then outstanding shares of Preferred Stock, including at least one of the Requisite Holders for so long as at least one of the Requisite Holders holds a majority of the shares of Series A-2 Preferred Stock purchased by such Requisite Holder from the Company prior to the Milestone Closing (subject to appropriate adjustment for any stock splits, stock dividends, combinations, recapitalizations and the like),".
- 8. <u>Amendments to Section 4.2</u>. The reference to "56% of outstanding Preferred Stock" in Section 4.2 is hereby deleted in its entirety, and the following inserted in lieu thereof:
  - "a majority of the then outstanding shares of Preferred Stock, including at least one of the Requisite Holders for so long as at least one of the Requisite Holders holds a majority of the shares of Series A-2 Preferred Stock purchased by such Requisite Holder from the Company prior to the Milestone Closing (subject to appropriate adjustment for any stock splits, stock dividends, combinations, recapitalizations and the like),".
- 9. <u>Amendment to Section 3.7(a)</u>. The first paragraph of Section 3.7(a) of the IRA is hereby deleted in its entirety, and the following is inserted in lieu thereof:
  - "(a) So long as the Company shall not be a company required to file reports with the SEC pursuant to Section 13 or Section 15(d) of the Exchange Act, the Company shall allow (1) two representatives designated by Longitude Venture Partners III, L.P. ("Longitude"), who are reasonably acceptable to the Company and who shall initially be Sandip Agarwala and Oren Isacoff, so long as Longitude shall hold any shares of Preferred Stock, (2) one representative designated by New Enterprise Associates 15, L.P. ("NEA"), who is reasonably acceptable to the Company and who shall initially be Jason Fuller, so long as NEA shall hold any shares of Preferred Stock, (3) one representative designated by Novo, who is reasonably acceptable to the Company and who shall initially be Jennifer Lee, so long as Novo shall hold any shares of Preferred Stock, (4), one representative designated by Sanofi US ("Sanofi"), who is reasonably acceptable to the Company and who shall initially be Ruchita Sinha, so long as Sanofi shall hold any shares of Preferred Stock, (5) Dr. Demetrios Braddock ("Braddock") so long as he shall own at least 25% of the shares of Common Stock that he owned on April 13, 2017, subject to appropriate adjustment for any stock splits, stock dividends, combinations, recapitalizations and the like, (6) one representative designated by Pivotal, who is

reasonably acceptable to the Company and who shall initially be Jim Trenkle, so long as Pivotal shall hold any shares of Preferred Stock, and (7) one representative designated by RA Capital, who is reasonably acceptable to the Company and who shall initially be Jake Simson, so long as RA Capital shall hold any shares of Preferred Stock, to attend all meetings of the Board as observers, but without any right to make any motion or to vote (the "Observers"), and in connection therewith, the Company shall give the Observers copies of all notices, minutes, written consents of the Board to action taken without a meeting and other materials, financial or otherwise, which the Company provides to the Board; provided, however, that the observation rights (including the right to receive notices, minutes, consents and other materials) provided hereby shall be temporarily suspended, and any one or more Observers shall be excluded from access to any material or meeting or portion thereof, if (i) the Company believes, upon the advice of counsel, that such exclusion is necessary or appropriate to preserve the attorney-client privilege or to protect confidential or proprietary information of the Company or a third party; or (ii) with respect to Braddock, there exists, with respect to any meeting of the Board or any portion thereof or any deliberation by the Board or consent or material being furnished to the Board, an actual or potential conflict of interest between Braddock and the Company."

10. <u>Amendment to Section 3.19</u>. The first sentence of Section 3.19 of the IRA is hereby deleted in its entirety, and the following is inserted in lieu thereof:

"The Company hereby acknowledges that Longitude and its Affiliates, NEA and its Affiliates, Novo and its Affiliates, Pivotal and its Affiliates, Sanofi and its Affiliates, RA Capital and its Affiliates, Sofinnova and its Affiliates, Cowen Healthcare Investments II LP ("Cowen") and its Affiliates, and Rock Springs and its Affiliates (collectively, "Funds") may invest in entities that operate in markets that may be competitive with the markets in which the Company operates."

11. <u>Amendment to Section 6.5</u>. The first sentence of Section 6.5(a) of the IRA is hereby deleted in its entirety, and the following is inserted in lieu thereof:

"Except as otherwise expressly provided, this Agreement may be amended or modified, and the obligations of the Company and the rights of the Holders under this Agreement may be waived, only by a written instrument duly executed by the Company and the holders of a majority of the Registrable Securities then outstanding, including at least one of the Requisite Holders for so long as at least one of the Requisite Holders holds a majority of the shares of Series A-2 Preferred Stock purchased by such Requisite Holder from the Company prior to the Milestone Closing (subject to appropriate adjustment for any stock splits, stock dividends, combinations, recapitalizations and the like); provided, however, that any such instrument that amends (i) Section 3.7 and Section 3.19 in a manner adverse to Longitude shall become effective only if duly executed and delivered by Longitude, (ii) Section 3.7 and Section 3.19 in a manner adverse to NEA shall become effective only if duly executed by NEA, (iii) Section 3.7 and Section 3.19 in a manner adverse to Sanofi shall become effective only if duly executed by Sanofi, (v) Section 3.7 and

Section 3.19 in a manner adverse to Pivotal shall become effective only if duly executed and delivered by Pivotal; (vi) Section 3.7 and Section 3.19 in a manner adverse to RA Capital shall become effective only if duly executed by RA Capital; (vii) Section 3.19 in a manner adverse to Sofinnova shall become effective only if duly executed by Sofinnova; (viii) Section 3.19 in a manner adverse to Cowen shall become effective only if duly executed by Cowen, and (ix) Sections 3.21 and 3.22 and this Section 6.5(ix), shall become effective only if duly executed by Novo and Pivotal; and provided further that any party may waive its rights under any provision hereof on such party's own behalf by an instrument in writing duly executed by such party without any action, instrument or concurrence of any other party."

- 12. <u>Entire Agreement</u>. The IRA, as amended by this Amendment, contains the entire agreement among the parties with respect to the subject matter thereof and amends, restates and supersedes all prior and contemporaneous arrangements or understandings with respect thereto.
- 13. <u>Effectiveness</u>. Upon the effectiveness of this Amendment, on and after the date hereof, each reference in the IRA to "this Agreement," "hereunder," "hereof," "herein" or words of like import, and each reference in the other documents entered into in connection with the IRA, shall mean and be a reference to the IRA, as amended hereby. All terms in the IRA that are not explicitly amended by this Amendment shall remain in full force and effect and are hereby ratified and confirmed.
- 14. Governing Law. This Amendment shall be governed by and construed under the laws of the State of Delaware as such laws are applied to agreements among Delaware residents entered into and performed entirely within the State of Delaware, without reference to the conflict of laws provisions thereof. The parties agree that any action brought by either party under or in relation to this Amendment, including without limitation to interpret or enforce any provision of this Amendment, shall be brought in, and each party agrees to and does hereby submit to the jurisdiction and venue of, any state or federal court located in the State of Delaware.
- 15. <u>Counterparts</u>. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Any or all parties may execute this Amendment by telephone line facsimile transmission bearing its signature or by electronic transmission of its signature image in Portable Document Format ("*PDF*"), and any such signature sent by facsimile transmission or a PDF signature image, if identified, legible and complete, shall be deemed an original signature and each of the other parties is hereby authorized to rely thereon.

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# INOZYME PHARMA, INC.

By: /s/ Axel Bolte

Name: Axel Bolte

Title: President and Chief Executive Officer

# **INVESTORS:**

# LONGITUDE VENTURE PARTNERS III, L.P.

By: Longitude Capital Partners III, LLC

Its: General Partner

Signature: /s/ Patrick Enright
Print Name: Patrick Enright
Title: Managing Member

## NEW ENTERPRISE ASSOCIATES 15, L.P.

By: NEA Partners 15, L.P. Its: General Partner

By: NEA 15 GP, LLC Its: General Partner

Signature: /s/ Louis Citron
Print Name: Louis Citron
Title: Chief Legal Officer

# NEA VENTURES 2016, LIMITED PARTNERSHIP

Signature: /s/ Louis Citron
Print Name: Louis Citron

Title: Chief Legal Officer

# NOVO HOLDINGS A/S

Signature: /s/ Thomas Dyrberg

Print Name: Thomas Dyrberg, under specific power of

attorney

Title: Managing Partner

# PIVOTAL BIOVENTURE PARTNERS FUND I, L.P.

By: Pivotal bioVenture Partners Fund I G.P., L.P., its general partner

By: Pivotal bioVenture Partners Fund I U.G.P. Ltd, its general partner

By: /s/ Robert Hopfner
Name: Robert Hopfner
Title: Managing Partner

### AMENDMENT NO. 2

TO

#### SECOND AMENDED AND RESTATED INVESTOR RIGHTS AGREEMENT

THIS AMENDMENT NO. 2 TO SECOND AMENDED AND RESTATED INVESTOR RIGHTS AGREEMENT (this "Amendment"), dated as of May 28, 2020, amends that certain Second Amended and Restated Investor Rights Agreement, dated as of November 9, 2018, by and among Inozyme Pharma, Inc. (the "Company") and the Investors identified therein, as amended by Amendment No. 1 thereto, dated as of March 22, 2019 (as so amended, the "IRA"). Capitalized terms used and not defined herein shall have the meanings set forth in the IRA.

WHEREAS, the Company and the Investors desire to amend the IRA to extend by an additional 12 months the date by which the Chief Executive Officer of the Company must relocate to the greater Boston, Massachusetts area; and

WHEREAS, Section 6.5 of the IRA provides that the IRA may be amended, and the obligations of the Company and the rights of the Holders under the IRA may be waived, by a written instrument duly executed by the Company and the holders of a majority of the Registrable Securities then outstanding, including at least one of the Requisite Holders;

NOW, THEREFORE, in consideration of the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and the undersigned, who constitute the holders required to amend the IRA, and waive obligations of the Company and rights of the Holders thereunder, hereby agree as follows:

- 1. Amendment to Section 3.10. Section 3.10 of the IRA is hereby deleted in its entirety and the following is inserted in lieu thereof:
- "CEO Relocation. Within 12 months following the termination of the travel suspension in effect under Presidential Proclamation 9993 (or any similar travel ban or suspension implemented in response to the COVID-19 pandemic) prohibiting travel from Switzerland to the United States, the Company's Chief Executive Officer shall be located or relocate to within a reasonable daily commuting distance from the Company's corporate headquarters in the greater Boston, Massachusetts area."
- 2. Waiver of Noncompliance. The Company and the undersigned hereby waive any noncompliance with Section 3.10 of the IRA existing prior to the effectiveness of this Amendment.
- 3. <u>Entire Agreement</u>. The IRA, as amended by this Amendment, contains the entire agreement among the parties with respect to the subject matter thereof and amends, restates and supersedes all prior and contemporaneous arrangements or understandings with respect thereto.

- 4. Effectiveness. Upon the effectiveness of this Amendment, on and after the date hereof, each reference in the IRA to "this Agreement," "hereunder," "herein" or words of like import, and each reference in the other documents entered into in connection with the IRA, shall mean and be a reference to the IRA, as amended hereby. All terms in the IRA that are not explicitly amended by this Amendment shall remain in full force and effect and are hereby ratified and confirmed.
- 5. <u>Governing Law.</u> This Amendment shall be governed by and construed under the laws of the State of Delaware as such laws are applied to agreements among Delaware residents entered into and performed entirely within the State of Delaware, without reference to the conflict of laws provisions thereof. The parties agree that any action brought by either party under or in relation to this Amendment, including without limitation to interpret or enforce any provision of this Amendment, shall be brought in, and each party agrees to and does hereby submit to the jurisdiction and venue of, any state or federal court located in the State of Delaware.
- 6. <u>Counterparts</u>. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Any or all parties may execute this Amendment by telephone line facsimile transmission bearing its signature or by electronic transmission of its signature image in Portable Document Format ("*PDF*"), and any such signature sent by facsimile transmission or a PDF signature image, if identified, legible and complete, shall be deemed an original signature and each of the other parties is hereby authorized to rely thereon.

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# INOZYME PHARMA, INC.

By: /s/ Axel Bolte
Name: Axel Bolte

Title: President and Chief Executive Officer

## **INVESTORS:**

# LONGITUDE VENTURE PARTNERS III, L.P.

By: Longitude Capital Partners III, LLC

Its: General Partner

Signature: /s/ Patrick Enright

Print Name: Patrick Enright

Title: Managing Member

### **INVESTORS:**

# NEW ENTERPRISE ASSOCIATES 15, L.P.

By: NEA Partners 15, L.P. Its: General Partner

By: NEA 15 GP, LLC Its: General Partner

Signature: /s/ Louis Citron

Print Name: Louis Citron

Title: Chief Administrative Officer and Chief Legal Officer

# NEA VENTURES 2016, LIMITED PARTNERSHIP

Signature: /s/ Louis Citron

Print Name: Louis Citron

Title: Vice President

## **INVESTORS:**

# **NOVO HOLDINGS A/S**

Signature: /s/ Thomas Dyrberg

Print Name: Thomas Dyrberg, under specific power of

attorney

Title: Managing Partner

### **INVESTORS:**

# PIVOTAL BIOVENTURE PARTNERS FUND I, L.P.

By: Pivotal bioVenture Partners Fund I G.P., L.P., its general partner

By: Pivotal bioVenture Partners Fund I U.G.P. Ltd, its general partner

By: /s/ Robert Hopfner
Name: Robert Hopfner
Title: Managing Partner

## **INVESTORS:**

# SOFINNOVA VENTURE PARTNERS X, L.P.

By: Sofinnova Management X, L.L.C., its General Partner

Signature: /s/ James I. Healy

Print Name: James I. Healy

Title: Managing Member

## AMENDMENT NO. 3

TO

### SECOND AMENDED AND RESTATED INVESTOR RIGHTS AGREEMENT

THIS AMENDMENT NO. 3 TO SECOND AMENDED AND RESTATED INVESTOR RIGHTS AGREEMENT (this "Amendment"), dated as of July 17, 2020, amends that certain Second Amended and Restated Investor Rights Agreement, dated as of November 9, 2018, by and among Inozyme Pharma, Inc. (the "Company") and the Investors identified therein, as amended by Amendment No. 1 thereto, dated as of March 22, 2019, and Amendment No. 2 thereto, dated as of May 28, 2020 (as so amended, the "IRA"). Capitalized terms used and not defined herein shall have the meanings set forth in the IRA.

WHEREAS, the Company and the Investors desire to amend the IRA to add Alexion Pharmaceuticals, Inc. ("Alexion") as a party thereto; and

WHEREAS, Section 6.5 of the IRA provides that the IRA may be amended, and the obligations of the Company and the rights of the Holders under the IRA may be waived, by a written instrument duly executed by the Company and the holders of a majority of the Registrable Securities then outstanding, including at least one of the Requisite Holders;

NOW, THEREFORE, in consideration of the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and the undersigned, who constitute the holders required to amend the IRA, and waive obligations of the Company and rights of the Holders thereunder, hereby agree as follows:

- 1. <u>Additional Party; Amendment of Exhibit A</u>. Upon its execution of this Amendment, Alexion is hereby added as a party to, and agrees to be bound by the terms and conditions of, the IRA, as amended hereby, as an Investor for all purposes thereunder. <u>Exhibit A</u> of the IRA is hereby amended and restated as set forth on Exhibit A attached to this Amendment.
- 2. <u>Amendment to Section 3.19</u>. The first sentence of Section 3.19 of the IRA is hereby deleted in its entirety and the following is inserted in lieu thereof:
  - "The Company hereby acknowledges that Longitude and its Affiliates, NEA and its Affiliates, Novo and its Affiliates, Pivotal and its Affiliates, Sanofi and its Affiliates, RA Capital and its Affiliates, Sofinnova and its Affiliates, Cowen Healthcare Investments II LP ("Cowen") and its Affiliates, Rock Springs and its Affiliates and Alexion Pharmaceuticals, Inc. and its Affiliates (collectively, "Funds") may invest in entities that operate in markets that may be competitive with the markets in which the Company operates."
- 3. <u>Entire Agreement</u>. The IRA, as amended by this Amendment, contains the entire agreement among the parties with respect to the subject matter thereof and amends, restates and supersedes all prior and contemporaneous arrangements or understandings with respect thereto.

- 4. Effectiveness. Upon the effectiveness of this Amendment, on and after the date hereof, each reference in the IRA to "this Agreement," "hereunder," "herein" or words of like import, and each reference in the other documents entered into in connection with the IRA, shall mean and be a reference to the IRA, as amended hereby. All terms in the IRA that are not explicitly amended by this Amendment shall remain in full force and effect and are hereby ratified and confirmed.
- 5. <u>Governing Law.</u> This Amendment shall be governed by and construed under the laws of the State of Delaware as such laws are applied to agreements among Delaware residents entered into and performed entirely within the State of Delaware, without reference to the conflict of laws provisions thereof. The parties agree that any action brought by either party under or in relation to this Amendment, including without limitation to interpret or enforce any provision of this Amendment, shall be brought in, and each party agrees to and does hereby submit to the jurisdiction and venue of, any state or federal court located in the State of Delaware.
- 6. <u>Counterparts</u>. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Any or all parties may execute this Amendment by telephone line facsimile transmission bearing its signature or by electronic transmission of its signature image in Portable Document Format ("*PDF*"), and any such signature sent by facsimile transmission or a PDF signature image, if identified, legible and complete, shall be deemed an original signature and each of the other parties is hereby authorized to rely thereon.

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# INOZYME PHARMA, INC.

By: /s/ Axel Bolte
Name: Axel Bolte

Title: President and Chief Executive Officer

## **INVESTORS:**

## ALEXION PHARMACEUTICALS, INC.

By: /s/ Aradhana Sarin

Print Name: Aradhana Sarin Title: Chief Financial Officer

### **INVESTORS:**

## LONGITUDE VENTURE PARTNERS III, L.P.

By: Longitude Capital Partners III, LLC

Its: General Partner

Signature: /s/ Patrick Enright
Print Name: Patrick Enright
Title: Managing Member

#### **INVESTORS:**

## NEW ENTERPRISE ASSOCIATES 15, L.P.

By: NEA Partners 15, L.P. Its: General Partner

By: NEA 15 GP, LLC Its: General Partner

Signature: /s/ Louis Citron
Print Name: Louis Citron

Title: Chief Legal Officer

## NEA VENTURES 2016, LIMITED PARTNERSHIP

Signature: /s/ Louis Citron
Print Name: Louis Citron
Title: Chief Legal Officer

## **INVESTORS:**

## **NOVO HOLDINGS A/S**

Signature: /s/ Thomas Dyrberg

Print Name: Thomas Dyrberg, under specific power of

attorney

Title: Managing Partner

#### **INVESTORS:**

## PIVOTAL BIOVENTURE PARTNERS FUND I, L.P.

By: Pivotal bioVenture Partners Fund I G.P., L.P., its general partner

By: Pivotal bioVenture Partners Fund I U.G.P. Ltd, its general partner

By: /s/ Robert Hopfner
Name: Robert Hopfner
Title: Managing Partner

### **INVESTORS:**

## SOFINNOVA VENTURE PARTNERS X, L.P.

By: Sofinnova Management X, L.L.C., its General Partner

Signature: /s/ Mike Powell
Print Name: Mike Powell
Title: Managing Member

# 2020 STOCK INCENTIVE PLAN OF INOZYME PHARMA, INC.

#### 1. Purpose

The purpose of this 2020 Stock Incentive Plan (the "*Plan*") of Inozyme Pharma, Inc., a Delaware corporation (the "*Company*"), is to advance the interests of the Company's stockholders by enhancing the Company's ability to attract, retain and motivate persons who are expected to make important contributions to the Company and by providing such persons with equity ownership opportunities and performance-based incentives that are intended to better align the interests of such persons with those of the Company's stockholders. Except where the context otherwise requires, the term "*Company*" shall include any of the Company's present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Internal Revenue Code of 1986, as amended, and any regulations thereunder (the "*Code*") and any other business venture (including, without limitation, joint venture or limited liability company) in which the Company has a controlling interest, as determined by the Board of Directors of the Company (the "*Board*").

### 2. Eligibility

All of the Company's employees, officers and directors, as well as consultants and advisors to the Company (as such terms consultants and advisors are defined and interpreted for purposes of Form S-8 under the Securities Act of 1933, as amended (the "Securities Act"), or any successor form) are eligible to be granted Awards (as defined below) under the Plan. Each person who is granted an Award under the Plan is deemed a "Participant." "Award" means Options (as defined in Section 5), SARs (as defined in Section 6), Restricted Stock (as defined in Section 7), Restricted Stock Units (as defined in Section 7) and Other Stock-Based Awards (as defined in Section 8).

#### 3. Administration and Delegation

(a) Administration by Board of Directors. The Plan will be administered by the Board. The Board shall have authority to grant Awards and to adopt, amend and repeal such administrative rules, guidelines and practices relating to the Plan as it shall deem advisable. The Board may construe and interpret the terms of the Plan and any Award agreements entered into under the Plan. The Board may correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Award in the manner and to the extent it shall deem expedient and it shall be the sole and final judge of such expediency. All decisions by the Board shall be made in the Board's sole discretion and shall be final and binding on all persons having or claiming any interest in the Plan or in any Award.

- (b) <u>Appointment of Committees</u>. To the extent permitted by applicable law, the Board may delegate any or all of its powers under the Plan to one or more committees or subcommittees of the Board (a "*Committee*"). All references in the Plan to the "*Board*" shall mean the Board or a Committee of the Board or the officers referred to in Section 3(c) to the extent that the Board's powers or authority under the Plan have been delegated to such Committee or officers.
- (c) <u>Delegation to Officers</u>. Subject to any requirements of applicable law (including as applicable Sections 152 and 157(c) of the General Corporation Law of the State of Delaware), the Board may delegate to one or more officers of the Company the power to grant Awards (subject to any limitations under the Plan) to employees or officers of the Company and to exercise such other powers under the Plan as the Board may determine, provided that the Board shall fix the terms of Awards to be granted by such officers, the maximum number of shares subject to Awards that the officers may grant, and the time period in which such Awards may be granted; and provided further, that no officer shall be authorized to grant Awards to any "executive officer" of the Company (as defined by Rule 3b-7 under the Securities Exchange Act of 1934, as amended (the "*Exchange Act*")) or to any "officer" of the Company (as defined by Rule 16a-1(f) under the Exchange Act).

#### 4. Stock Available for Awards

- (a) Number of Shares; Share Counting.
- (1) <u>Authorized Number of Shares</u>. Subject to adjustment under Section 9, Awards may be made under the Plan for up to such number of shares of common stock, \$0.0001 par value per share, of the Company (the "Common Stock") as is equal to the sum of:
  - (A) 1,588,315 shares of Common Stock; plus
- (B) such additional number of shares of Common Stock (up to 2,613,638 shares) as is equal to the sum of (x) the number of shares of Common Stock reserved for issuance under the Company's 2017 Stock Incentive Plan, as amended (the "Existing Plan") that remain available for grant under the Existing Plan immediately prior to the effectiveness of the registration statement for the Company's initial public offering and (y) the number of shares of Common Stock subject to awards granted under the Existing Plan which awards expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right (subject, however, in the case of Incentive Stock Options to any limitations of the Code); plus
- (C) an annual increase to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2021 and continuing for each fiscal year until, and including, the fiscal year ending December 31, 2030, equal to the least of (i) 4% of the outstanding shares on such date and (ii) the number of shares of Common Stock determined by the Board.

Any or all of the shares of Common Stock available for issuance under the Plan may be issued as Incentive Stock Options (as defined in Section 5(b)) under the Plan, provided that no more than 1,588,315 shares of Common Stock may be issued as Incentive Stock Options under the Plan. Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares.

- (2) <u>Share Counting</u>. For purposes of counting the number of shares available for the grant of Awards under the Plan under this Section 4(a):
- (A) all shares of Common Stock covered by SARs shall be counted against the number of shares available for the grant of Awards under the Plan; *provided*, *however*, that (i) SARs that may be settled only in cash shall not be so counted and (ii) if the Company grants an SAR in tandem with an Option for the same number of shares of Common Stock and provides that only one such Award may be exercised (a "*Tandem SAR*"), only the shares covered by the Option, and not the shares covered by the Tandem SAR, shall be so counted, and the expiration of one in connection with the other's exercise will not restore shares to the Plan;
- (B) to the extent a Restricted Stock Unit award may be settled only in cash, no shares shall be counted against the shares available for the grant of Awards under the Plan;
- (C) if any Award (i) expires or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase right) or (ii) results in any Common Stock not being issued (including as a result of an SAR that was settleable either in cash or in stock actually being settled in cash), the unused Common Stock covered by such Award shall again be available for the grant of Awards; provided, however, that (1) in the case of Incentive Stock Options, the foregoing shall be subject to any limitations under the Code, (2) in the case of the exercise of an SAR, the number of shares counted against the shares available under the Plan shall be the full number of shares subject to the SAR multiplied by the percentage of the SAR actually exercised, regardless of the number of shares actually used to settle such SAR upon exercise and (3) the shares covered by a Tandem SAR shall not again become available for grant upon the expiration or termination of such Tandem SAR; and
- (D) shares of Common Stock delivered (by actual delivery, attestation, or net exercise) to the Company by a Participant to (i) purchase shares of Common Stock upon the exercise of an Award or (ii) satisfy tax withholding obligations with respect to Awards (including shares retained from the Award creating the tax obligation) shall be added back to the number of shares available for the future grant of Awards.
- (b) <u>Substitute Awards</u>. In connection with a merger or consolidation of an entity with the Company or the acquisition by the Company of property or stock of an entity, the Board may grant Awards in substitution for any options or other stock or stock-based awards granted by such entity or an affiliate thereof. Substitute Awards may be granted on such terms as the Board deems appropriate in the circumstances, notwithstanding any limitations on Awards contained in the Plan. Substitute Awards shall not count against the overall share limit set forth in Section 4(a)(1) or any sublimit contained in the Plan, except as may be required by reason of Section 422 and related provisions of the Code.

(c) <u>Limit on Awards to Non-Employee Directors</u>. The maximum aggregate amount of cash and value (calculated based on grant date fair value for financial reporting purposes) of Awards granted in any calendar year to any individual non-employee director in his or her capacity as a non-employee director shall not exceed \$750,000; provided, however, that such maximum aggregate amount shall not exceed \$1,000,000 in any calendar year for any individual non-employee director in such non-employee director's initial year of election; and provided, further, however, that fees paid by the Corporation on behalf of any non-employee director in connection with regulatory compliance and any amounts paid to a non-employee director as reimbursement of an expense shall not count against the foregoing limit. The Board may make additional exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the Board may determine in its discretion, provided that the non-employee director receiving such additional compensation may not participate in the decision to award such compensation. For the avoidance of doubt, this limitation shall not apply to cash or Awards granted to the non-employee director in his or her capacity as an advisor or consultant to the Company.

#### 5. Stock Options

- (a) <u>General</u>. The Board may grant options to purchase Common Stock (each, an "*Option*") and determine the number of shares of Common Stock to be covered by each Option, the exercise price of each Option and the conditions and limitations applicable to the exercise of each Option, including conditions relating to applicable federal or state securities laws, as it considers necessary or advisable.
- (b) <u>Incentive Stock Options</u>. An Option that the Board intends to be an "incentive stock option" as defined in Section 422 of the Code (an "*Incentive Stock Option*") shall only be granted to employees of Inozyme Pharma, Inc., any of Inozyme Pharma, Inc.'s present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Code, and any other entities the employees of which are eligible to receive Incentive Stock Options under the Code, and shall be subject to and shall be construed consistently with the requirements of Section 422 of the Code. An Option that is not intended to be an Incentive Stock Option shall be designated a "*Nonstatutory Stock Option*." The Company shall have no liability to a Participant, or any other party, if an Option (or any part thereof) that is intended to be an Incentive Stock Option is not an Incentive Stock Option or if the Company converts an Incentive Stock Option to a Nonstatutory Stock Option.
- (c) Exercise Price. The Board shall establish the exercise price of each Option or the formula by which such exercise price will be determined. The exercise price shall be specified in the applicable Option agreement. The exercise price shall be not less than 100% of the Grant Date Fair Market Value (as defined below) of the Common Stock on the date the Option is granted; *provided* that if the Board approves the grant of an Option with an exercise price to be determined on a future date, the exercise price shall be not less than 100% of the Grant Date Fair Market Value on such future date. "Grant Date Fair Market Value" of a share of Common Stock for purposes of the Plan will be determined as follows:
- (1) if the Common Stock trades on a national securities exchange, the closing sale price (for the primary trading session) on the date of grant; or

- (2) if the Common Stock does not trade on any such exchange, the average of the closing bid and asked prices on the date of grant as reported by an over-the-counter marketplace designated by the Board; or
- (3) if the Common Stock is not publicly traded, the Board will determine the Grant Date Fair Market Value for purposes of the Plan using any measure of value it determines to be appropriate (including, as it considers appropriate, relying on appraisals) in a manner consistent with the valuation principles under Code Section 409A, except as the Board may expressly determine otherwise.

For any date that is not a trading day, the Grant Date Fair Market Value of a share of Common Stock for such date will be determined by using the closing sale price or average of the bid and asked prices, as appropriate, for the immediately preceding trading day and with the timing in the formulas above adjusted accordingly. The Board can substitute a particular time of day or other measure of "closing sale price" or "bid and asked prices" if appropriate because of exchange or market procedures or can, in its sole discretion, use weighted averages either on a daily basis or such longer period as complies with Code Section 409A.

Notwithstanding the foregoing, in respect of Options granted effective upon the pricing of the Company's initial public offering (the "Offering"), the Grant Date Fair Market Value of a share of Common Stock shall be the per share price at which shares of Common Stock are sold by the underwriters to the public in the Offering.

The Board has sole discretion to determine the Grant Date Fair Market Value for purposes of the Plan, and all Awards are conditioned on the Participants' agreement that the Board's determination is conclusive and binding even though others might make a different determination.

- (d) <u>Duration of Options</u>. Each Option shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable option agreement; *provided*, *however*, that no Option will be granted with a term in excess of 10 years.
- (e) <u>Exercise of Options</u>. Options may be exercised by delivery to the Company of a notice of exercise in a form (which may be electronic, and which may be provided to a third party equity plan administrator) approved by the Company, together with payment in full (in the manner specified in Section 5(f)) of the exercise price for the number of shares for which the Option is exercised. Shares of Common Stock subject to the Option will be delivered by the Company as soon as practicable following exercise.
  - (f) Payment Upon Exercise. Common Stock purchased upon the exercise of an Option granted under the Plan shall be paid for as follows:
    - (1) in cash or by check, payable to the order of the Company;
- (2) except as may otherwise be provided in the applicable Option agreement or approved by the Board, by (i) delivery of an irrevocable and unconditional undertaking by a creditworthy broker to deliver promptly to the Company sufficient funds to pay the exercise price and any required tax withholding or (ii) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to the Company cash or a check sufficient to pay the exercise price and any required tax withholding;

- (3) to the extent provided for in the applicable Option agreement or approved by the Board, by delivery (either by actual delivery or attestation) of shares of Common Stock owned by the Participant valued at their fair market value (valued in the manner determined by (or in a manner approved by) the Board), provided (i) such method of payment is then permitted under applicable law, (ii) such Common Stock, if acquired directly from the Company, was owned by the Participant for such minimum period of time, if any, as may be established by the Board and (iii) such Common Stock is not subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements;
- (4) to the extent provided for in the applicable Nonstatutory Stock Option agreement or approved by the Board, by delivery of a notice of "net exercise" to the Company, as a result of which the Participant would receive (i) the number of shares underlying the portion of the Option being exercised, less (ii) such number of shares as is equal to (A) the aggregate exercise price for the portion of the Option being exercised divided by (B) the fair market value of the Common Stock (valued in the manner determined by (or in a manner approved by) the Board) on the date of exercise;
- (5) to the extent permitted by applicable law and provided for in the applicable Option agreement or approved by the Board by payment of such other lawful consideration as the Board may determine; or
  - (6) by any combination of the above permitted forms of payment, to the extent approved by the Board.
- (g) <u>Limitation on Repricing</u>. Unless such action is approved by the Company's stockholders, the Company may not (except as provided for under Section 9): (1) amend any outstanding Option granted under the Plan to provide an exercise price per share that is lower than the then-current exercise price per share of such outstanding Option, (2) cancel any outstanding option (whether or not granted under the Plan) and grant in substitution therefor new Awards under the Plan (other than Awards granted pursuant to Section 4(b)) covering the same or a different number of shares of Common Stock and having an exercise price per share lower than the then-current exercise price per share of the cancelled option, (3) cancel in exchange for a cash payment any outstanding Option with an exercise price per share above the then-current fair market value of the Common Stock (valued in the manner determined by (or in the manner approved by) the Board) or (4) take any other action under the Plan that constitutes a "repricing" within the meaning of the rules of the Nasdaq Stock Market or any other exchange or marketplace on which the Company stock is listed or traded (the "Exchange").

#### 6. Stock Appreciation Rights

(a) <u>General</u>. The Board may grant Awards consisting of stock appreciation rights ("*SARs*") entitling the holder, upon exercise, to receive an amount of Common Stock or cash or a combination thereof (such form to be determined by the Board) determined by reference to

appreciation, from and after the date of grant, in the fair market value of a share of Common Stock (valued in the manner determined by (or in the manner approved by) the Board) over the measurement price established pursuant to Section 6(b). The date as of which such appreciation is determined shall be the exercise date.

- (b) Measurement Price. The Board shall establish the measurement price of each SAR and specify it in the applicable SAR agreement. The measurement price shall not be less than 100% of the Grant Date Fair Market Value of the Common Stock on the date the SAR is granted; *provided* that if the Board approves the grant of an SAR effective as of a future date, the measurement price shall be not less than 100% of the Grant Date Fair Market Value on such future date.
- (c) <u>Duration of SARs</u>. Each SAR shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable SAR agreement; *provided*, *however*, that no SAR will be granted with a term in excess of 10 years.
- (d) <u>Exercise of SARs</u>. SARs may be exercised by delivery to the Company of a notice of exercise in a form (which may be electronic) approved by the Company, together with any other documents required by the Board.
- (e) <u>Limitation on Repricing</u>. Unless such action is approved by the Company's stockholders, the Company may not (except as provided for under Section 9): (1) amend any outstanding SAR granted under the Plan to provide a measurement price per share that is lower than the then-current measurement price per share of such outstanding SAR, (2) cancel any outstanding SAR (whether or not granted under the Plan) and grant in substitution therefor new Awards under the Plan (other than Awards granted pursuant to Section 4(b)) covering the same or a different number of shares of Common Stock and having an exercise or measurement price per share lower than the then-current measurement price per share of the cancelled SAR, (3) cancel in exchange for a cash payment any outstanding SAR with a measurement price per share above the then-current fair market value of the Common Stock (valued in the manner determined by (or in a manner approved by) the Board) or (4) take any other action under the Plan that constitutes a "repricing" within the meaning of the rules of the Exchange.

#### 7. Restricted Stock; Restricted Stock Units

(a) <u>General</u>. The Board may grant Awards entitling recipients to acquire shares of Common Stock ("*Restricted Stock*"), subject to the right of the Company to repurchase all or part of such shares at their issue price or other stated or formula price (or to require forfeiture of such shares if issued at no cost) from the recipient in the event that conditions specified by the Board in the applicable Award are not satisfied prior to the end of the applicable restriction period or periods established by the Board for such Award. The Board may also grant Awards entitling the recipient to receive shares of Common Stock or cash to be delivered as soon as practicable after the time such Award vests or is settled ("*Restricted Stock Units*") (Restricted Stock and Restricted Stock Units are each referred to herein as a "*Restricted Stock Award*").

(b) <u>Terms and Conditions for All Restricted Stock Awards</u>. The Board shall determine the terms and conditions of a Restricted Stock Award, including the conditions for vesting and repurchase (or forfeiture) and the issue price, if any.

### (c) Additional Provisions Relating to Restricted Stock.

- (1) <u>Dividends</u>. Unless otherwise provided in the applicable Award agreement, any dividends (whether paid in cash, stock or property) declared and paid by the Company with respect to shares of Restricted Stock ("*Accrued Dividends*") shall be paid to the Participant only if and when such shares become free from the restrictions on transferability and forfeitability that apply to such shares. Each payment of Accrued Dividends will be made no later than the end of the calendar year in which the dividends are paid to stockholders of that class of stock or, if later, the 15th day of the third month following the lapsing of the restrictions on transferability and the forfeitability provisions applicable to the underlying shares of Restricted Stock.
- (2) <u>Stock Certificates</u>. The Company may require that any stock certificates issued in respect of shares of Restricted Stock, as well as dividends or distributions paid on such Restricted Stock, shall be deposited in escrow by the Participant, together with a stock power endorsed in blank, with the Company (or its designee). At the expiration of the applicable restriction periods, the Company (or such designee) shall deliver the certificates no longer subject to such restrictions to the Participant or if the Participant has died, to his or her Designated Beneficiary. "*Designated Beneficiary*" means (i) the beneficiary designated, in a manner determined by the Board, by a Participant to receive amounts due or exercise rights of the Participant in the event of the Participant's death or (ii) in the absence of an effective designation by a Participant, the Participant's estate.

#### (d) Additional Provisions Relating to Restricted Stock Units.

- (1) <u>Settlement</u>. As soon as practicable after the vesting of and/or lapsing of any other restrictions (i.e., settlement) with respect to each Restricted Stock Unit, the Participant shall be entitled to receive from the Company such number of shares of Common Stock or (if so provided in the applicable Award agreement) an amount of cash equal to the fair market value (valued in the manner determined by (or in a manner approved by) the Board) of such number of shares of Common Stock as are set forth in the applicable Restricted Stock Unit agreement. The Board may provide that settlement of Restricted Stock Units shall be deferred, on a mandatory basis or at the election of the Participant in a manner that complies with Section 409A of the Code.
  - (2) Voting Rights. A Participant shall have no voting rights with respect to any Restricted Stock Units.
- (3) <u>Dividend Equivalents</u>. The Award agreement for Restricted Stock Units may provide Participants with the right to receive an amount equal to any dividends or other distributions declared and paid on an equal number of outstanding shares of Common Stock ("*Dividend Equivalents*"). Dividend Equivalents may be settled in cash and/or shares of Common Stock, as provided in the Award agreement, and shall be subject to the same restrictions on transfer and forfeitability as the Restricted Stock Units with respect to which paid.

#### 8. Other Stock-Based Awards

- (a) <u>General</u>. The Board may grant other Awards of shares of Common Stock, and other Awards that are valued in whole or in part by reference to, or are otherwise based on, shares of Common Stock or other property ("*Other Stock-Based Awards*"). Such Other Stock-Based Awards shall also be available as a form of payment in the settlement of other Awards granted under the Plan or as payment in lieu of compensation to which a Participant is otherwise entitled. Other Stock-Based Awards may be paid in shares of Common Stock or cash, as the Board shall determine.
- (b) <u>Terms and Conditions</u>. Subject to the provisions of the Plan, the Board shall determine the terms and conditions of each Other Stock-Based Award, including any purchase price applicable thereto.

#### 9. Adjustments for Changes in Common Stock and Certain Other Events

(a) Changes in Capitalization. In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of Common Stock other than an ordinary cash dividend, (i) the number and class of securities available under the Plan, (ii) the share counting rules set forth in Section 4(a), (iii) the number and class of securities and exercise price per share of each outstanding Option, (iv) the share and per-share provisions and the measurement price of each outstanding SAR, (v) the number of shares subject to and the repurchase price per share subject to each outstanding award of Restricted Stock and (vi) the share and per-share-related provisions and the purchase price, if any, of each outstanding Restricted Stock Unit award and each outstanding Other Stock-Based Award, shall be equitably adjusted by the Company (or substituted Awards may be made, if applicable) in the manner determined by the Board. Without limiting the generality of the foregoing, in the event the Company effects a split of the Common Stock by means of a stock dividend and the exercise price of and the number of shares subject to an outstanding Option are adjusted as of the date of the distribution of the dividend (rather than as of the record date for such dividend), then an optionee who exercises an Option between the record date and the distribution date for such stock dividend shall be entitled to receive, on the distribution date, the stock dividend with respect to the shares of Common Stock acquired upon such Option exercise, notwithstanding the fact that such shares were not outstanding as of the close of business on the record date for such stock dividend.

#### (b) Reorganization Events.

(1) <u>Definition</u>. A "*Reorganization Event*" shall mean: (a) any merger or consolidation of the Company with or into another entity as a result of which all of the Common Stock of the Company is converted into or exchanged for the right to receive cash, securities or other property or is cancelled, (b) any transfer or disposition of all of the Common Stock of the Company for cash, securities or other property pursuant to a share exchange or other transaction or (c) any liquidation or dissolution of the Company.

#### (2) Consequences of a Reorganization Event on Awards Other than Restricted Stock.

(A) In connection with a Reorganization Event, the Board may take any one or more of the following actions as to all or any (or any portion of) outstanding Awards other than Restricted Stock on such terms as the Board determines (except to the extent specifically provided otherwise in an applicable Award agreement or another agreement between the Company and the Participant): (i) provide that such Awards shall be assumed, or substantially equivalent Awards shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (ii) upon written notice to a Participant, provide that all of the Participant's unvested Awards will be forfeited immediately prior to the consummation of such Reorganization Event and/or unexercised Awards will terminate immediately prior to the consummation of such Reorganization Event unless exercised by the Participant (to the extent then exercisable) within a specified period following the date of such notice, (iii) provide that outstanding Awards shall become exercisable, realizable or deliverable, or restrictions applicable to an Award shall lapse, in whole or in part prior to or upon such Reorganization Event, (iv) in the event of a Reorganization Event under the terms of which holders of Common Stock will receive upon consummation thereof a cash payment for each share surrendered in the Reorganization Event (the "Acquisition Price"), make or provide for a cash payment to Participants with respect to each Award held by a Participant equal to (A) the number of shares of Common Stock subject to the vested portion of the Award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such Reorganization Event) multiplied by (B) the excess, if any, of (I) the Acquisition Price over (II) the exercise, measurement or purchase price of such Award and any applicable tax withholdings, in exchange for the termination of such Award, (v) provide that, in connection with a liquidation or dissolution of the Company, Awards shall convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings) and (vi) any combination of the foregoing. In taking any of the actions permitted under this Section 9(b)(2), the Board shall not be obligated by the Plan to treat all Awards, all Awards held by a Participant, or all Awards of the same type, identically.

(B) Notwithstanding the terms of Section 9(b)(2)(A), in the case of outstanding Restricted Stock Units that are subject to Section 409A of the Code: (i) if the applicable Restricted Stock Unit agreement provides that the Restricted Stock Units shall be settled upon a "change in control event" within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(i), and the Reorganization Event constitutes such a "change in control event", then no assumption or substitution shall be permitted pursuant to Section 9(b)(2)(A)(i) and the Restricted Stock Units shall instead be settled in accordance with the terms of the applicable Restricted Stock Unit agreement; and (ii) the Board may only undertake the actions set forth in clauses (iii), (iv) or (v) of Section 9(b)(2)(A) if the Reorganization Event constitutes a "change in control event" as defined under Treasury Regulation Section 1.409A-3(i)(5)(i) and such action is permitted or required by Section 409A of the Code; if the Reorganization Event is not a "change in control event" as so defined or such action is not permitted or required by Section 409A of the Code, and the acquiring or succeeding corporation does not assume or substitute the Restricted

Stock Units pursuant to clause (i) of Section 9(b)(2)(A), then the unvested Restricted Stock Units shall terminate immediately prior to the consummation of the Reorganization Event without any payment in exchange therefor.

- (C) For purposes of Section 9(b)(2)(A)(i), an Award (other than Restricted Stock) shall be considered assumed if, following consummation of the Reorganization Event, such Award confers the right to purchase or receive pursuant to the terms of such Award, for each share of Common Stock subject to the Award immediately prior to the consummation of the Reorganization Event, the consideration (whether cash, securities or other property) received as a result of the Reorganization Event by holders of Common Stock for each share of Common Stock held immediately prior to the consummation of the Reorganization Event (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding shares of Common Stock); *provided, however*, that if the consideration received as a result of the Reorganization Event is not solely common stock of the acquiring or succeeding corporation (or an affiliate thereof), the Company may, with the consent of the acquiring or succeeding corporation, provide for the consideration to be received upon the exercise or settlement of the Award to consist solely of such number of shares of common stock of the acquiring or succeeding corporation (or an affiliate thereof) that the Board determines to be equivalent in value (as of the date of such determination or another date specified by the Board) to the per share consideration received by holders of outstanding shares of Common Stock as a result of the Reorganization Event.
- (3) <u>Consequences of a Reorganization Event on Restricted Stock</u>. Upon the occurrence of a Reorganization Event other than a liquidation or dissolution of the Company, the repurchase and other rights of the Company with respect to outstanding Restricted Stock shall inure to the benefit of the Company's successor and shall, unless the Board determines otherwise, apply to the cash, securities or other property which the Common Stock was converted into or exchanged for pursuant to such Reorganization Event in the same manner and to the same extent as they applied to such Restricted Stock; provided, however, that the Board may provide for termination or deemed satisfaction of such repurchase or other rights under the instrument evidencing any Restricted Stock or any other agreement between a Participant and the Company, either initially or by amendment. Upon the occurrence of a Reorganization Event involving the liquidation or dissolution of the Company, except to the extent specifically provided to the contrary in the instrument evidencing any Restricted Stock or any other agreement between a Participant and the Company, all restrictions and conditions on all Restricted Stock then outstanding shall automatically be deemed terminated or satisfied.

#### 10. General Provisions Applicable to Awards

(a) <u>Transferability of Awards</u>. Awards shall not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution or, other than in the case of an Incentive Stock Option, pursuant to a qualified domestic relations order, and, during the life of the Participant, shall be exercisable only by the Participant; *provided*, *however*, that, except with respect to Awards subject to Section 409A of the Code, the Board may permit or provide in an Award for the gratuitous transfer of the Award by the Participant to or for the benefit of any immediate family member, family trust or other entity established for the benefit of the

Participant and/or an immediate family member thereof if the Company would be eligible to use a Form S-8 under the Securities Act for the registration of the sale of the Common Stock subject to such Award to such proposed transferee; *provided further*, that the Company shall not be required to recognize any such permitted transfer until such time as such permitted transferee shall, as a condition to such transfer, deliver to the Company a written instrument in form and substance satisfactory to the Company confirming that such transferee shall be bound by all of the terms and conditions of the Award. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees. For the avoidance of doubt, nothing contained in this Section 10(a) shall be deemed to restrict a transfer to the Company.

- (b) <u>Documentation</u>. Each Award shall be evidenced in such form (written, electronic or otherwise) as the Board shall determine. Each Award may contain terms and conditions in addition to those set forth in the Plan.
- (c) <u>Board Discretion</u>. Except as otherwise provided by the Plan, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award need not be identical, and the Board need not treat Participants uniformly.
- (d) <u>Termination of Status</u>. The Board shall determine the effect on an Award of the disability, death, termination or other cessation of employment, authorized leave of absence or other change in the employment or other status of a Participant and the extent to which, and the period during which, the Participant, or the Participant's legal representative, conservator, guardian or Designated Beneficiary, may exercise rights under the Award.
- (e) Withholding. The Participant must satisfy all applicable federal, state, and local or other income and employment tax withholding obligations before the Company will deliver stock certificates or otherwise recognize ownership of Common Stock under an Award. The Company may elect to satisfy the withholding obligations through additional withholding on salary or wages. If the Company elects not to or cannot withhold from other compensation, the Participant must pay the Company the full amount, if any, required for withholding or have a broker tender to the Company cash equal to the withholding obligations. Payment of withholding obligations is due before the Company will issue any shares on exercise, vesting or release from forfeiture of an Award or at the same time as payment of the exercise or purchase price, unless the Company determines otherwise. If provided for in an Award or approved by the Board, a Participant may satisfy the tax obligations in whole or in part by delivery (either by actual delivery or attestation) of shares of Common Stock, including shares retained from the Award creating the tax obligation, valued at their fair market value (valued in the manner determined by (or in a manner approved by) the Company); provided, however, except as otherwise provided by the Board, that the total tax withholding where stock is being used to satisfy such tax obligations cannot exceed the Company's minimum statutory withholding obligations (based on minimum statutory withholding rates for federal, state and local tax purposes, including payroll taxes, that are applicable to such supplemental taxable income), except that, to the extent that the Company is able to retain shares of Common Stock having a fair market value (determined by, or in a manner approved by, the Company) that exceeds the statutory minimum applicable withholding tax, the Company may retain such number of shares of Common Stock (up to the number of

shares having a fair market value equal to the maximum individual statutory rate of tax (determined by, or in a manner approved by, the Company)) as the Company shall determine in its sole discretion to satisfy the tax liability associated with any Award. Shares used to satisfy tax withholding requirements cannot be subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements.

- (f) Amendment of Award. Except as otherwise provided in Sections 5(g) and 6(e) with respect to repricings and Section 11(d) with respect to actions requiring stockholder approval, the Board may amend, modify or terminate any outstanding Award, including but not limited to, substituting therefor another Award of the same or a different type, changing the date of exercise or realization, and converting an Incentive Stock Option to a Nonstatutory Stock Option. The Participant's consent to such action shall be required unless (i) the Board determines that the action, taking into account any related action, does not materially and adversely affect the Participant's rights under the Plan or (ii) the change is permitted under Section 9.
- (g) <u>Conditions on Delivery of Stock</u>. The Company will not be obligated to deliver any shares of Common Stock pursuant to the Plan or to remove restrictions from shares previously issued or delivered under the Plan until (i) all conditions of the Award have been met or removed to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including any applicable securities laws and regulations and any applicable stock exchange or stock market rules and regulations and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Company may consider appropriate to satisfy the requirements of any applicable laws, rules or regulations.
- (h) <u>Acceleration</u>. The Board may at any time provide that any Award shall become immediately exercisable in whole or in part, free from some or all restrictions or conditions, or otherwise realizable in whole or in part, as the case may be.

#### 11. Miscellaneous

- (a) No Right To Employment or Other Status. No person shall have any claim or right to be granted an Award by virtue of the adoption of the Plan, and the grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan, except as expressly provided in the applicable Award.
- (b) No Rights As Stockholder; Clawback Policy. Subject to the provisions of the applicable Award, no Participant or Designated Beneficiary shall have any rights as a stockholder with respect to any shares of Common Stock to be issued with respect to an Award until becoming the record holder of such shares. In accepting an Award under the Plan, a Participant agrees to be bound by any clawback policy the Company has in effect or may adopt in the future.

- (c) <u>Effective Date and Term of Plan</u>. The Plan shall become effective immediately prior to the effectiveness of the Company's registration statement for the Company's initial public offering (the "*Effective Date*"). No Awards shall be granted under the Plan after the expiration of 10 years from the Effective Date, but Awards previously granted may extend beyond that date.
- (d) Amendment of Plan. The Board may amend, suspend or terminate the Plan or any portion thereof at any time provided that no amendment that would require stockholder approval under the rules of the Exchange may be made effective unless and until the Company's stockholders approve such amendment. In addition, if at any time the approval of the Company's stockholders is required as to any other modification or amendment under Section 422 of the Code or any successor provision with respect to Incentive Stock Options, the Board may not effect such modification or amendment without such approval. Unless otherwise specified in the amendment, any amendment to the Plan adopted in accordance with this Section 11(d) shall apply to, and be binding on the holders of, all Awards outstanding under the Plan at the time the amendment is adopted, provided the Board determines that such amendment, taking into account any related action, does not materially and adversely affect the rights of Participants under the Plan. No Award shall be made that is conditioned upon stockholder approval of any amendment to the Plan unless the Award provides that (i) it will terminate or be forfeited if stockholder approval of such amendment is not obtained within no more than 12 months from the date of grant and (ii) it may not be exercised or settled (or otherwise result in the issuance of Common Stock) prior to such stockholder approval.
- (e) <u>Authorization of Sub-Plans (including for Grants to non-U.S. Employees)</u>. The Board may from time to time establish one or more sub-plans under the Plan for purposes of satisfying applicable securities, tax or other laws of various jurisdictions. The Board shall establish such sub-plans by adopting supplements to the Plan containing (i) such limitations on the Board's discretion under the Plan as the Board deems necessary or desirable or (ii) such additional terms and conditions not otherwise inconsistent with the Plan as the Board shall deem necessary or desirable. All supplements adopted by the Board shall be deemed to be part of the Plan, but each supplement shall apply only to Participants within the affected jurisdiction and the Company shall not be required to provide copies of any supplement to Participants in any jurisdiction which is not the subject of such supplement.
- (f) Compliance with Section 409A of the Code. If and to the extent (i) any portion of any payment, compensation or other benefit provided to a Participant pursuant to the Plan in connection with his or her employment termination constitutes "nonqualified deferred compensation" within the meaning of Section 409A of the Code and (ii) the Participant is a specified employee as defined in Section 409A(a)(2)(B)(i) of the Code, in each case as determined by the Company in accordance with its procedures, by which determinations the Participant (through accepting the Award) agrees that he or she is bound, such portion of the payment, compensation or other benefit shall not be paid before the day that is six months plus one day after the date of "separation from service" (as determined under Section 409A of the Code) (the "New Payment Date"), except as Section 409A of the Code may then permit. The aggregate of any payments that otherwise would have been paid to the Participant during the period between the date of separation from service and the New Payment Date shall be paid to the Participant in a lump sum on such New Payment Date, and any remaining payments will be paid on their original schedule.

The Company makes no representations or warranty and shall have no liability to the Participant or any other person if any provisions of or payments, compensation or other benefits under the Plan are determined to constitute nonqualified deferred compensation subject to Section 409A of the Code but do not to satisfy the conditions of that section.

- (g) <u>Limitations on Liability</u>. Notwithstanding any other provisions of the Plan, no individual acting as a director, officer, employee or agent of the Company will be liable to any Participant, former Participant, spouse, beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the Plan, nor will such individual be personally liable with respect to the Plan because of any contract or other instrument he or she executes in his or her capacity as a director, officer, employee or agent of the Company. The Company will indemnify and hold harmless each director, officer, employee or agent of the Company to whom any duty or power relating to the administration or interpretation of the Plan has been or will be delegated, against any cost or expense (including attorneys' fees) or liability (including any sum paid in settlement of a claim with the Board's approval) arising out of any act or omission to act concerning the Plan unless arising out of such person's own fraud or bad faith.
- (h) <u>Governing Law</u>. The provisions of the Plan and all Awards made hereunder shall be governed by and interpreted in accordance with the laws of the State of Delaware, excluding choice-of-law principles of the law of such state that would require the application of the laws of a jurisdiction other than the State of Delaware.

## Inozyme Pharma, Inc. STOCK OPTION AGREEMENT

Inozyme Pharma, Inc. (the "Company") hereby grants the following stock option pursuant to its 2020 Stock Incentive Plan. The terms and conditions attached hereto are also a part hereof.

Notice of Grant	
Name of optionee (the " <u>Participant</u> "):	
Grant Date:	
Incentive Stock Option or Nonstatutory Stock Option: Number of shares of the Company's Common Stock subject to this option	
("Shares"):	
Option exercise price per Share: <sup>1</sup>	
Number, if any, of Shares that vest immediately on the grant date:	
Shares that are subject to vesting schedule:	
Vesting Start Date:	
Final Exercise Date: 2	
Vesting Schedule:	
Vesting Date:	Number of Options that Vest:
All vesting is dependent on the Participant remaining an Eligible Participant,	as provided herein.
This option satisfies in full all commitments that the Company has to the equity securities.	e Participant with respect to the issuance of stock, stock options or other
Inoz	zyme Pharma, Inc.
Signature of Participant	
Dru	

1 This must be at least 100% of the Grant Date Fair Market Value (as defined in the Plan) of the Common Stock on the date of grant (110% in the case of a Participant that owns more than 10% of the total combined voting power of all classes of stock of the Company or its parent or subsidiary (a "10% Shareholder")) for the option to qualify as an incentive stock option (an "ISO") under Section 422 of the Internal Revenue Code.

Name of Officer

Title:

Street Address

City/State/Zip Code

<sup>2</sup> The Final Exercise Date must be no more than 10 years (5 years in the case of a 10% Shareholder) from the date of grant for the option to qualify as an ISO. The correct approach to calculate the final exercise date is to use the day immediately prior to the date ten years out from the date of the stock option award grant (5 years in the case of a 10% stockholder).

#### Inozyme Pharma, Inc.

#### Stock Option Agreement Incorporated Terms and Conditions

### 1. Grant of Option.

This agreement evidences the grant by the Company, on the grant date (the "<u>Grant Date</u>") set forth in the Notice of Grant that forms part of this agreement (the "<u>Notice of Grant</u>"), to the Participant of an option to purchase, in whole or in part, on the terms provided herein and in the Company's 2020 Stock Incentive Plan (the "<u>Plan</u>"), the number of Shares set forth in the Notice of Grant of common stock, \$0.0001 par value per share, of the Company ("<u>Common Stock</u>"), at the exercise price per Share set forth in the Notice of Grant. Unless earlier terminated, this option shall expire at 5:00 p.m., Eastern time, on the Final Exercise Date set forth in the Notice of Grant (the "<u>Final Exercise Date</u>").

The option evidenced by this agreement is intended to be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "<u>Code</u>") to the maximum extent permitted by law, solely to the extent designated as an incentive stock option in the Notice of Grant. Except as otherwise indicated by the context, the term "<u>Participant</u>", as used in this option, shall be deemed to include any person who acquires the right to exercise this option validly under its terms.

#### 2. Vesting Schedule.

This option will become exercisable ("vest") in accordance with the vesting schedule set forth in the Notice of Grant.

The right of exercise shall be cumulative so that to the extent the option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Final Exercise Date or the termination of this option under Section 3 hereof or the Plan.

#### 3. Exercise of Option.

- (a) <u>Form of Exercise</u>. Each election to exercise this option shall be in writing, in the form of the Stock Option Exercise Notice attached as <u>Annex A</u>, signed by the Participant, and received by the Company at its principal office, accompanied by this agreement, or in such other form (which may be electronic) as is approved by the Company, together with payment in full in the manner provided in the Plan. The Participant may purchase less than the number of shares covered hereby, provided that no partial exercise of this option may be for any fractional share.
- (b) <u>Continuous Relationship with the Company Required</u>. Except as otherwise provided in this Section 3, this option may not be exercised unless the Participant, at the time he or she exercises this option, is, and has been at all times since the Grant Date, an employee, director or officer of, or consultant or advisor to, the Company or any other entity the employees, officers, directors, consultants, or advisors of which are eligible to receive option grants under the Plan (an "<u>Eligible Participant</u>").

- (c) <u>Termination of Relationship with the Company</u>. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in paragraphs (d) and (e) below, the right to exercise this option shall terminate three months after such cessation (but in no event after the Final Exercise Date), <u>provided that</u> this option shall be exercisable only to the extent that the Participant was entitled to exercise this option on the date of such cessation. Notwithstanding the foregoing, if the Participant, prior to the Final Exercise Date, violates the restrictive covenants (including, without limitation, the non-competition, non-solicitation, or confidentiality provisions) of any employment contract, any non-competition, non-solicitation, confidentiality or assignment agreement to which the Participant is a party, or any other agreement between the Participant and the Company, the right to exercise this option shall terminate immediately upon such violation.
- (d) Exercise Period Upon Death or Disability. If the Participant dies or becomes disabled (within the meaning of Section 22(e)(3) of the Code) prior to the Final Exercise Date while he or she is an Eligible Participant and the Company has not terminated such relationship for "cause" as specified in paragraph (e) below, this option shall be exercisable, within the period of one year following the date of death or disability of the Participant, by the Participant (or in the case of death by an authorized transferee), provided that this option shall be exercisable only to the extent that this option was exercisable by the Participant on the date of his or her death or disability, and further provided that this option shall not be exercisable after the Final Exercise Date.
- (e) Termination for Cause. If, prior to the Final Exercise Date, the Participant's employment or other service is terminated by the Company for Cause (as defined in below), the right to exercise this option shall terminate immediately upon the effective date of such termination of service. If, prior to the Final Exercise Date, the Participant is given notice by the Company of the termination of his or her employment or other service by the Company for Cause, and the effective date of such termination is subsequent to the date of delivery of such notice, the right to exercise this option shall be suspended from the time of the delivery of such notice until the earlier of (i) such time as it is determined or otherwise agreed that the Participant's service shall not be terminated for Cause as provided in such notice or (ii) the effective date of such termination of service (in which case the right to exercise this option shall, pursuant to the preceding sentence, terminate upon the effective date of such termination of employment). If the Participant is subject to an individual employment, consulting or other service agreement with the Company or eligible to participate in a Company severance plan or arrangement, in any case which agreement, plan or arrangement contains a definition of "cause" for termination of service, "Cause" shall have the meaning ascribed to such term in such agreement, plan or arrangement. Otherwise, "Cause" shall mean willful misconduct by the Participant or willful failure by the Participant to perform his or her responsibilities to the Company (including, without limitation, breach by the Participant of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Participant and the Company), as determined by the Company, which determination shall be conclusive. The Participant's employment or other service shall be considered to have been terminated for Cause if the Company determines, within 30 days after the Participant's

#### 4. <u>Tax Matters</u>.

- (a) <u>Withholding</u>. No Shares will be issued pursuant to the exercise of this option unless and until the Participant pays to the Company, or makes provision satisfactory to the Company for payment of, any federal, state or local withholding taxes required by law to be withheld in respect of this option.
- (b) <u>Disqualifying Disposition</u>. If this option is an incentive stock option and the Participant disposes of Shares acquired upon exercise of this option within two years from the Grant Date or one year after such Shares were acquired pursuant to exercise of this option, the Participant shall notify the Company in writing of such disposition.

### 5. <u>Transfer Restrictions; Clawback.</u>

- (a) This option may not be sold, assigned, transferred, pledged, encumbered or otherwise disposed of by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, this option shall be exercisable only by the Participant.
  - (b) In accepting this option, the Participant agrees to be bound by any clawback policy that the Company has in place or may adopt in the future.

#### 6. Provisions of the Plan.

This option is subject to the provisions of the Plan (including the provisions relating to amendments to the Plan), a copy of which is furnished to the Participant with this option.

## ANNEX A

Inozyme Pharma, Inc.

## Stock Option Exercise Notice

Inozyme Pharma, Inc. 321 Summer Street Suite 400 Boston, MA 02210

Dear Sir or Madam:
I, (the " <u>Participant</u> "), hereby irrevocably exercise the right to purchase shares of the Common Stock, \$0.0001 par value per share (the " <u>Shares</u> "), of Inozyme Pharma, Inc. (the " <u>Company</u> ") at \$ per share pursuant to the Company's 2020 Stock Incentive Plan and a stock option agreement with the Company dated (the " <u>Option Agreement</u> "). Enclosed herewith is a payment of \$ , the aggregate purchase price for the Shares. The certificate for the Shares should be registered in my name as it appears below or, if so indicated below, jointly in my name and the name of the person designated below, with right of survivorship.
Dated:
Signature Print Name:
Address:
Name and address of persons in whose name the Shares are to be jointly registered (if applicable):

# Inozyme Pharma, Inc. RESTRICTED STOCK UNIT AGREEMENT

Inozyme Pharma, Inc. (the "Company") hereby grants the following restricted stock units pursuant to its 2020 Stock Incentive Plan. The terms and conditions attached hereto are also a part hereof.

	Notice of Grant
Name of recipient (the " <u>Participant</u> "): Grant Date: Number of restricted stock units (" <u>RSUs</u> ") granted: Vesting Start Date:	
Vesting Schedule:	
Vesting Date:	Number of RSUs that Vest:
All vesting is dependent on the Participant remaining an Eligible	Participant, as provided herein.
This grant of RSUs satisfies in full all commitments that the other equity securities.	e Company has to the Participant with respect to the issuance of stock, stock options or
	Inozyme Pharma, Inc.
Signature of Participant	By:
Street Address	Name of Officer Title:
City/State/Zip Code	

Inozyme Pharma, Inc.

## Restricted Stock Unit Agreement Incorporated Terms and Conditions

For valuable consideration, receipt of which is acknowledged, the parties hereto agree as follows:

#### 1. Award of Restricted Stock Units.

In consideration of services rendered and to be rendered to the Company, by the Participant, the Company has granted to the Participant, subject to the terms and conditions set forth in this Restricted Stock Unit Agreement (this "Agreement") and in the Company's 2020 Stock Incentive Plan (the "Plan"), an award with respect to the number of restricted stock units (the "RSUs") set forth in the Notice of Grant that forms part of this Agreement (the "Notice of Grant"). Each RSU represents the right to receive one share of common stock, \$0.0001 par value per share, of the Company (the "Common Stock") upon vesting of the RSU, subject to the terms and conditions set forth herein.

### 2. <u>Vesting</u>.

The RSUs shall vest in accordance with the Vesting Schedule set forth in the Notice of Grant (the "<u>Vesting Schedule</u>"). Any fractional shares resulting from the application of any percentages used in the Vesting Schedule shall be rounded down to the nearest whole number of RSUs. Upon the vesting of the RSU, the Company will deliver to the Participant, for each RSU that becomes vested, one share of Common Stock, subject to the payment of any taxes pursuant to Section 7. The Common Stock will be delivered to the Participant as soon as practicable following each vesting date, but in any event within 30 days of such date.

#### 3. <u>Forfeiture of Unvested RSUs Upon Cessation of Service</u>.

In the event that the Participant ceases to be an employee, director or officer of, or consultant or advisor to, the Company or any other entity the employees, officers, directors, consultants, or advisors of which are eligible to receive awards under the Plan (an "Eligible Participant") for any reason or no reason, with or without cause, all of the RSUs that are unvested as of the time of such cessation shall be forfeited immediately and automatically to the Company, without the payment of any consideration to the Participant, effective as of such cessation. The Participant shall have no further rights with respect to the unvested RSUs or any Common Stock that may have been issuable with respect thereto. If the Participant provides services to a subsidiary of the Company, any references in this Agreement to provision of services to the Company shall instead be deemed to refer to service with such subsidiary.

#### 4. Restrictions on Transfer.

The Participant shall not sell, assign, transfer, pledge, hypothecate, encumber or otherwise dispose of, by operation of law or otherwise (collectively "transfer") any RSUs, or any interest therein. The Company shall not be required to treat as the owner of any RSUs or issue any Common Stock to any transferree to whom such RSUs have been transferred in violation of any of the provisions of this Agreement.

#### Rights as a Stockholder.

The Participant shall have no rights as a stockholder of the Company with respect to any shares of Common Stock that may be issuable with respect to the RSUs until the issuance of the shares of Common Stock to the Participant following the vesting of the RSUs.

#### 6. <u>Provisions of the Plan.</u>

This Agreement is subject to the provisions of the Plan, a copy of which is furnished to the Participant with this Agreement.

#### 7. <u>Tax Matters</u>.

- (a) Acknowledgments; No Section 83(b) Election. The Participant acknowledges that he or she is responsible for obtaining the advice of the Participant's own tax advisors with respect to the award of RSUs and the Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents with respect to the tax consequences relating to the RSUs. The Participant understands that the Participant (and not the Company) shall be responsible for the Participant's tax liability that may arise in connection with the acquisition, vesting and/or disposition of the RSUs. The Participant acknowledges that no election under Section 83(b) of the Internal Revenue Code of 1986, as amended (the "Code"), is available with respect to RSUs.
- (b) Withholding. The Participant acknowledges and agrees that the Company has the right to deduct from payments of any kind otherwise due to the Participant any federal, state, local or other taxes of any kind required by law to be withheld with respect to the vesting of the RSUs. At such time as the Participant is not aware of any material nonpublic information about the Company or the Common Stock and is not prohibited from doing so by the Company's insider trading policy or otherwise, the Participant shall execute the instructions set forth in Schedule A attached hereto (the "Automatic Sale Instructions") as the means of satisfying such tax obligation. If the Participant does not execute the Automatic Sale Instructions prior to an applicable vesting date, then the Participant agrees that if under applicable law the Participant will owe taxes at such vesting date on the portion of the award then vested the Company shall be entitled to immediate payment from the Participant of the amount of any tax required to be withheld by the Company. The Company shall not deliver any shares of Common Stock to the Participant until it is satisfied that all required withholdings have been made.

#### 8. <u>Miscellaneous</u>.

(a) <u>No Right to Continued Service</u>. The Participant acknowledges and agrees that, notwithstanding the fact that the vesting of the RSUs is contingent upon his or her continued service to the Company, this Agreement does not constitute an express or implied promise of continued service relationship with the Participant or confer upon the Participant any rights with respect to a continued service relationship with the Company or any affiliate of the Company.

- (b) <u>Section 409A</u>. The RSUs awarded pursuant to this Agreement are intended to be exempt from or comply with the requirements of Section 409A of the Code and the Treasury Regulations issued thereunder ("<u>Section 409A</u>"). The delivery of shares of Common Stock on the vesting of the RSUs may not be accelerated or deferred unless permitted or required by Section 409A.
- (c) <u>Participant's Acknowledgments</u>. The Participant acknowledges that he or she: (i) has read this Agreement; (ii) has been represented in the preparation, negotiation and execution of this Agreement by legal counsel of the Participant's own choice or has voluntarily declined to seek such counsel; (iii) understands the terms and consequences of this Agreement; (iv) is agreeing, in accepting this award, to be bound by any clawback policy that the Company has in place or may adopt in the future; and (iv) is fully aware of the legal and binding effect of this Agreement.
- (d) <u>Governing Law</u>. This Agreement shall be construed, interpreted and enforced in accordance with the internal laws of the State of Delaware without regard to any applicable conflicts of laws provisions.

#### Schedule A

#### **Automatic Sale Instructions**

The undersigned hereby consents and agrees that any taxes due on a vesting date as a result of the vesting of RSUs on such date shall be paid through an automatic sale of shares as follows:

- (a) Upon any vesting of RSUs pursuant to Section 2 hereof, the Company shall arrange for the sale of such number of shares of Common Stock issuable with respect to the RSUs that vest pursuant to Section 2 as is sufficient to generate net proceeds sufficient to satisfy the Company's minimum statutory withholding obligations with respect to the income recognized by the Participant upon the vesting of the RSUs (based on minimum statutory withholding rates for all tax purposes, including payroll and social security taxes, that are applicable to such income), and the net proceeds of such sale shall be delivered to the Company in satisfaction of such tax withholding obligations.
- (b) The Participant hereby appoints the Chief Executive Officer, the Chief Operating Officer and the Principal Financial Officer, and any of them acting alone and with full power of substitution, to serve as his or her attorneys in fact to arrange for the sale of the Participant's Common Stock in accordance with this Schedule A. The Participant agrees to execute and deliver such documents, instruments and certificates as may reasonably be required in connection with the sale of the shares pursuant to this Schedule A.
- (c) The Participant represents to the Company that, as of the date hereof, he or she is not aware of any material nonpublic information about the Company or the Common Stock and is not prohibited from entering into these Automatic Sale Instructions by the Company's insider trading policy or otherwise. The Participant and the Company have structured this Agreement, including this Schedule A, to constitute a "binding contract" relating to the sale of Common Stock, consistent with the affirmative defense to liability under Section 10(b) of the Securities Exchange Act of 1934 under Rule 10b5-1(c) promulgated under such Act.

The Company shall not deliver any shares of Common Stock to the Participant until it is satisfied that all required withholdings have been made.

Participant Name:
Date:

#### Inozyme Pharma, Inc.

## 2020 EMPLOYEE STOCK PURCHASE PLAN

The purpose of this 2020 Employee Stock Purchase Plan (this "Plan") is to provide eligible employees of Inozyme Pharma, Inc., (the "Company") and certain of its subsidiaries with opportunities to purchase shares of the Company's common stock, \$0.0001 par value per share (the "Common Stock"), commencing at such time and on such dates as the Board of Directors of the Company (the "Board") shall determine. Subject to adjustment under Section 15 hereof, the number of shares of Common Stock that have been approved for this purpose is the sum of:

- (a) 198,539 shares of Common Stock; plus
- (b) an annual increase to be added on the first day of each fiscal year, commencing on January 1, 2021 and continuing for each fiscal year until, and including, January 1, 2031, equal to the least of (i) 397,079 shares of Common Stock, (ii) 1% of the outstanding shares on the first day of such fiscal year and (iii) an amount determined by the Board.

This Plan is intended to qualify as an "employee stock purchase plan" as defined in Section 423 of the Internal Revenue Code of 1986, as amended (the "Code"), and the regulations issued thereunder, and shall be interpreted consistent therewith.

- 1. <u>Administration</u>. The Plan will be administered by the Board or by a committee appointed by the Board (the "Committee"). The Board or the Committee has authority to make rules and regulations for the administration of the Plan and its interpretation and decisions with regard thereto shall be final and conclusive.
- 2. <u>Eligibility</u>. All employees of the Company and all employees of any subsidiary of the Company (as defined in Section 424(f) of the Code) designated by the Board or the Committee from time to time (a "Designated Subsidiary"), are eligible to participate in any one or more of the offerings of Options (as defined in Section 9) to purchase Common Stock under the Plan provided that:
  - (a) they are customarily employed by the Company or a Designated Subsidiary for more than 20 hours a week and for more than five months in a calendar year;
  - (b) they have been employed by the Company or a Designated Subsidiary for at least three months prior to enrolling in the Plan; and
  - (c) they are employees of the Company or a Designated Subsidiary on the first day of the applicable Plan Period (as defined below).

No employee may be granted an Option hereunder if such employee, immediately after the Option is granted, owns 5% or more of the total combined voting power or value of the stock

of the Company or any subsidiary. For purposes of the preceding sentence, the attribution rules of Section 424(d) of the Code shall apply in determining the stock ownership of an employee, and all stock that the employee has a contractual right to purchase shall be treated as stock owned by the employee.

The Company retains the discretion to determine which eligible employees may participate in an offering pursuant to and consistent with Treasury Regulation Sections 1.423-2(e) and (f).

- 3. Offerings. The Company will make one or more offerings ("Offerings") to employees to purchase stock under this Plan. Offerings will begin at such time and on such dates as the Board shall determine, or the first business day thereafter (such dates, the "Offering Commencement Dates"). Each Offering Commencement Date will begin a six-month period (a "Plan Period") during which payroll deductions will be made and held for the purchase of Common Stock at the end of the Plan Period. However, the Board or the Committee may, at its discretion, choose a different Plan Period of not more than twelve (12) months for Offerings.
- 4. Participation. An employee eligible on the Offering Commencement Date of any Offering may participate in such Offering by completing and forwarding either a written or electronic payroll deduction authorization form to the employee's appropriate payroll office at least 15 days (or such other number of days as is determined by the Company) prior to the applicable Offering Commencement Date. The form will authorize a regular payroll deduction from the Compensation received by the employee during the Plan Period. Unless an employee files a new form or withdraws from the Plan, his or her deductions and purchases will continue at the same rate for future Offerings under the Plan as long as the Plan remains in effect. The term "Compensation" means the amount of money reportable on the employee's Federal Income Tax Withholding Statement (or analogous non-U.S. statement), excluding overtime, shift premium, incentive or bonus awards, allowances and reimbursements for expenses such as relocation allowances for travel expenses, income or gains associated with the grant or vesting of restricted stock, income or gains on the exercise of Company stock options or stock appreciation rights, and similar items, whether or not shown or separately identified on the employee's Federal Income Tax Withholding Statement (or analogous non-U.S. statement), but including, in the case of salespersons, sales commissions to the extent determined by the Board or the Committee.
- 5. <u>Deductions</u>. The Company will maintain payroll deduction accounts for all participating employees. With respect to any Offering made under this Plan, an employee may authorize a payroll deduction in any percentage amount (in whole percentages) up to a maximum of 15% of the Compensation he or she receives during the Plan Period or such shorter period during which deductions from payroll are made. The Board or the Committee may, at its discretion, designate a lower maximum contribution rate. The minimum payroll deduction is such percentage of Compensation as may be established from time to time by the Board or the Committee.
- 6. <u>Deduction Changes</u>. An employee may decrease or discontinue his or her payroll deduction once during any Plan Period, by filing either a written or electronic new payroll deduction authorization form, as determined by the Company. However, an employee may not increase his or her payroll deduction during a Plan Period. If an employee elects to discontinue

his or her payroll deductions during a Plan Period, but does not elect to withdraw his or her funds pursuant to Section 8 hereof, funds deducted prior to his or her election to discontinue will be applied to the purchase of Common Stock on the Exercise Date (as defined below).

- 7. <u>Interest</u>. Interest will not be paid on any employee accounts, except to the extent that the Board or the Committee, in its sole discretion, elects to credit employee accounts with interest at such rate as it may from time to time determine.
- 8. Withdrawal of Funds. An employee may at any time prior to the close of business on the fifteenth business day prior to the end of a Plan Period (or such other number of days as is determined by the Company) and for any reason permanently draw out the balance accumulated in the employee's account and thereby withdraw from participation in an Offering. Partial withdrawals are not permitted. The employee may not begin participation again during the remainder of the Plan Period during which the employee withdrew his or her balance. The employee may participate in any subsequent Offering in accordance with terms and conditions established by the Board or the Committee.

#### 9. Purchase of Shares.

- (a) Number of Shares. On the Offering Commencement Date for the applicable Plan Period, the Company will grant to each eligible employee who is then a participant in the Plan an option (an "Option") to purchase on the last business day of such Plan Period (the "Exercise Date") at the applicable purchase price (the "Option Price") up to that whole number of shares of Common Stock determined by multiplying \$2,083 by the number of full months in the Plan Period and dividing the result by the closing price (as determined below) on the Offering Commencement Date; provided, however, that no employee may be granted an Option which permits his or her rights to purchase Common Stock under this Plan and any other employee stock purchase plan (as defined in Section 423(b) of the Code) of the Company and its subsidiaries, to accrue at a rate which exceeds \$25,000 of the fair market value of such Common Stock (determined at the date such Option is granted) for each calendar year in which the Option is outstanding at any time; and, provided, further, however, that the Committee may, in its discretion, set a fixed maximum number of shares of Common Stock that each eligible employee may purchase per Plan Period which number may not be greater than the number of shares of Common Stock determined by using the formula in the first clause of this Section 9(a) and which number shall be subject to the second clause of this Section 9(a).
- (b) Option Price. The Board or the Committee shall determine the Option Price for each Plan Period, including whether such Option Price shall be determined based on the lesser of the closing price of the Common Stock on (i) the first business day of the Plan Period or (ii) the Exercise Date, or shall be based solely on the closing price of the Common Stock on the Exercise Date; provided, however, that such Option Price shall be at least 85% of the applicable closing price. In the absence of a determination by the Board or the Committee, the Option Price will be 85% of the lesser of the closing price of the Common Stock on (i) the first business day of the Plan Period or (ii) the Exercise Date. The closing price shall be (a) the closing price (for the primary trading session) on any national securities exchange on which the Common Stock is listed or (b) the average of the closing bid and asked prices in the over-the-counter-market, whichever is applicable, as published in The Wall Street Journal or another source selected by the Board or the Committee. If no sales of Common Stock were made on such a day, the price of the Common Stock shall be the reported price for the next preceding day on which sales were made.

- (c) Exercise of Option. Each employee who continues to be a participant in the Plan on the Exercise Date shall be deemed to have exercised his or her Option at the Option Price on such date and shall be deemed to have purchased from the Company the number of whole shares of Common Stock reserved for the purpose of the Plan that his or her accumulated payroll deductions on such date will pay for, but not in excess of the maximum numbers determined in the manner set forth above.
- (d) <u>Return of Unused Payroll Deductions</u>. Any balance remaining in an employee's payroll deduction account at the end of a Plan Period will be automatically refunded to the employee, except that any balance that is less than the purchase price of one share of Common Stock will be carried forward into the employee's payroll deduction account for the following Offering, unless the employee elects not to participate in the following Offering under the Plan, in which case the balance in the employee's account shall be refunded.
- 10. <u>Issuance of Certificates</u>. Certificates representing shares of Common Stock purchased under the Plan may be issued only in the name of the employee, in the name of the employee and another person of legal age as joint tenants with rights of survivorship, or (in the Company's sole discretion) in the name of a brokerage firm, bank, or other nominee holder designated by the employee. The Company may, in its sole discretion and in compliance with applicable laws, authorize the use of book entry registration of shares in lieu of issuing stock certificates.
- 11. Rights on Retirement, Death or Termination of Employment. If a participating employee's employment ends before the last business day of a Plan Period, no payroll deduction shall be taken from any pay then due and owing to the employee and the balance in the employee's account shall be paid to the employee. In the event of the employee's death before the last business day of a Plan Period, the Company shall, upon notification of such death, pay the balance of the employee's account (a) to the executor or administrator of the employee's estate or (b) if no such executor or administrator has been appointed to the knowledge of the Company, to such other person(s) as the Company may, in its discretion, designate. If, before the last business day of the Plan Period, the Designated Subsidiary by which an employee is employed ceases to be a subsidiary of the Company, or if the employee is transferred to a subsidiary of the Company that is not a Designated Subsidiary, the employee shall be deemed to have terminated employment for the purposes of this Plan.
- 12. <u>Optionees Not Stockholders</u>. Neither the granting of an Option to an employee nor the deductions from his or her pay shall make such employee a stockholder of the shares of Common Stock covered by an Option under this Plan until he or she has purchased and received such shares.
- 13. Options Not Transferable. Options under this Plan are not transferable by a participating employee other than by will or the laws of descent and distribution, and are exercisable during the employee's lifetime only by the employee.

14. <u>Application of Funds</u>. All funds received or held by the Company under this Plan may be combined with other corporate funds and may be used for any corporate purpose.

#### 15. Adjustment for Changes in Common Stock and Certain Other Events.

(a) <u>Changes in Capitalization</u>. In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of Common Stock other than an ordinary cash dividend, (i) the number and class of securities available under this Plan, (ii) the share limitations set forth in Section 9, and (iii) the Option Price shall be equitably adjusted to the extent determined by the Board or the Committee.

#### (b) Reorganization Events.

- (1) <u>Definition</u>. A "Reorganization Event" shall mean: (a) any merger or consolidation of the Company with or into another entity as a result of which all of the Common Stock of the Company is converted into or exchanged for the right to receive cash, securities or other property or is cancelled, (b) any transfer or disposition of all of the Common Stock of the Company for cash, securities or other property pursuant to a share exchange or other transaction or (c) any liquidation or dissolution of the Company.
- (2) <u>Consequences of a Reorganization Event on Options</u>. In connection with a Reorganization Event, the Board or the Committee may take any one or more of the following actions as to outstanding Options on such terms as the Board or the Committee determines: (i) provide that Options shall be assumed, or substantially equivalent Options shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (ii) upon written notice to employees, provide that all outstanding Options will be terminated immediately prior to the consummation of such Reorganization Event and that all such outstanding Options will become exercisable to the extent of accumulated payroll deductions as of a date specified by the Board or the Committee in such notice, which date shall not be less than ten (10) days preceding the effective date of the Reorganization Event, (iii) upon written notice to employees, provide that all outstanding Options will be cancelled as of a date prior to the effective date of the Reorganization Event and that all accumulated payroll deductions will be returned to participating employees on such date, (iv) in the event of a Reorganization Event under the terms of which holders of Common Stock will receive upon consummation thereof a cash payment for each share surrendered in the Reorganization Event (the "Acquisition Price"), change the last day of the Plan Period to be the date of the consummation of the Reorganization Event and make or provide for a cash payment to each employee equal to (A) (1) the Acquisition Price times (2) the number of shares of Common Stock that the employee's accumulated payroll deductions as of immediately prior to the Reorganization Event could purchase at the Option Price, where the Acquisition Price is treated as the fair market value of the Common Stock on the last day of the applicable Plan Period for purposes of determining the Option Price under Section 9(b) hereof, and where the number of shares that could be purchased is subject to the limitations set forth in Section 9(a), minus (B) the result of multiplying such number of shares by such Option Price, (v) provide that, in connection with a liquidation or dissolution of the Company, Options shall convert into the right to receive liquidation proceeds (net of the Option Price thereof) and (vi) any combination of the foregoing.

For purposes of clause (i) above, an Option shall be considered assumed if, following consummation of the Reorganization Event, the Option confers the right to purchase, for each share of Common Stock subject to the Option immediately prior to the consummation of the Reorganization Event, the consideration (whether cash, securities or other property) received as a result of the Reorganization Event by holders of Common Stock for each share of Common Stock held immediately prior to the consummation of the Reorganization Event (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding shares of Common Stock); provided, however, that if the consideration received as a result of the Reorganization Event is not solely common stock of the acquiring or succeeding corporation (or an affiliate thereof), the Company may, with the consent of the acquiring or succeeding corporation, provide for the consideration to be received upon the exercise of Options to consist solely of such number of shares of common stock of the acquiring or succeeding corporation (or an affiliate thereof) that the Board determines to be equivalent in value (as of the date of such determination or another date specified by the Board) to the per share consideration received by holders of outstanding shares of Common Stock as a result of the Reorganization Event.

- 16. <u>Amendment of the Plan</u>. The Board may at any time, and from time to time, amend or suspend this Plan or any portion thereof, except that (a) if the approval of any such amendment by the shareholders of the Company is required by Section 423 of the Code, such amendment shall not be effected without such approval, and (b) in no event may any amendment be made that would cause the Plan to fail to comply with Section 423 of the Code.
- 17. <u>Insufficient Shares</u>. If the total number of shares of Common Stock specified in elections to be purchased under any Offering plus the number of shares purchased under previous Offerings under this Plan exceeds the maximum number of shares issuable under this Plan, the Board or the Committee will allot the shares then available on a pro-rata basis.
- 18. <u>Termination of the Plan</u>. This Plan may be terminated at any time by the Board. Upon termination of this Plan all amounts in the accounts of participating employees shall be promptly refunded.
- 19. <u>Governmental Regulations</u>. The Company's obligation to sell and deliver Common Stock under this Plan is subject to listing on a national stock exchange (to the extent the Common Stock is then so listed or quoted) and the approval of all governmental authorities required in connection with the authorization, issuance or sale of such stock.
  - 20. Governing Law. The Plan shall be governed by Delaware law except to the extent that such law is preempted by federal law.
- 21. <u>Issuance of Shares</u>. Shares may be issued upon exercise of an Option from authorized but unissued Common Stock, from shares held in the treasury of the Company, or from any other proper source.
- 22. <u>Notification upon Sale of Shares</u>. Each employee agrees, by participating in the Plan, to promptly give the Company notice of any disposition of shares purchased under the Plan where such disposition occurs within two years after the date of grant of the Option pursuant to which such shares were purchased.

- 23. Grants to Employees in Foreign Jurisdictions. The Company may, to comply with the laws of a foreign jurisdiction, grant Options to employees of the Company or a Designated Subsidiary who are citizens or residents of such foreign jurisdiction (without regard to whether they are also citizens of the United States or resident aliens (within the meaning of Section 7701(b)(1)(A) of the Code)) with terms that are less favorable (but not more favorable) than the terms of Options granted under the Plan to employees of the Company or a Designated Subsidiary who are resident in the United States. Notwithstanding the preceding provisions of this Plan, employees of the Company or a Designated Subsidiary who are citizens or residents of a foreign jurisdiction (without regard to whether they are also citizens of the United States or resident aliens (within the meaning of Section 7701(b)(1)(A) of the Code)) may be excluded from eligibility under the Plan if (a) the grant of an Option under the Plan to a citizen or resident of the foreign jurisdiction is prohibited under the laws of such jurisdiction or (b) compliance with the laws of the foreign jurisdiction would cause the Plan to violate the requirements of Section 423 of the Code. The Company may add one or more appendices to this Plan describing the operation of the Plan in those foreign jurisdictions in which employees are excluded from participation or granted less favorable Options.
- 24. <u>Authorization of Sub-Plans</u>. The Board may from time to time establish one or more sub-plans under the Plan with respect to one or more Designated Subsidiaries, provided that such sub-plan complies with Section 423 of the Code.
- 25. <u>Withholding</u>. If applicable tax laws impose a tax withholding obligation, each affected employee shall, no later than the date of the event creating the tax liability, make provision satisfactory to the Board for payment of any taxes required by law to be withheld in connection with any transaction related to Options granted to or shares acquired by such employee pursuant to the Plan. The Company may, to the extent permitted by law, deduct any such taxes from any payment of any kind otherwise due to an employee.
- 26. <u>Effective Date and Approval of Shareholders</u>. The Plan shall take effect as of immediately prior to the effectiveness of the Company's registration statement with respect to its initial public offering, subject to approval by the shareholders of the Company as required by Section 423 of the Code, which approval must occur within twelve months of the adoption of the Plan by the Board.

Adopted by the Board of Directors on June 24, 2020

Approved by the stockholders on July 13, 2020

## **INOZYME PHARMA, INC.**

## NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Effective on the effective date of the Registration Statement on Form S-1 relating to the initial public offering ("IPO") of Inozyme Pharma, Inc. (the "Company"), the Company's non-employee directors shall receive the following compensation for their service as members of the Board of Directors (the "Board") of the Company.

# **Director Compensation**

Our goal is to provide compensation for our non-employee directors in a manner that enables us to attract and retain outstanding director candidates and reflects the substantial time commitment necessary to oversee the Company's affairs. We also seek to align the interests of our directors and our stockholders and we have chosen to do so by compensating our non-employee directors with a mix of cash and equity-based compensation.

## **Cash Compensation**

The fees that will be paid to our non-employee directors for service on the Board, and for service on each committee of the Board on which the director is then a member, and the fees that will be paid to the chairman of the Board, if one is then appointed, and the chairman of each committee of the Board will be as follows:

	Member Annual Fee		Chairman Incremental Annual Fee	
Board of Directors	\$	35,000	\$ 30,000	
Audit Committee	\$	7,500	\$ 7,500	
Compensation Committee	\$	5,000	\$ 5,000	
Nominating and Corporate Governance Committee	\$	4,000	\$ 4,000	

The foregoing fees will be payable in arrears in four equal quarterly installments on the last day of each quarter, provided that (i) the amount of such payment will be prorated for any portion of such quarter that the director is not serving on the Board, on such committee or in such position, and (ii) no fee shall be payable in respect of any period prior to the effective date of the Registration Statement on Form S-1 relating to our IPO and the first payment hereunder after such effective date shall be prorated.

## **Equity Compensation**

<u>Initial Grants</u>. Upon initial election to the Board, each non-employee director will be granted, automatically and without the need for any further action by the Board, an initial equity award of an option to purchase 18,734 shares of our common stock. The initial award shall have a term of ten years from the grant date of the award, and shall vest and become exercisable as to 2.7778% of the shares underlying such award at the end of each successive one-month period following the grant date until the third anniversary of the grant date, subject to the director's continued service to the Company as a director through each applicable vesting date. The vesting shall accelerate as to 100% of the shares upon a change in control of the Company. The exercise price shall be the closing price of our common stock on the date of grant.

Annual Grants. Each non-employee director who has served as a member of the Board for at least six months prior to the date of our annual meeting of stockholders for a particular year will be granted, automatically and without the need for any further action by the Board, an equity award on the date of the first Board meeting held after our annual meeting of stockholders for such year of an option to purchase 9,367 shares of our common stock. The annual award shall have a term of ten years from the grant date of the award, and shall vest and become exercisable in full on the one-year anniversary of the grant date (or, if earlier, immediately prior to the first annual meeting of stockholders occurring after the grant date), subject to the director's continued service to the Company as a director through each applicable vesting date. The vesting shall accelerate as to 100% of the shares upon a change in control of the Company. The exercise price shall be the closing price of our common stock on the date of grant.

The foregoing share amounts shall be automatically adjusted in the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event effecting our common stock, or any distribution to holders of our common stock other than an ordinary cash dividend, in each case only if such event occurs after the effective date of the Registration Statement on Form S-1 relating to our IPO.

The initial awards and the annual awards shall be subject to the terms and conditions of our 2020 Stock Incentive Plan, or any successor plan, and the terms of the option agreements entered into with each director in connection with such awards.

### Expenses

Upon presentation of documentation of such expenses reasonably satisfactory to the Company, each non-employee director shall be reimbursed for his or her reasonable out-of-pocket business expenses incurred in connection with attending meetings of the Board and committees thereof or in connection with other business related to the Board, and each non-employee director shall also be reimbursed for his or her reasonable out-of-pocket business expenses authorized by the Board or a committee of the Board that are incurred in connection with attendance at various conferences or meetings with management of the Company, in accordance with the Company's travel policy, as it may be in effect from time to time.

## **INDEMNIFICATION AGREEMENT**

This Indemnification Agreement ("Agreement") is made	le as of [ ], 20[	] by and between Inozyme Pharma, Inc., a Delaware corporation (the
"Company"), and [ ] ("Indemnitee") [[Sole	ly with respect to office	ers and directors that execute this form of indemnification agreement on o
prior to the Company's initial public offering:] and sha	ll be effective as of the	e effectiveness of a Registration Statement on Form S-1 relating to the
initial registration under the Securities Act of 1933, as	amended, of shares of	the Company's common stock].

### RECITALS

WHEREAS, the Board of Directors of the Company (the "Board") believes that highly competent persons have become more reluctant to serve publicly-held corporations as directors or officers or in other capacities unless they are provided with adequate protection through insurance or adequate indemnification against inordinate risks of claims and actions against them arising out of their service to and activities on behalf of the corporation;

WHEREAS, the Board has determined that, in order to attract and retain qualified individuals, the Company will attempt to maintain on an ongoing basis, at its sole expense, liability insurance to protect persons serving the Company and its subsidiaries from certain liabilities. Although the furnishing of such insurance has been a customary and widespread practice among United States-based corporations and other business enterprises, the Company believes that, given current market conditions and trends, such insurance may be available to it in the future only at higher premiums and with more exclusions. At the same time, directors, officers, and other persons in service to corporations or business enterprises are being increasingly subjected to expensive and time-consuming litigation relating to, among other things, matters that traditionally would have been brought only against the Company or business enterprise itself. The Certificate of Incorporation of the Company (as the same may be amended from time to time, the "Certificate of Incorporation") requires indemnification of the officers and directors of the Company. Indemnitee may also be entitled to indemnification pursuant to the General Corporation Law of the State of Delaware (the "DGCL"). The Certificate of Incorporation and the DGCL expressly provide that the indemnification provisions set forth therein are not exclusive, and thereby contemplate that contracts may be entered into between the Company and members of the Board, officers and other persons with respect to indemnification;

WHEREAS, the uncertainties relating to such insurance and to indemnification have increased the difficulty of attracting and retaining such persons;

WHEREAS, the Board has determined that the increased difficulty in attracting and retaining such persons is detrimental to the best interests of the Company and its stockholders and that the Company should act to assure such persons that there will be increased certainty of such protection in the future:

WHEREAS, it is reasonable, prudent and necessary for the Company contractually to obligate itself to indemnify, and to advance expenses on behalf of, such persons to the fullest extent permitted by applicable law so that they will serve or continue to serve the Company free from undue concern that they will not be so indemnified;

WHEREAS, this Agreement is a supplement to and in furtherance of the Certificate of Incorporation and any resolutions adopted pursuant thereto, as well as any rights of Indemnitee under any directors' and officers' liability insurance policy, and this Agreement shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder; and

[WHEREAS, Indemnitee is a representative of [•] [and its affiliated investment funds] (the "Fund"), and has certain rights to indemnification and/or insurance provided by the Fund which Indemnitee and the Fund intend to be secondary to the primary obligation of the Company to indemnify Indemnitee as provided herein, with the Company's acknowledgement and agreement to the foregoing being a material condition to Indemnitee's willingness to serve on the Board;]

WHEREAS, Indemnitee does not regard the protection available under the Certificate of Incorporation and insurance as adequate in the present circumstances, and may not be willing to serve or continue to serve as an officer or director without adequate protection, and the Company desires Indemnitee to serve or continue to serve in such capacity. Indemnitee is willing to serve, continue to serve and to take on additional service for or on behalf of the Company on the condition that Indemnitee be so indemnified.

NOW, THEREFORE, in consideration of the premises and the covenants contained herein, the Company and Indemnitee do hereby covenant and agree as follows:

Section 1. Services to the Company. Indemnitee agrees to serve as a [officer] [director] of the Company. Indemnitee may at any time and for any reason resign from such position (subject to any other contractual obligation or any obligation imposed by operation of law), in which event the Company shall have no obligation under this Agreement to continue Indemnitee in such position. This Agreement shall not be deemed an employment contract between the Company (or any of its subsidiaries or any Enterprise) and Indemnitee. Indemnitee specifically acknowledges that Indemnitee's employment with the Company (or any of its subsidiaries or any Enterprise), if any, is at will, and Indemnitee may be discharged at any time for any reason, with or without cause, except as may be otherwise provided in any written employment contract between Indemnitee and the Company (or any of its subsidiaries or any Enterprise), other applicable formal severance policies duly adopted by the Board, or, with respect to service as a director or officer of the Company, by the Certificate of Incorporation, the Bylaws of the Company (the "Bylaws"), and the DGCL. The foregoing notwithstanding, this Agreement shall continue in force after Indemnitee has ceased to serve as an [officer] [director] of the Company, as provided in Section 16 hereof.

# Section 2. <u>Definitions</u>. As used in this Agreement:

(a) References to "agent" shall mean any person who is or was a director, officer, or employee of the Company or a subsidiary of the Company or other person authorized by the Company to act for the Company, to include such person serving in such capacity as a director, officer, employee, fiduciary or other official of another corporation, partnership, limited liability company, joint venture, trust or other enterprise at the request of, for the convenience of, or to represent the interests of the Company or a subsidiary of the Company.

- (b) A "Change in Control" shall be deemed to occur upon the earliest to occur after the date of this Agreement of any of the following events:
- i. Acquisition of Stock by Third Party. Any Person (as defined below) is or becomes the Beneficial Owner (as defined below), directly or indirectly, of securities of the Company representing fifty percent (50%) or more of the combined voting power of the Company's then outstanding securities unless the change in relative Beneficial Ownership of the Company's securities by any Person results solely from a reduction in the aggregate number of outstanding shares of securities entitled to vote generally in the election of directors;
- ii. Change in Board of Directors. During any period of two (2) consecutive years (not including any period prior to the execution of this Agreement), individuals who at the beginning of such period constitute the Board, and any new director (other than a director designated by a person who has entered into an agreement with the Company to effect a transaction described in Sections 2(b)(i), 2(b)(iii) or 2(b)(iv)) whose election by the Board or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the period or whose election or nomination for election was previously so approved, cease for any reason to constitute at least a majority of the members of the Board;
- iii. Corporate Transactions. The effective date of a merger or consolidation of the Company with any other entity, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the Surviving Entity) more than fifty-one percent (51%) of the combined voting power of the voting securities of the Surviving Entity outstanding immediately after such merger or consolidation and with the power to elect at least a majority of the board of directors or other governing body of such Surviving Entity;
- iv. Liquidation or Sale of Assets. The approval by the stockholders of the Company of a complete liquidation of the Company or an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets; and
- v. Other Events. There occurs any other event of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A (or a response to any similar item on any similar schedule or form) promulgated under the Exchange Act (as defined below), whether or not the Company is then subject to such reporting requirement.

For purposes of this Section 2(b), the following terms shall have the following meanings:

- (A) "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended from time to time.
- (B) "Person" shall have the meaning as set forth in Sections 13(d) and 14(d) of the Exchange Act; provided, however, that Person shall exclude (i) the

Company, (ii) any trustee or other fiduciary holding securities under an employee benefit plan of the Company, and (iii) any entity owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company.

- (C) "Beneficial Owner" shall have the meaning given to such term in Rule 13d-3 under the Exchange Act; provided, however, that Beneficial Owner shall exclude any Person otherwise becoming a Beneficial Owner by reason of the stockholders of the Company approving a merger of the Company with another entity.
- (D) "Surviving Entity" shall mean the surviving entity in a merger or consolidation or any entity that controls, directly or indirectly, such surviving entity.
- (c) "Corporate Status" describes the status of a person who is or was a director, trustee, partner, managing member, officer, employee, agent or fiduciary of the Company or of any other corporation, limited liability company, partnership or joint venture, trust or other enterprise which such person is or was serving at the request of the Company.
- (d) "Disinterested Director" shall mean a director of the Company who is not and was not a party to the Proceeding in respect of which indemnification is sought by Indemnitee.
- (e) "Enterprise" shall mean the Company and any other corporation, limited liability company, partnership, joint venture, trust or other enterprise of which Indemnitee is or was serving at the request of the Company as a director, officer, trustee, partner, managing member, employee, agent or fiduciary.
- (f) "Expenses" shall include all reasonable attorneys' fees, retainers, court costs, transcript costs, fees and other costs of experts and other professionals, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, any federal, state, local or foreign taxes imposed on Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement, ERISA excise taxes and penalties, and all other disbursements, obligations or expenses of the types customarily incurred in connection with, or as a result of, prosecuting, defending, preparing to prosecute or defend, investigating, being or preparing to be a deponent or witness in, or otherwise participating in, a Proceeding. Expenses also shall include (i) Expenses incurred in connection with any appeal resulting from any Proceeding, including without limitation the premium, security for, and other costs relating to any cost bond, supersedeas bond, or other appeal bond or its equivalent, (ii) expenses incurred in connection with recovery under any directors' and officers' liability insurance policies maintained by the Company, regardless of whether Indemnitee is ultimately determined to be entitled to such indemnification, advancement or Expenses or insurance recovery, as the case may be, and (iii) for purposes of Section 14(d) only, Expenses incurred by Indemnitee in connection with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement, the Certificate of Incorporation, the Bylaws or under any directors' and officers' liability insurance policies maintained by the Company, by litigation or otherwise. The

parties agree that for the purposes of any advancement of Expenses for which Indemnitee has made written demand to the Company in accordance with this Agreement, all Expenses included in such demand that are certified by affidavit of Indemnitee's counsel as being reasonable in the good faith judgment of such counsel shall be presumed conclusively to be reasonable. Expenses, however, shall not include amounts paid in settlement by Indemnitee or the amount of judgments or fines against Indemnitee.

- (g) "Independent Counsel" shall mean a law firm, or a member of a law firm, that is experienced in matters of corporation law and neither presently is, nor in the past five years has been, retained to represent: (i) the Company or Indemnitee in any matter material to either such party (other than with respect to matters concerning Indemnitee under this Agreement, or of other indemnitees under similar indemnification agreements), or (ii) any other party to the Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or Indemnitee in an action to determine Indemnitee's rights under this Agreement. The Company agrees to pay the reasonable fees and expenses of the Independent Counsel referred to above and to fully indemnify such counsel against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.
- (h) The term "Proceeding" shall include any threatened, pending or completed action, suit, claim, counterclaim, cross claim, arbitration, mediation, alternate dispute resolution mechanism, investigation, inquiry, administrative hearing or any other actual, threatened or completed proceeding, whether brought in the right of the Company or otherwise and whether of a civil, criminal, administrative, legislative, regulatory or investigative (formal or informal) nature, including any appeal therefrom, in which Indemnitee was, is or will be involved as a party, potential party, non-party witness or otherwise by reason of Indemnitee's Corporate Status, by reason of any action taken by Indemnitee (or a failure to take action by Indemnitee) or of any action (or failure to act) on Indemnitee's part while acting pursuant to Indemnitee's Corporate Status, in each case whether or not serving in such capacity at the time any liability or Expense is incurred for which indemnification, reimbursement, or advancement of Expenses can be provided under this Agreement. If Indemnitee believes in good faith that a given situation may lead to or culminate in the institution of a Proceeding, this shall be considered a Proceeding under this paragraph.
- (i) Reference to "other enterprise" shall include employee benefit plans; references to "fines" shall include any excise tax assessed with respect to any employee benefit plan; references to "serving at the request of the Company" shall include any service as a director, officer, employee or agent of the Company which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner Indemnitee reasonably believed to be in the best interests of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "not opposed to the best interests of the Company" as referred to in this Agreement.

Section 3. <u>Indemnity in Third-Party Proceedings</u>. The Company shall indemnify Indemnitee in accordance with the provisions of this Section 3 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding, other than a Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 3, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses, judgments, fines and amounts paid in settlement (including all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses, judgments, fines and amounts paid in settlement) actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner Indemnitee reasonably believed to be in or not opposed to the best interests of the Company and, in the case of a criminal Proceeding had no reasonable cause to believe that Indemnitee's conduct was unlawful. The parties hereto intend that this Agreement shall provide to the fullest extent permitted by law for indemnification in excess of that expressly permitted by statute, including, without limitation, any indemnification provided by the Certificate of Incorporation, the Bylaws, vote of the Company's stockholders or disinterested directors or applicable law.

Section 4. Indemnity in Proceedings by or in the Right of the Company. The Company shall indemnify Indemnitee in accordance with the provisions of this Section 4 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 4, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner Indemnitee reasonably believed to be in or not opposed to the best interests of the Company. No indemnification for Expenses shall be made under this Section 4 in respect of any claim, issue or matter as to which Indemnitee shall have been finally adjudged by a court to be liable to the Company, unless and only to the extent that the Court of Chancery of the State of Delaware (the "Delaware Court") or any court in which the Proceeding was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnification.

Section 5. <u>Indemnification for Expenses of a Party Who is Wholly or Partly Successful</u>. Notwithstanding any other provisions of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is a party to (or a participant in) and is successful, on the merits or otherwise, in any Proceeding or in defense of any claim, issue or matter therein, in whole or in part, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by or on behalf of Indemnitee in connection therewith. If Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, as to one or more but less than all claims, issues or matters in such Proceeding, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with or related to each successfully resolved claim, issue or matter to the fullest extent permitted by law. For purposes of this Section and without limitation, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, shall be deemed to be a successful result as to such claim, issue or matter.

- Section 6. <u>Indemnification For Expenses of a Witness</u>. Notwithstanding any other provision of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is, by reason of Indemnitee's Corporate Status, a witness, is or was made (or asked) to respond to discovery requests in any Proceeding, or otherwise asked to participate in any Proceeding to which Indemnitee is not a party, Indemnitee shall be indemnified against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection therewith.
- Section 7. <u>Partial Indemnification</u>. If Indemnitee is entitled under any provision of this Agreement to indemnification by the Company for some or a portion of Expenses, but not, however, for the total amount thereof, the Company shall nevertheless indemnify Indemnitee for the portion thereof to which Indemnitee is entitled.

## Section 8. Additional Indemnification.

- (a) Notwithstanding any limitation in Sections 3, 4, or 5, the Company shall indemnify Indemnitee to the fullest extent permitted by applicable law if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding (including a Proceeding by or in the right of the Company to procure a judgment in its favor) by reason of Indemnitee's Corporate Status.
- (b) For purposes of Section 8(a), the meaning of the phrase "to the fullest extent permitted by applicable law" shall include, but not be limited to:
- i. to the fullest extent permitted by the provision of the DGCL that authorizes or contemplates additional indemnification by agreement, or the corresponding provision of any amendment to or replacement of the DGCL, and
- ii. to the fullest extent authorized or permitted by any amendments to or replacements of the DGCL adopted after the date of this Agreement that increase the extent to which a corporation may indemnify its officers and directors.
- Section 9. <u>Exclusions</u>. Notwithstanding any provision in this Agreement, the Company shall not be obligated under this Agreement to make any indemnification payment in connection with any claim involving Indemnitee:
- (a) for which payment has actually been made to or on behalf of Indemnitee under any insurance policy or other indemnity provision, except with respect to any excess beyond the amount paid under any insurance policy or other indemnity provision; or
- (b) for (i) an accounting of profits made from the purchase and sale (or sale and purchase) by Indemnitee of securities of the Company within the meaning of Section 16(b) of the Exchange Act (as defined in Section 2(b) hereof) or similar provisions of state statutory law or common law, or (ii) any reimbursement of the Company by Indemnitee of any bonus or other incentive-based or equity-based compensation or of any profits realized by Indemnitee from the sale of securities of the Company, as required in each case under the Exchange Act (including any such reimbursements that arise from an accounting restatement of the Company

pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), or the payment to the Company of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 306 of the Sarbanes-Oxley Act) or (iii) any reimbursement of the Company by Indemnitee of any compensation pursuant to any compensation recoupment or clawback policy adopted by the Board or the compensation committee of the Board, including but not limited to any such policy adopted to comply with stock exchange listing requirements implementing Section 10D of the Exchange Act; or

- (c) except as provided in Section 14(d) of this Agreement, in connection with any Proceeding (or any part of any Proceeding) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against the Company or its directors, officers, employees or other indemnitees, unless (i) the Board authorized the Proceeding (or any part of any Proceeding) prior to its initiation, (ii) such payment arises in connection with any mandatory counterclaim or cross claim brought or raised by Indemnitee in any Proceeding (or any part of any Proceeding), or (iii) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law.
- Section 10. Advances of Expenses. Notwithstanding any provision of this Agreement to the contrary (other than Section 14(d)), the Company shall advance, to the extent not prohibited by law, the Expenses incurred by or on behalf of Indemnitee in connection with any Proceeding (or any part of any Proceeding) (x) not initiated by Indemnitee (other than in connection with any mandatory counterclaim or cross claim brought or raised by Indemnitee therein as provided in Section 9(c)) or (y) initiated by Indemnitee with the prior approval of the Board as provided in Section 9(c), and such advancement shall be made within thirty (30) days after the receipt by the Company of a statement or statements requesting such advances from time to time, whether prior to or after final disposition of any Proceeding. Advances shall be unsecured and interest free. Advances shall be made without regard to Indemnitee's ability to repay the Expenses and without regard to Indemnitee's ultimate entitlement to indemnification under the other provisions of this Agreement. In accordance with Section 14(d), advances shall include any and all reasonable Expenses incurred pursuing an action to enforce this right of advancement, including Expenses incurred preparing and forwarding statements to the Company to support the advances claimed. Indemnitee shall qualify for advances upon the execution and delivery to the Company of this Agreement, which shall constitute an undertaking providing that Indemnitee undertakes to repay the amounts advanced (without interest) by the Company pursuant to this Section 10, if and only to the extent that it is ultimately determined that Indemnitee is not entitled to be indemnified by the Company. No other form of undertaking shall be required other than the execution of this Agreement. This Section 10 shall not apply to any claim made by Indemnitee for which indemnity is excluded pursuant to Section 9.

## Section 11. Procedure for Notification and Defense of Claim.

(a) Indemnitee shall notify the Company in writing of any matter with respect to which Indemnitee intends to seek indemnification or advancement of Expenses hereunder as soon as reasonably practicable following the receipt by Indemnitee of written notice thereof. The written notification to the Company shall include a description of the nature of the Proceeding and the facts underlying the Proceeding. To obtain indemnification under this

Agreement, Indemnitee shall submit to the Company a written request, including therein or therewith such documentation and information as is reasonably available to Indemnitee and is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification following the final disposition of such Proceeding. The omission by Indemnitee to notify the Company hereunder will not relieve the Company from any liability which it may have to Indemnitee hereunder or otherwise than under this Agreement, and any delay in so notifying the Company shall not constitute a waiver by Indemnitee of any rights under this Agreement. The Secretary of the Company shall, promptly upon receipt of such a request for indemnification, advise the Board in writing that Indemnitee has requested indemnification.

- (b) The Company will be entitled to participate in the Proceeding at its own expense.
- (c) The Company shall not settle any Proceeding (in whole or in part) if such settlement would impose any Expense, judgment, liability, fine, penalty or limitation on Indemnitee in respect of which Indemnitee is not entitled to be indemnified hereunder without Indemnitee's prior written consent, which shall not be unreasonably withheld.

# Section 12. Procedure Upon Application for Indemnification.

- (a) Upon written request by Indemnitee for indemnification pursuant to Section 11(a), a determination, if required by applicable law, with respect to Indemnitee's entitlement thereto shall be made in the specific case: (i) if a Change in Control shall have occurred, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to Indemnitee; or (ii) if a Change in Control shall not have occurred, (A) by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (B) by a committee of Disinterested Directors designated by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (C) if there are no such Disinterested Directors or, if such Disinterested Directors so direct, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to Indemnitee or (D) if so directed by the Board, by the stockholders of the Company; and, if it is so determined that Indemnitee is entitled to indemnification, payment to Indemnitee shall be made within ten (10) days after such determination. Indemnitee shall cooperate with the person, persons or entity making such determination with respect to Indemnitee's entitlement to indemnification, including providing to such person, persons or entity upon reasonable advance request any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to Indemnitee and reasonably necessary to such determination. Any costs or Expenses (including attorneys' fees and disbursements) incurred by or on behalf of Indemnitee in so cooperating with the person, persons or entity making such determination shall be borne by the Company (irrespective of the determination as to Indemnitee's entitlement to indemnification) and the Company hereby indemnifies and agrees to hold Indemnitee harmless therefrom. The Company promptly will advise Indemnitee in writing with respect to any determination that Indemnitee is or is
- (b) In the event the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 12(a) hereof, the Independent Counsel shall

be selected as provided in this Section 12(b). If a Change in Control shall not have occurred, the Independent Counsel shall be selected by the Board, and the Company shall give written notice to Indemnitee advising Indemnitee of the identity of the Independent Counsel so selected. If a Change in Control shall have occurred, the Independent Counsel shall be selected by Indemnitee (unless Indemnitee shall request that such selection be made by the Board, in which event the preceding sentence shall apply), and Indemnitee shall give written notice to the Company advising it of the identity of the Independent Counsel so selected. In either event, Indemnitee or the Company, as the case may be, may, within ten (10) days after such written notice of selection shall have been given, deliver to the Company or to Indemnitee, as the case may be, a written objection to such selection; provided, however, that such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the requirements of "Independent Counsel" as defined in Section 2 of this Agreement, and the objection shall set forth with particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected shall act as Independent Counsel. If such written objection is so made and substantiated, the Independent Counsel so selected may not serve as Independent Counsel unless and until such objection is withdrawn or the Delaware Court has determined that such objection is without merit. If, within twenty (20) days after the later of submission by Indemnitee of a written request for indemnification pursuant to Section 11(a) hereof and the final disposition of the Proceeding, no Independent Counsel shall have been selected and not objected to, either the Company or Indemnitee may petition the Delaware Court for resolution of any objection which shall have been made by the Company or Indemnitee to the other's selection of Independent Counsel and/or for the appointment as Independent Counsel of a person selected by such court or by such other person as such court shall designate, and the person with respect to whom all objections are so resolved or the person so appointed shall act as Independent Counsel under Section 12(a) hereof. Upon the due commencement of any judicial proceeding or arbitration pursuant to Section 14(a) of this Agreement, Independent Counsel shall be discharged and relieved of any further responsibility in such capacity (subject to the applicable standards of professional conduct then prevailing).

(c) If the Company disputes a portion of the amounts for which indemnification is requested, the undisputed portion shall be paid and only the disputed portion withheld pending resolution of any such dispute.

## Section 13. Presumptions and Effect of Certain Proceedings.

(a) In making a determination with respect to entitlement to indemnification hereunder, the person or persons or entity making such determination shall, to the fullest extent not prohibited by law, presume that Indemnitee is entitled to indemnification under this Agreement if Indemnitee has submitted a request for indemnification in accordance with Section 11(a) of this Agreement, and the Company shall, to the fullest extent not prohibited by law, have the burden of proof to overcome that presumption in connection with the making by any person, persons or entity of any determination contrary to that presumption. Neither the failure of the Company (including by its directors or Independent Counsel) to have made a determination prior to the commencement of any action pursuant to this Agreement that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Company (including by its directors or Independent Counsel) that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct.

- (b) Subject to Section 14(e), if the person, persons or entity empowered or selected under Section 12 of this Agreement to determine whether Indemnitee is entitled to indemnification shall not have made a determination within sixty (60) days after receipt by the Company of the request therefor, the requisite determination of entitlement to indemnification shall, to the fullest extent not prohibited by law, be deemed to have been made and Indemnitee shall be entitled to such indemnification, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law; provided, however, that such 60-day period may be extended for a reasonable time, not to exceed an additional thirty (30) days, if the person, persons or entity making the determination with respect to entitlement to indemnification in good faith requires such additional time for the obtaining or evaluating of documentation and/or information relating thereto; and provided, further, that the foregoing provisions of this Section 13(b) shall not apply (i) if the determination of entitlement to indemnification is to be made by the stockholders pursuant to Section 12(a) of this Agreement and if (A) within fifteen (15) days after receipt by the Company of the request for such determination the Board has resolved to submit such determination to the stockholders for their consideration at an annual meeting thereof to be held within seventy-five (75) days after such receipt and such determination is made thereat, or (B) a special meeting of stockholders is called within fifteen (15) days after such receipt for the purpose of making such determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 12(a) of this Agreement.
- (c) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of <u>nolo contendere</u> or its equivalent, shall not (except as otherwise expressly provided in this Agreement) of itself adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee did not act in good faith and in a manner which Indemnitee reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that Indemnitee's conduct was unlawful.
- (d) For purposes of any determination of good faith, Indemnitee shall be deemed to have acted in good faith if Indemnitee's action is based on the records or books of account of the Enterprise, including financial statements, or on information supplied to Indemnitee by the directors or officers of the Enterprise in the course of their duties, or on the advice of legal counsel for the Enterprise or on information or records given or reports made to the Enterprise by an independent certified public accountant or by an appraiser, financial advisor or other expert selected with reasonable care by or on behalf of the Enterprise. The provisions of this Section 13(d) shall not be deemed to be exclusive or to limit in any way the other circumstances in which Indemnitee may be deemed to have met the applicable standard of conduct set forth in this Agreement.

(e) The knowledge and/or actions, or failure to act, of any director, officer, trustee, partner, managing member, fiduciary, agent or employee of the Enterprise shall not be imputed to Indemnitee for purposes of determining the right to indemnification under this Agreement.

## Section 14. Remedies of Indemnitee.

- (a) Subject to Section 14(e), in the event that (i) a determination is made pursuant to Section 12 of this Agreement that Indemnitee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made pursuant to Section 10 of this Agreement, (iii) no determination of entitlement to indemnification shall have been made pursuant to Section 12(a) of this Agreement within ninety (90) days after receipt by the Company of the request for indemnification, (iv) payment of indemnification is not made pursuant to Section 5, 6 or 7 or the second to last sentence of Section 12(a) of this Agreement within ten (10) days after receipt by the Company of a written request therefor, (v) payment of indemnification pursuant to Section 3, 4 or 8 of this Agreement is not made within ten (10) days after a determination has been made that Indemnitee is entitled to indemnification, or (vi) the Company or any other person takes or threatens to take any action to declare this Agreement void or unenforceable, or institutes any litigation or other action or Proceeding designed to deny, or to recover from, Indemnitee the benefits provided or intended to be provided to Indemnitee hereunder, Indemnitee shall be entitled to an adjudication by a court of Indemnitee's entitlement to such indemnification or advancement of Expenses. Alternatively, Indemnitee, at Indemnitee's option, may seek an award in arbitration to be conducted by a single arbitrator pursuant to the Commercial Arbitration Rules of the American Arbitration Association. Indemnitee shall commence such proceeding seeking an adjudication or an award in arbitration within 180 days following the date on which Indemnitee first has the right to commence such proceeding pursuant to this Section 14(a). The Company shall not oppose Indemnitee's right to seek any such adjudication or award in arbitration.
- (b) In the event that a determination shall have been made pursuant to Section 12(a) of this Agreement that Indemnitee is not entitled to indemnification, any judicial proceeding or arbitration commenced pursuant to this Section 14 shall be conducted in all respects as a <u>de novo</u> trial, or arbitration, on the merits and Indemnitee shall not be prejudiced by reason of that adverse determination. In any judicial proceeding or arbitration commenced pursuant to this Section 14 the Company shall have the burden of proving Indemnitee is not entitled to indemnification or advancement of Expenses, as the case may be.
- (c) If a determination shall have been made pursuant to Section 12(a) of this Agreement that Indemnitee is entitled to indemnification, the Company shall be bound by such determination in any judicial proceeding or arbitration commenced pursuant to this Section 14, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law.
- (d) The Company shall, to the fullest extent not prohibited by law, be precluded from asserting in any judicial proceeding or arbitration commenced pursuant to this Section 14 that the procedures and presumptions of this Agreement are not valid, binding and

enforceable and shall stipulate in any such court or before any such arbitrator that the Company is bound by all the provisions of this Agreement. It is the intent of the Company that, to the fullest extent permitted by law, Indemnitee not be required to incur legal fees or other Expenses associated with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement by litigation or otherwise because the cost and expense thereof would substantially detract from the benefits intended to be extended to Indemnitee hereunder. The Company shall, to the fullest extent permitted by law, indemnify Indemnitee against any and all Expenses and, if requested by Indemnitee, shall (within ten (10) days after receipt by the Company of a written request therefor) advance, to the extent not prohibited by law, such Expenses to Indemnitee, which are incurred by or on behalf of Indemnitee in connection with any action brought by Indemnitee for indemnification or advancement of Expenses from the Company under this Agreement or under any directors' and officers' liability insurance policies maintained by the Company if, in the case of indemnification, Indemnitee is wholly successful on the underlying claims; if Indemnitee is not wholly successful on the underlying claims, then such indemnification shall be only to the extent Indemnitee is successful on such underlying claims or otherwise as permitted by law, whichever is greater.

(e) Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement of Indemnitee to indemnification under this Agreement shall be required to be made prior to the final disposition of the Proceeding.

# Section 15. Non-exclusivity; Survival of Rights; Insurance; Subrogation.

- (a) The rights of indemnification and to receive advancement of Expenses as provided by this Agreement (i) shall not be deemed exclusive of any other rights to which Indemnitee may at any time be entitled under applicable law, the Certificate of Incorporation, the Bylaws, any agreement, a vote of stockholders or a resolution of directors, or otherwise and (ii) shall be interpreted independently of, and without reference to, any other such rights to which Indemnitee may at any time be entitled. No amendment, alteration or repeal of this Agreement or of any provision hereof shall limit or restrict any right of Indemnitee under this Agreement in respect of any action taken or omitted by Indemnitee in Indemnitee's Corporate Status prior to such amendment, alteration or repeal. To the extent that a change in Delaware law, whether by statute or judicial decision, permits greater indemnification or advancement of Expenses than would be afforded currently under the Certificate of Incorporation and this Agreement, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change. No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.
- (b) To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, officers, employees, or agents of the Enterprise, Indemnitee shall be covered by such policy or policies in accordance with its or their terms to the maximum extent of the coverage available for any such director, officer, employee or agent under such policy or policies. If, at the time of the receipt of a notice of a claim pursuant to the terms hereof, the Company has director and officer liability insurance in effect, the Company

shall give prompt notice of such claim or of the commencement of a Proceeding, as the case may be, to the insurers in accordance with the procedures set forth in the respective policies. The Company shall thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of Indemnitee, all amounts payable as a result of such Proceeding in accordance with the terms of such policies.

- (c) In the event of any payment made by the Company under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee, who shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Company to bring suit to enforce such rights.
- (d) The Company shall not be liable under this Agreement to make any payment of amounts otherwise indemnifiable hereunder (or for which advancement is provided hereunder) if and to the extent that Indemnitee has otherwise actually received such payment under any insurance policy, contract, agreement or otherwise.
- (e) [The Company hereby acknowledges that Indemnitee has certain rights to indemnification, advancement of expenses and/or insurance provided by the Fund and certain of its affiliates (collectively, the "Fund Indemnitors"). The Company hereby agrees (i) that it is the indemnitor of first resort (i.e., its obligations to Indemnitee are primary and any obligation of the Fund Indemnitors to advance expenses or to provide indemnification for the same expenses or liabilities incurred by Indemnitee are secondary), (ii) that it shall be required to advance the full amount of Expenses incurred by Indemnitee and shall be liable for the full amount of all Expenses, judgments, penalties, fines and amounts paid in settlement to the extent legally permitted and as required by the Certificate of Incorporation or Bylaws (or any agreement between the Company and Indemnitee), without regard to any rights Indemnitee may have against the Fund Indemnitors, and (iii) that it irrevocably waives, relinquishes and releases the Fund Indemnitors from any and all claims against the Fund Indemnitors for contribution, subrogation or any other recovery of any kind in respect thereof. The Company further agrees that no advancement or payment by the Fund Indemnitors on behalf of Indemnitee with respect to any claim for which Indemnitee has sought indemnification from the Company shall affect the foregoing and the Fund Indemnitors shall have a right of contribution and/or be subrogated to the extent of such advancement or payment to all of the rights of recovery of Indemnitee against the Company. The Company and Indemnitee agree that the Fund Indemnitors are express third party beneficiaries of the terms hereof.]
- (f) [Except as provided in paragraph (e) above,] [T]he Company's obligation to indemnify or advance Expenses hereunder to Indemnitee who is or was serving at the request of the Company as a director, officer, trustee, partner, managing member, fiduciary, employee or agent of any other corporation, limited liability company, partnership, joint venture, trust, employee benefit plan or other enterprise shall be reduced by any amount Indemnitee has actually received as indemnification or advancement of Expenses from such other corporation, limited liability company, partnership, joint venture, trust or other enterprise.

Section 16. <u>Duration of Agreement</u>. This Agreement shall continue until and terminate upon the later of: (a) ten (10) years after the date that Indemnitee shall have ceased to

serve as a [officer] [director] of the Company or (b) one (1) year after the final termination of any Proceeding then pending in respect of which Indemnitee is granted rights of indemnification or advancement of Expenses hereunder and of any proceeding (including any appeal thereof) commenced by Indemnitee pursuant to Section 14 of this Agreement relating thereto. The indemnification and advancement of expenses rights provided by or granted pursuant to this Agreement shall be binding upon and be enforceable by the parties hereto and their respective successors and assigns (including any direct or indirect successor by purchase, merger, consolidation or otherwise to all or substantially all of the business or assets of the Company), shall continue as to an Indemnitee who has ceased to be a director, officer, employee or agent of the Company or of any other Enterprise, and shall inure to the benefit of Indemnitee and Indemnitee's spouse, assigns, heirs, devisees, executors and administrators and other legal representatives. The Company shall require and shall cause any successor (whether direct or indirect by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company to, by written agreement, expressly assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform if no such succession had taken place.

Section 17. Severability. Nothing in this Agreement is intended to require or shall be construed as requiring the Company to do or fail to do any act in violation of applicable law. If any provision or provisions of this Agreement shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (a) the validity, legality and enforceability of the remaining provisions of this Agreement (including without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and shall remain enforceable to the fullest extent permitted by law; (b) such provision or provisions shall be deemed reformed to the extent necessary to conform to applicable law and to give the maximum effect to the intent of the parties hereto; and (c) to the fullest extent possible, the provisions of this Agreement (including, without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested thereby.

### Section 18. Enforcement.

- (a) The Company expressly confirms and agrees that it has entered into this Agreement and assumed the obligations imposed on it hereby in order to induce Indemnitee to serve as a director or officer of the Company, and the Company acknowledges that Indemnitee is relying upon this Agreement in serving or continuing to serve as a director or officer of the Company.
- (b) This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes and replaces all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the subject matter hereof, including any agreement covering the subject matter of this Agreement previously entered into between the Company and Indemnitee; provided, however, that this Agreement is a supplement to and in furtherance of the Certificate of Incorporation, the Bylaws, any directors' and officers' insurance maintained by the Company and applicable law, and shall

not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder[; provided, further, however, that the Indemnification Agreement, dated [ ], by and between the Company and Indemnitee (the "Existing Agreement") shall continue to apply with respect to any Proceeding related to claims, issues or matters solely arising or occurring prior to the closing of the Company's initial public offering of shares of its common stock (with the understanding that the Existing Agreement shall not apply to any Proceeding in connection with or related to any claims, issues or matters arising or occurring after the closing of the Company's initial public offering of shares of its common stock)].

- Section 19. <u>Modification and Waiver</u>. No supplement, modification or amendment of this Agreement shall be binding unless executed in writing by the parties hereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions of this Agreement nor shall any waiver constitute a continuing waiver.
- Section 20. <u>Notice by Indemnitee</u>. Indemnitee agrees promptly to notify the Company in writing upon being served with any summons, citation, subpoena, complaint, indictment, information or other document relating to any Proceeding or matter which may be subject to indemnification or advancement of Expenses covered hereunder. The failure of Indemnitee to so notify the Company shall not relieve the Company of any obligation which it may have to Indemnitee under this Agreement or otherwise.
- Section 21. Notices. All notices, requests, demands and other communications under this Agreement shall be in writing and shall be deemed to have been duly given if (a) delivered by hand and receipted for by the party to whom said notice or other communication shall have been directed, (b) mailed by certified or registered mail with postage prepaid, on the third business day after the date on which it is so mailed, (c) mailed by reputable overnight courier and receipted for by the party to whom said notice or other communication shall have been directed or (d) sent by facsimile transmission, with receipt of oral confirmation that such transmission has been received:
- (a) If to Indemnitee, at the address indicated on the signature page of this Agreement, or such other address as Indemnitee shall provide to the Company.
  - (b) If to the Company, to

Inozyme Pharma, Inc. 321 Summer Street, Suite 400 Boston, MA 02210 Attn: Chief Operating Officer

or to any other address as may have been furnished to Indemnitee by the Company.

Section 22. <u>Contribution</u>. To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Company, in lieu of indemnifying Indemnitee, shall contribute to the amount incurred by Indemnitee, whether for judgments, fines, penalties, excise taxes, amounts paid or to be paid in settlement and/or for Expenses, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in

light of all of the circumstances of such Proceeding in order to reflect (i) the relative benefits received by the Company, on the one hand, and Indemnitee, on the other hand, as a result of the event(s) and/or transaction(s) giving cause to such Proceeding; and/or (ii) the relative fault of the Company (and its other directors, officers, employees and agents), on the one hand, and Indemnitee, on the other hand, in connection with such event(s) and/or transaction(s).

- Section 23. Applicable Law and Consent to Jurisdiction. This Agreement and the legal relations among the parties shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, without regard to its conflict of laws rules. Except with respect to any arbitration commenced by Indemnitee pursuant to Section 14(a) of this Agreement, the Company and Indemnitee hereby irrevocably and unconditionally (i) agree that any action or proceeding arising out of or in connection with this Agreement shall be brought only in the Delaware Court, and not in any other state or federal court in the United States of America or any court in any other country, (ii) consent to submit to the exclusive jurisdiction of the Delaware Court for purposes of any action or proceeding arising out of or in connection with this Agreement, (iii) waive any objection to the laying of venue of any such action or proceeding in the Delaware Court, and (iv) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Delaware Court has been brought in an improper or inconvenient forum.
- Section 24. <u>Identical Counterparts</u>. This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement. Only one such counterpart signed by the party against whom enforceability is sought needs to be produced to evidence the existence of this Agreement.
- Section 25. <u>Miscellaneous</u>. Use of the masculine pronoun shall be deemed to include usage of the feminine pronoun where appropriate. The headings of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

[Remainder of Page Intentionally Left Blank]

INOZYME PHARMA, INC.	INDEMNITEE
By: Name: Title:	By: Name: Address:

IN WITNESS WHEREOF, the parties have caused this Agreement to be signed as of the day and year first above written.

Signature Page to Inozyme Pharma, Inc. Indemnification Agreement



June 30, 2020

Axel Bolte

Dear Axel:

This letter (the "Letter Agreement") sets forth the terms and conditions of your employment with Inozyme Pharma, Inc. ("Inozyme" or the "Company") and will be effective as of the date on which the registration statement related to the Company's initial public offering is effective (the "Effective Date"). Until the Effective Date, the Consulting Agreement, dated June 28, 2017, by and between the Company and Healthcare Advisors GmbH, as amended (the "Consulting Agreement"), will remain in full force and effect and continue to govern your provision of services to the Company and you and the Company mutually agree that the Consulting Agreement will terminate on the Effective Date. This Letter Agreement sets forth the terms of your employment with the Company, should you accept our offer.

- 1. <u>Position and Duties</u>. You will be employed to serve as the Company's Chief Executive Officer, commencing employment on the Effective Date. You will be employed on a full-time basis and you will report to the Company's Board of Directors (the "Board") and have such duties and responsibilities as are customary for such position. You agree to devote your best efforts, skill, knowledge, attention and energies to the advancement of the Company's business and interests and to the performance of your duties and responsibilities as an employee of the Company. You agree to abide by the rules, regulations, personnel practices and policies of the Company and any changes therein that may be adopted from time to time by the Company. You shall have the flexibility to work remotely from your home as your duties permit, but at the request of the Board and/or as necessitated by business needs you shall also work out of the Company's office in Boston, Massachusetts (current expectation is up to two weeks per month but may vary in the Company's discretion based on business needs) and travel to other locations; provided, however, that the primary location where you perform work shall become Boston should the Board of Directors (the "Board") so determine at any time on or after the date that is 24 months following the Effective Date with 90 days' notice.
- 2. <u>Base Salary</u>. Your base salary will be at the rate of twenty-one thousand eight hundred seventy-five dollars (\$21,875) per regular semi-monthly pay period (annualized rate of five hundred twenty-five thousand dollars (\$525,000)), subject to tax and other withholdings as required by law, and will be paid in accordance with the Company's regularly established payroll procedure. Such base salary may be adjusted from time to time in accordance with normal business practice and in the sole discretion of the Company.
- 3. <u>Discretionary Bonus</u>. Following the end of each calendar year, and subject to the approval of the Board (or a committee thereof), you will be eligible for a discretionary retention and

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performance bonus, targeted at fifty-five percent (55%) of your gross base salary for the applicable calendar year, based on your individual performance and the Company's performance during the applicable calendar year, as determined by the Company in its sole discretion (the "<u>Discretionary Bonus</u>"). You must be an active employee of the Company on the date any bonus is distributed in order to be eligible for and to earn any bonus award, as it also serves as an incentive to remain employed by the Company. Any bonus hereunder will be awarded and paid before March 15<sup>th</sup> of the calendar year following that to which such bonus relates, and will be subject to tax and other withholdings as required by law. You acknowledge and agree that you will not be entitled to any Consulting Bonus as described in the Consulting Agreement.

## 4. Benefits and Expenses.

- a. You may participate in any and all benefit programs that the Company establishes and makes available to its employees from time to time, provided you are eligible under (and subject to all provisions of) the plan documents governing those programs; provided, however that in lieu of your participation in the Company's health insurance plan, the Company will reimburse you up to CHF1500 per month in order for you to obtain health insurance for you and your family. The benefit programs made available by the Company, and the rules, terms and conditions for participation in such benefit programs, may be changed by the Company at any time without advance notice (other than as required by such programs or under law).
- b. All reasonable business expenses that are documented by you and incurred in the ordinary course of business will be reimbursed in accordance with the Company's standard policies and procedures. Notwithstanding the foregoing, unless the Board otherwise determines (i) for up to 24 months following the Effective Date travel expenses for travel between your home and the Company's Boston area headquarters will be reimbursed in accordance with the Company's Travel and Expense Policy and (ii) beginning 24 months following the Effective Date, the Company will no longer reimburse you for travel expenses for travel between your home and the Company's Boston area headquarters.
- 5. Vacation. You will be eligible for paid vacation time in accordance with Company policy.
- 6. <u>Equity</u>. You will be granted, in connection with the initial public offering and subject to Board approval, options to acquire an aggregate of 2,649,144 shares of the Company's common stock at an exercise price equal to the price at which the underwriters sell shares to the public in the offering. The option is contingent on the occurrence of the initial public offering, will be granted under the Company's 2020 Stock Incentive Plan (the "<u>Plan</u>"), and will be subject to the Plan and such terms and conditions as are set forth in the applicable option agreement.
- 7. <u>Severance Benefits</u>. Effective on the date of the closing of the Company's initial public offering (the "Closing Date"), provided that you remain employed by the Company as of the Closing Date, you shall be eligible to receive the following severance benefits in accordance with the terms and conditions set forth below:
  - a. Termination by the Company without Cause or by You for Good Reason Not In Connection with a Change In Control. If your employment is terminated by the

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Company without Cause or you terminate your employment for Good Reason (each as defined below) and such termination does not take place during the sixty (60) day period prior to a Change in Control (as defined below) or the twelve (12) month period following a Change in Control, and provided you execute and allow to become effective (within 60 days following the termination or such shorter period as may be directed by the Company) a separation and release of claims agreement in a form to be provided by the Company on or about the termination (which will include, at a minimum, a release of all releasable claims, non-disparagement and cooperation obligations, a reaffirmation of your continuing obligations under any existing restrictive covenant agreements, and an agreement not to compete with the Company for twelve (12) months following your separation from employment) (a "Release Agreement"), the Company will provide you with the following severance benefits (subject to the terms of Appendix A hereto):

- i. The Company will pay you as severance pay an amount equivalent to twelve (12) months of your then current base salary, less all applicable taxes and withholdings, which severance pay will be paid in installments in accordance with the Company's regular payroll practices beginning in the Company's first regular payroll cycle after the Release Agreement becomes effective; provided, however, that if the 60th day referenced above occurs in the calendar year following the date of your termination, then the severance payments shall begin no earlier than January 1 of such subsequent calendar year.
- ii. Should you timely elect and be eligible to continue receiving group medical coverage pursuant to the "COBRA" law, and so long as the Company can provide such benefit without violating the nondiscrimination requirements of applicable law, the Company will continue to pay the share of the premium for such coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage until the earlier of (x) twelve (12) months following your termination date, or (y) the date upon which you commence full-time employment (or employment that provides you with eligibility for healthcare benefits substantially comparable to those provided by the Company) with an entity other than the Company. If applicable, the remaining balance of any premium costs shall timely be paid by you on a monthly basis for as long as, and to the extent that, you remain eligible for COBRA continuation.
- iii. The Company will pay you a pro-rated portion of the target Discretionary Bonus, if any, that the Board determines in good faith and in its sole discretion you would have received based on your individual performance and the Company's performance during the applicable calendar year until your date of termination, to be paid, less all applicable taxes and withholdings, in a lump sum on the date the first installment of severance pay is paid. For the avoidance of doubt, for purposes of calculating the amount due under this Section 7(b)(iii), your target Discretionary Bonus shall be equal to the percent described in Section 3 of your annualized base salary at the time of your termination.

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- b. **Termination by the Company without Cause or by You for Good Reason In Connection with a Change In Control.** If your employment is terminated by the Company without Cause or you terminate your employment for Good Reason and such termination takes place during the sixty (60) day period prior to a Change in Control (as defined below) or the twelve (12) month period following a Change in Control, and provided you execute and allow to become effective a Release Agreement, the Company will provide you with the following severance benefits (subject to the terms of Appendix A hereto):
  - i. The Company will pay you as severance pay an amount equivalent to eighteen (18) months of your then current base salary, less all applicable taxes and withholdings, which severance pay will be paid in installments in accordance with the Company's regular payroll practices beginning in the Company's first regular payroll cycle after the Release Agreement becomes effective; provided, however, that if the 60th day referenced above occurs in the calendar year following the date of your termination, then the severance payments shall begin no earlier than January 1 of such subsequent calendar year.
  - ii. Should you timely elect and be eligible to continue receiving group medical coverage pursuant to the "COBRA" law, and so long as the Company can provide such benefit without violating the nondiscrimination requirements of applicable law, the Company will continue to pay the share of the premium for such coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage until the earlier of (x) eighteen (18) months following your termination date, or (y) the date upon which you commence full-time employment (or employment that provides you with eligibility for healthcare benefits substantially comparable to those provided by the Company) with an entity other than the Company. If applicable, the remaining balance of any premium costs shall timely be paid by you on a monthly basis for as long as, and to the extent that, you remain eligible for COBRA continuation.
  - iii. The Company will pay you 150% of your annual target Discretionary Bonus, less all applicable taxes and withholdings, for the year in which your termination occurs in a lump sum on the date the first installment of severance pay is paid. For the avoidance of doubt, for purposes of calculating the amount due under this Section 7(b)(iii), your target Discretionary Bonus shall be equal to the percent of your annualized base salary at the time of your termination that is set forth in Section 3.
  - iv. All outstanding and unvested stock options and other equity awards in each case that vest solely based on continued service that are then held by you shall become fully vested and exercisable and, with respect to any stock options then held by you, those options shall remain exercisable for the period of time set forth in the applicable grant agreement; provided, however, that no such accelerated vesting shall occur unless and until the closing of a Change of Control which closing occurs within 60 days of the date of termination of your employment (the period between the date of termination of your employment and the closing of such a Change of Control, the "Interim Period"). During the Interim Period, any equity awards that were vested as of the

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date of termination shall continue to be subject to the terms of the respective original award agreements, and any equity awards that were unvested shall remain outstanding but shall not vest or become exercisable unless or until a Change of Control closes on or before the last day of the Interim Period.

- c. Definitions. For purposes of this Letter Agreement:
  - i. "Cause" means any of: (a) your conviction of, or plea of guilty or nolo contendere to, any crime involving dishonesty or moral turpitude or any felony; or (b) a good faith finding by the Company that you have (i) engaged in dishonesty, willful misconduct or gross negligence, (ii) committed an act that materially injures or would reasonably be expected to materially injure the reputation, business or business relationships of the Company, (iii) materially breached the terms of any agreement between you and the Company, including without limitation this Letter Agreement, the Restrictive Covenant Agreement (as defined below) or any other restrictive covenant or confidentiality agreement with the Company; or (iv) failed or refused to comply in any material respect with the Company's material policies or procedures.
  - ii. "Good Reason" means the occurrence, without your prior written consent, of any of the following events: (a) a material reduction in your authority, duties, or responsibilities; (b) the relocation of the principal place at which you provide services to the Company by at least 50 miles and to a location such that your daily commuting distance is increased, other than in connection with a decision by the Board at any time on or after the date that is 24 months following the Effective Date that your primary place of work will become Boston; (c) a material reduction of your base salary (except for across the board pay cuts of all management level employees of the Company); or (d) a material breach by the Company of its obligations under this Letter Agreement. No resignation will be treated as a resignation for Good Reason unless (i) you have given written notice to the Company of your intention to terminate your employment for Good Reason, describing the grounds for such action, no later than 90 days after the first occurrence of such circumstances, (ii) you have provided the Company with at least 30 days in which to cure the circumstances, and (iii) if the Company is not successful in curing the circumstances, you end your employment within 30 days following the cure period in (ii).
  - iii. "Change of Control" means any of the following events provided that such event also constitutes a "change in control event" within the meaning of Treasury Regulation Section 1.409A-3(i)(5):
  - (a) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act) (a "Person") of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 under the Exchange Act) 50% or more of either (x) the then-outstanding shares of common stock of the Company (the "Outstanding Company Common Stock") or (y) the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors (the

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"Outstanding Company Voting Securities"); provided, however, that for purposes of this subsection (A), the following acquisitions shall not constitute a Change in Control Event: (1) any acquisition directly from the Company (excluding an acquisition pursuant to the exercise, conversion or exchange of any security exercisable for, convertible into or exchangeable for common stock or voting securities of the Company, unless the Person exercising, converting or exchanging such security acquired such security directly from the Company or an underwriter or agent of the Company), (2) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlled by the Company, or (3) any acquisition by any corporation pursuant to a Business Combination (as defined below) which complies with clauses (x) and (y) of subsection (C) of this definition; or

- (b) a change in the composition of the Board that results in the Continuing Directors (as defined below) no longer constituting a majority of the Board (or, if applicable, the Board of Directors of a successor corporation to the Company), where the term "Continuing Director" means at any date a member of the Board (x) who was a member of the Board on the date of the initial adoption of the Plan by the Board or (y) who was nominated or elected subsequent to such date by at least a majority of the directors who were Continuing Directors at the time of such nomination or election or whose election to the Board was recommended or endorsed by at least a majority of the directors who were Continuing Directors at the time of such nomination or election; *provided*, *however*, that there shall be excluded from this clause (y) any individual whose initial assumption of office occurred as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents, by or on behalf of a person other than the Board: or
- (c) the consummation of a merger, consolidation, reorganization, recapitalization or share exchange involving the Company or a sale or other disposition of all or substantially all of the assets of the Company (a "Business Combination"), unless, immediately following such Business Combination, each of the following two conditions is satisfied: (x) all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Common Stock and Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the then-outstanding shares of common stock and the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one or more subsidiaries) (such resulting or acquiring corporation is referred to herein as the "Acquiring Corporation") in substantially the same proportions as their ownership of the Outstanding Company Common Stock and Outstanding Company Voting Securities, respectively, immediately prior to such Business Combination and (y) no Person (excluding any employee benefit plan (or related trust) maintained or sponsored by the Company or by the Acquiring Corporation) beneficially owns, directly or indirectly, 50% or more of the then-outstanding shares of common stock of the Acquiring Corporation, or of the combined voting power of the then-

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outstanding securities of such corporation entitled to vote generally in the election of directors (except to the extent that such ownership existed prior to the Business Combination); or

(d) the liquidation or dissolution of the Company.

For the avoidance of doubt, you will not be eligible for, nor shall you have a right to receive, any payments or benefits from the Company following your termination from employment other than as set forth in this Section 7.

# 8. Section 280G.

- a. Notwithstanding any other provision of this Letter Agreement, except as set forth in Section 8(b), in the event that the Company undergoes a "Change in Ownership or Control" (as defined below), the Company shall not be obligated to provide to you a portion of any "Contingent Compensation Payments" (as defined below) that you would otherwise be entitled to receive to the extent necessary to eliminate any "excess parachute payments" (as defined in Code Section 280G(b)(1)) for you. For purposes of this Section 8, the Contingent Compensation Payments so eliminated shall be referred to as the "Eliminated Payments" and the aggregate amount (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-30 or any successor provision) of the Contingent Compensation Payments so eliminated shall be referred to as the "Eliminated Amount."
- b. Notwithstanding the provisions of 8(a), no such reduction in Contingent Compensation Payments shall be made if the Eliminated Amount (computed without regard to this sentence) exceeds 100% of the aggregate present value (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-31 and Q/A-32 or any successor provisions) of the amount of any additional taxes that would be incurred by you if the Eliminated Payments (determined without regard to this sentence) were paid to you (including, state and federal income taxes on the Eliminated Payments, the excise tax imposed by Section 4999 of the Code payable with respect to all of the Contingent Compensation Payments in excess of your "base amount" (as defined in Section 280G(b)(3) of the Code), and any withholding taxes). The override of such reduction in Contingent Compensation Payments pursuant to this Section 8(b) shall be referred to as a "Section 8(b) Override." For purposes of this paragraph, if any federal or state income taxes would be attributable to the receipt of any Eliminated Payment, the amount of such taxes shall be computed by multiplying the amount of the Eliminated Payment by the maximum combined federal and state income tax rate provided by law.
  - c. For purposes of this Section 8 the following terms shall have the following respective meanings:
    - (I) "Change in Ownership or Control" shall mean a change in the ownership or effective control of the Company or in the ownership of a substantial portion of the assets of the Company determined in accordance with Section 280G(b)(2) of the Code.
    - (II) "Contingent Compensation Payment" shall mean any payment (or benefit) in the nature of compensation that is made or made available (under this letter agreement or

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otherwise) to a "disqualified individual" (as defined in Section 280G(c) of the Code) and that is contingent (within the meaning of Section 280G(b)(2)(A)(i) of the Code) on a Change in Ownership or Control of the Company.

d. Any payments or other benefits otherwise due to you following a Change in Ownership or Control that could reasonably be characterized (as determined by the Company) as Contingent Compensation Payments (the "Potential Payments") shall not be made until the dates provided for in this Section 8(d). Within 30 days after each date on which you first become entitled to receive (whether or not then due) a Contingent Compensation Payment relating to such Change in Ownership or Control, the Company shall determine and notify you (with reasonable detail regarding the basis for its determinations) (i) which Potential Payments constitute Contingent Compensation Payments, (ii) the Eliminated Amount and (iii) whether the Section 8(b) Override is applicable. Within 30 days after delivery of such notice to you, you shall deliver a response to the Company (the "Executive Response") stating either (A) that you agree with the Company's determination pursuant to the preceding sentence, or (B) that you disagree with such determination, in which case you shall set forth (i) which Potential Payments should be characterized as Contingent Compensation Payments, (ii) the Eliminated Amount, and (iii) whether the Section 8(b) Override is applicable. In the event that you fail to deliver an Executive Response on or before the required date, the Company's initial determination shall be final. If and to the extent that any Contingent Compensation Payments are required to be treated as Eliminated Payments pursuant to this Section 8, then the payments shall be reduced or eliminated, as determined by the Company, in the following order: (i) any cash payments, (ii) any taxable benefits, (iii) any nontaxable benefits, and (iv) any vesting of equity awards in each case in reverse order beginning with payments or benefits that are to be paid the farthest in time from the date that triggers the applicability of the excise tax, to the extent necessary to maximize the Eliminated Payments. If you state in the Executive Response that you agree with the Company's determination, the Company shall make the Potential Payments to you within three business days following delivery to the Company of the Executive Response (except for any Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). If you state in the Executive Response that you disagree with the Company's determination, then, for a period of 60 days following delivery of the Executive Response, you and the Company shall use good faith efforts to resolve such dispute. If such dispute is not resolved within such 60-day period. such dispute shall be settled exclusively by arbitration in the Commonwealth of Massachusetts, in accordance with the rules of the American Arbitration Association then in effect. Judgment may be entered on the arbitrator's award in any court having jurisdiction. The Company shall, within three business days following delivery to the Company of the Executive Response, make to you those Potential Payments as to which there is no dispute between the Company and you regarding whether they should be made (except for any such Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). The balance of the Potential Payments shall be made within three business days following the resolution of such dispute. Subject to the limitations contained in Sections 8(a) and 8(b) hereof, the amount of any payments to be made to you following the resolution of such dispute shall be increased by the amount of the accrued interest thereon computed at the prime rate announced from time to time by The Wall Street Journal, compounded monthly from the date that such payments originally were due.

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- e. The provisions of this Section 8 are intended to apply to any and all payments or benefits available to you under this letter agreement or any other agreement or plan of the Company under which you may receive Contingent Compensation Payments.
- 9. Restrictive Covenants/Absence of Restrictions. In exchange for your employment with the Company pursuant to the terms and conditions herein and, with respect to the non-competition provision, the grant of equity described in Section 6, you hereby agree to execute the enclosed Inventions, Non-Disclosure, Non-Competition and Non-Solicitation Agreement (the "Restrictive Covenant Agreement"). By executing this Letter Agreement, you acknowledge that your eligibility for the grant of equity set forth in Section 6 of this Letter Agreement is contingent upon your agreement to the non-competition provisions set forth in the Restrictive Covenant Agreement. You further acknowledge that such consideration was mutually agreed upon by you and the Company and is fair and reasonable in exchange for your compliance with such non-competition obligations and that you were provided at least ten (10) business days to review the Restrictive Covenant Agreement. You represent that you are not bound by any employment contract, restrictive covenant or other restriction preventing (or that purports to prevent) you from entering into employment with or carrying out your responsibilities for the Company, or which is in any way inconsistent with the terms of this Letter Agreement.
- 10. <u>Proof of Legal Right to Work.</u> You agree to provide to the Company, within three (3) days of your date of hire, documentation proving your eligibility to work in the United States, as required by the Immigration Reform and Control Act of 1986. You may need a work visa in order to be eligible to work in the United States. If that is the case, your employment with the Company will be conditioned upon your obtaining a work visa in a timely manner as determined by the Company.
- 11. <u>At-Will Employment</u>. This Letter Agreement shall not be construed as an agreement, either expressed or implied, to employ you for any stated term, and shall in no way alter the Company's policy of employment at will, under which both you and the Company remain free to terminate the employment relationship, with or without cause, at any time, with or without notice. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at-will" nature of your employment may only be changed by a written agreement signed by you and the Board, which expressly states the intention to modify the at-will nature of your employment. Similarly, nothing in this Letter Agreement shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company, except to the extent explicitly set forth in Section 7 hereof.
- 12. <u>Company Premises and Property.</u> The Company's premises, including all workspaces, furniture, documents, and other tangible materials, and all information technology resources of the Company (including computers, data and other electronic files, and all internet and email) are subject to oversight and inspection by the Company at any time. Company employees should have no expectation of privacy with regard to any Company premises, materials, resources, or information.
- 13. Entire Agreement/Governing Law. This Letter Agreement is your formal offer of employment and supersedes any and all prior or contemporaneous agreements, discussions and

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understandings, whether written or oral, relating to the subject matter of this Letter Agreement. This Letter Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts (without reference to the conflict of laws provisions thereof). Any action, suit or other legal proceeding arising under or relating to any provision of this Letter Agreement shall be commenced only in a court of the Commonwealth of Massachusetts (or, if appropriate, a federal court located within the Commonwealth of Massachusetts), and the Company and you each consents to the jurisdiction of such a court.

\* \* \*

If you would like to accept this offer of employment on the terms set forth herein as of the Effective Date, please sign and return this Letter Agreement on or before 5:00pm ET on Wednesday, July 1, 2020.

We look forward to you becoming an Inozyme employee and helping to build what we hope will be an exceptional organization.

Very Truly Yours,

By: /s/ Douglas A. Treco

Name: Douglas A. Treco

Title: Chairman of the Board of Directors

The foregoing correctly sets forth the terms of my employment by Inozyme Pharma, Inc. I am not relying on any representations other than those set forth above.

/s/ Axel Bolte	Date: July 1, 2020	
Name: Axel Bolte		



### APPENDIX A

## **Payments Subject to Section 409A**

- 1. Subject to this Appendix A, any severance payments that may be due under the Letter Agreement to which it is attached shall begin only upon the date of your "separation from service" (determined as set forth below) which occurs on or after the termination of your employment. The following rules shall apply with respect to distribution of the severance payments, if any, to be provided to you under the Letter Agreement, as applicable:
  - (a) It is intended that each installment of the severance payments under the Letter Agreement shall be treated as a separate "payment" for purposes of Section 409A of the Internal Revenue Code and the guidance issued thereunder ("Section 409A"). Neither the Company nor you shall have the right to accelerate or defer the delivery of any such payments except to the extent specifically permitted or required by Section 409A.
  - (b) If, as of the date of your "separation from service" from the Company, you are not a "specified employee" (within the meaning of Section 409A), then each installment of the severance payments shall be made on the dates and terms set forth in the Letter Agreement.
  - (c) If, as of the date of your "separation from service" from the Company, you are a "specified employee" (within the meaning of Section 409A), then:
    - (i) Each installment of the severance payments due under the Letter Agreement that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when your separation from service occurs, be paid within the short-term deferral period (as defined under Section 409A) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A and shall be paid on the dates and terms set forth in the Letter Agreement; and
    - (ii) Each installment of the severance payments due under the Letter Agreement that is not described in this Appendix A, Section 1(c)(i) and that would, absent this subsection, be paid within the six-month period following your "separation from service" from the Company shall not be paid until the date that is six months and one day after such separation from service (or, if earlier, your death) (the "New Payment Date"), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the New Payment Date and any subsequent installments, if any, being paid in accordance with the dates and terms set forth herein; provided, however, that the preceding provisions of this sentence shall not apply to any installment of

Axel Bolte Appendix A of Letter Agreement Page 2 of 2

payments if and to the maximum extent that such installment is deemed to be paid under a separation pay plan that does not provide for a deferral of compensation by reason of the application of Treasury Regulation 1.409A-1(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-1(b)(9)(iii) must be paid no later than the last day of your second taxable year following the taxable year in which the separation from service occurs.

- 2. The determination of whether and when your separation from service from the Company has occurred shall be made in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h). Solely for purposes of this Appendix A, Section 2, "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Internal Revenue Code.
- 3. All reimbursements and in-kind benefits provided under the Letter Agreement shall be made or provided in accordance with the requirements of Section 409A to the extent that such reimbursements or in-kind benefits are subject to Section 409A, including, where applicable, the requirements that (i) any reimbursement is for expenses incurred during your lifetime (or during a shorter period of time specified in the Letter Agreement), (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred and (iv) the right to reimbursement is not subject to set off or liquidation or exchange for any other benefit.
- 4. The Company makes no representation or warranty and shall have no liability to you or to any other person if any of the provisions of the Letter Agreement (including this Appendix) are determined to constitute deferred compensation subject to Section 409A but that do not satisfy an exemption from, or the conditions of, that section.



June 30, 2020

Henric Bjarke

Dear Henric:

This letter (the "Letter Agreement") amends and restates the terms and conditions of your employment with Inozyme Pharma, Inc. ("Inozyme" or the "Company"), as initially set forth in the offer letter dated June 22, 2017 and as amended if applicable (the "Original Offer Letter"), and will be effective as of the date on which the registration statement relating to the Company's initial public offering is effective (the "Effective Date"), provided that you remain employed by the Company as of the Effective Date. Until the Effective Date, the Original Offer Letter will remain in full force and effect and continue to govern your employment with the Company. This Letter Agreement contains the following terms:

- 1. <u>Position and Duties</u>. You will continue to be employed to serve as the Company's Senior Vice President and Chief Operating Officer. You will be employed on a full time basis, and you will report to the Company's Chief Executive Officer and have such duties and responsibilities as are customary for such position. You agree to devote your best efforts, skill, knowledge, attention and energies to the advancement of the Company's business and interests and to the performance of your duties and responsibilities as an employee of the Company. You agree to abide by the rules, regulations, personnel practices and policies of the Company and any changes therein that may be adopted from time to time by the Company. You will be primarily located in the Company's Boston area offices and may be required to travel as directed by the Company and consistent with the Company's business needs.
- 2. <u>Base Salary</u>. Your base salary will be at the rate of seventeen thousand nine hundred twenty five dollars (\$17,925) per regular semi-monthly pay period (annualized rate of four hundred thirty thousand two hundred dollars (\$430,200), subject to tax and other withholdings as required by law, and will be paid in accordance with the Company's regularly established payroll procedure. Such base salary may be adjusted from time to time in accordance with normal business practice and in the sole discretion of the Company.
- 3. <u>Discretionary Bonus</u>. Following the end of each calendar year, and subject to the approval of the Board (or a committee thereof), you will be eligible for a discretionary retention and performance bonus, targeted at forty percent (40%) of your gross base salary for the applicable calendar year, based on your individual performance and the Company's performance during the applicable calendar year, as determined by the Company in its sole discretion (the "<u>Discretionary Bonus</u>"). You must be an active employee of the Company on the date any bonus is distributed in order to be eligible for and to earn any bonus award, as it also serves as an incentive to remain employed by the Company. Any bonus hereunder will be awarded and paid before March 15th of the calendar year following that to which such bonus relates, and will be subject to tax and other withholdings as required by law.

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## 4. Benefits and Expenses.

- a. You may continue to participate in any and all benefit programs that the Company establishes and makes available to its employees from time to time, provided you are eligible under (and subject to all provisions of) the plan documents governing those programs. The benefit programs made available by the Company, and the rules, terms and conditions for participation in such benefit programs, may be changed by the Company at any time without advance notice (other than as required by such programs or under law).
- b. All reasonable business expenses that are documented by you and incurred in the ordinary course of business will be reimbursed in accordance with the Company's standard policies and procedures. Notwithstanding the foregoing, unless the Board determines otherwise (i) for up to 24 months following the Effective Date, the Company will reimburse you for travel expenses between your home and the Company's Boston area headquarters in accordance with the Company's Travel and Expense Policy, subject to applicable withholding which amount shall be paid to you on a "grossed up" basis and (ii) beginning 24 months following the Effective Date, the Company will no longer reimburse you for travel expenses for travel between your home and the Company's Boston area headquarters.
- 5. <u>Vacation</u>. You will continue to be eligible for paid vacation time in accordance with Company policy.
- 6. <u>Equity.</u> You will be granted, in connection with the initial public offering and subject to Board approval, an option to acquire 245,905 shares of the Company's common stock at an exercise price equal to the price at which the underwriters sell shares to the public in the offering. The option is contingent on the occurrence of the initial public offering, will be granted under the Company's 2020 Stock Incentive Plan (the "<u>Plan</u>"), and will be subject to the Plan and such terms and conditions as are set forth in the applicable option agreement.
- 7. <u>Severance Benefits</u>. Effective on the date of the closing of the Company's initial public offering (the "Closing Date"), provided that you remain employed by the Company as of the Closing Date, you shall be eligible to receive the following severance benefits in accordance with the terms and conditions set forth below:
  - a. **Termination by the Company without Cause or by You for Good Reason Not In Connection with a Change In Control.** If your employment is terminated by the Company without Cause or you terminate your employment for Good Reason (each as defined below) and such termination does not take place during the twelve (12) month period following a Change in Control (as defined below), and provided you execute and allow to become effective (within 60 days following the termination or such shorter period as may be directed by the Company) a separation and release of claims agreement in a form to be provided by the Company on or about the termination (which will include, at a minimum, a release of all releasable claims, non-disparagement and cooperation obligations, a reaffirmation of your continuing obligations under any existing restrictive

Henric Bjarke Letter Agreement Page 3 of 9

covenant agreements, and an agreement not to compete with the Company for twelve (12) months following your separation from employment) (a "Release Agreement"), the Company will provide you with the following severance benefits (subject to the terms of Appendix A hereto):

- i. The Company will pay you as severance pay an amount equivalent to nine (9) months of your then current base salary, less all applicable taxes and withholdings, which severance pay will be paid in installments in accordance with the Company's regular payroll practices beginning in the Company's first regular payroll cycle after the Release Agreement becomes effective; provided, however, that if the 60th day referenced above occurs in the calendar year following the date of your termination, then the severance payments shall begin no earlier than January 1 of such subsequent calendar year.
- ii. Should you timely elect and be eligible to continue receiving group medical coverage pursuant to the "COBRA" law, and so long as the Company can provide such benefit without violating the nondiscrimination requirements of applicable law, the Company will continue to pay the share of the premium for such coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage until the earlier of (x) nine (9) months following your termination date, or (y) the date upon which you commence full-time employment (or employment that provides you with eligibility for healthcare benefits substantially comparable to those provided by the Company) with an entity other than the Company. If applicable, the remaining balance of any premium costs shall timely be paid by you on a monthly basis for as long as, and to the extent that, you remain eligible for COBRA continuation.
- b. **Termination by the Company without Cause or by You for Good Reason In Connection with a Change In Control.** If your employment is terminated by the Company without Cause or you terminate your employment for Good Reason and such termination takes place during the twelve (12) month period following a Change in Control (as defined below), and provided you execute and allow to become effective a Release Agreement, the Company will provide you with the following severance benefits (subject to the terms of Appendix A hereto):
  - i. The Company will pay you as severance pay an amount equivalent to twelve (12) months of your then current base salary, less all applicable taxes and withholdings, which severance pay will be paid in installments in accordance with the Company's regular payroll practices beginning in the Company's first regular payroll cycle after the Release Agreement becomes effective; provided, however, that if the 60th day referenced above occurs in the calendar year following the date of your termination, then the severance payments shall begin no earlier than January 1 of such subsequent calendar year.
  - ii. Should you timely elect and be eligible to continue receiving group medical coverage pursuant to the "COBRA" law, and so long as the Company can provide such benefit

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without violating the nondiscrimination requirements of applicable law, the Company will continue to pay the share of the premium for such coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage until the earlier of (x) twelve (12) months following your termination date, or (y) the date upon which you commence full-time employment (or employment that provides you with eligibility for healthcare benefits substantially comparable to those provided by the Company) with an entity other than the Company. If applicable, the remaining balance of any premium costs shall timely be paid by you on a monthly basis for as long as, and to the extent that, you remain eligible for COBRA continuation.

- iii. The Company will pay you 100% of your annual target Discretionary Bonus, less all applicable taxes and withholdings, for the year in which your termination occurs in a lump sum on the date the first installment of severance pay is paid. For the avoidance of doubt, for purposes of calculating the amount due under this Section 7(b)(iii), your target Discretionary Bonus shall be equal to the percent of your annualized base salary at the time of your termination that is set forth in Section 3.
- iv. All outstanding and unvested stock options and other equity awards in each case that vest solely based on continued service that are then held by you shall become fully vested and exercisable and, with respect to any stock options then held by you, those options shall remain exercisable for the period of time set forth in the applicable grant agreement.

## c. Definitions. For purposes of this Letter Agreement:

- i. "Cause" means any of: (a) your conviction of, or plea of guilty or nolo contendere to, any crime involving dishonesty or moral turpitude or any felony; (b) a good faith finding by the Company that you have (i) engaged in dishonesty, willful misconduct or gross negligence, (ii) committed an act that materially injures or would reasonably be expected to materially injure the reputation, business or business relationships of the Company, (iii) materially breached the terms of any agreement between you and the Company, including without limitation this Letter Agreement, the Restrictive Covenant Agreement (as defined below) or any other restrictive covenant or confidentiality agreement with the Company; or (iv) failed or refused to comply in any material respect with the Company's material policies or procedures.
- ii. "Good Reason" means the occurrence, without your prior written consent, of any of the following events: (a) a material reduction in your authority, duties, or responsibilities; (b) the relocation of the principal place at which you provide services to the Company by at least 50 miles and to a location such that your daily commuting distance is increased; (c) a material reduction of your base salary (except for across the board pay cuts of all management level employees of the Company); or (d) a material breach by the Company of its obligations under this Letter Agreement. No resignation will be treated as a resignation for Good Reason unless (i) you have given written notice to the Company of your intention to terminate your employment for

Henric Bjarke Letter Agreement Page 5 of 9

- Good Reason, describing the grounds for such action, no later than 90 days after the first occurrence of such circumstances, (ii) you have provided the Company with at least 30 days in which to cure the circumstances, and (iii) if the Company is not successful in curing the circumstances, you end your employment within 30 days following the cure period in (ii).
- iii. "<u>Change of Control</u>" means any of the following events provided that such event also constitutes a "change in control event" within the meaning of Treasury Regulation Section 1.409A-3(i)(5):
- (a) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act) (a "Person") of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 under the Exchange Act) 50% or more of either (x) the then-outstanding shares of common stock of the Company (the "Outstanding Company Common Stock") or (y) the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors (the "Outstanding Company Voting Securities"); provided, however, that for purposes of this subsection (A), the following acquisitions shall not constitute a Change in Control Event: (1) any acquisition directly from the Company (excluding an acquisition pursuant to the exercise, conversion or exchange of any security exercisable for, convertible into or exchangeable for common stock or voting securities of the Company, unless the Person exercising, converting or exchanging such security acquired such security directly from the Company or an underwriter or agent of the Company), (2) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlled by the Company, or (3) any acquisition by any corporation pursuant to a Business Combination (as defined below) which complies with clauses (x) and (y) of subsection (C) of this definition; or
- (b) a change in the composition of the Board that results in the Continuing Directors (as defined below) no longer constituting a majority of the Board (or, if applicable, the Board of Directors of a successor corporation to the Company), where the term "Continuing Director" means at any date a member of the Board (x) who was a member of the Board on the date of the initial adoption of the Plan by the Board or (y) who was nominated or elected subsequent to such date by at least a majority of the directors who were Continuing Directors at the time of such nomination or election or whose election to the Board was recommended or endorsed by at least a majority of the directors who were Continuing Directors at the time of such nomination or election; *provided*, *however*, that there shall be excluded from this clause (y) any individual whose initial assumption of office occurred as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents, by or on behalf of a person other than the Board; or
- (c) the consummation of a merger, consolidation, reorganization, recapitalization or share exchange involving the Company or a sale or other disposition of all or substantially all of the assets of the Company (a "Business Combination"), unless, immediately following

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such Business Combination, each of the following two conditions is satisfied: (x) all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Common Stock and Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the then-outstanding shares of common stock and the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one or more subsidiaries) (such resulting or acquiring corporation is referred to herein as the "Acquiring Corporation") in substantially the same proportions as their ownership of the Outstanding Company Common Stock and Outstanding Company Voting Securities, respectively, immediately prior to such Business Combination and (y) no Person (excluding any employee benefit plan (or related trust) maintained or sponsored by the Company or by the Acquiring Corporation) beneficially owns, directly or indirectly, 50% or more of the then-outstanding shares of common stock of the Acquiring Corporation, or of the combined voting power of the then-outstanding securities of such corporation entitled to vote generally in the election of directors (except to the extent that such ownership existed prior to the Business Combination); or

(d) the liquidation or dissolution of the Company.

For the avoidance of doubt, you will not be eligible for, nor shall you have a right to receive, any payments or benefits from the Company following your termination from employment other than as set forth in this Section 7; provided, however, that if your employment terminates between the Effective Date and the Closing Date under circumstances that would have entitled you to severance under the Original Offer Letter, then such severance will be paid on the terms and subject to the conditions described in the Original Offer Letter.

### 8. Section 280G.

- a. Notwithstanding any other provision of this Letter Agreement, except as set forth in Section 8(b), in the event that the Company undergoes a "Change in Ownership or Control" (as defined below), the Company shall not be obligated to provide to you a portion of any "Contingent Compensation Payments" (as defined below) that you would otherwise be entitled to receive to the extent necessary to eliminate any "excess parachute payments" (as defined in Code Section 280G(b)(1)) for you. For purposes of this Section 8, the Contingent Compensation Payments so eliminated shall be referred to as the "Eliminated Payments" and the aggregate amount (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-30 or any successor provision) of the Contingent Compensation Payments so eliminated shall be referred to as the "Eliminated Amount."
- b. Notwithstanding the provisions of 8(a), no such reduction in Contingent Compensation Payments shall be made if the Eliminated Amount (computed without regard to this sentence) exceeds 100% of the aggregate present value (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-31 and Q/A-32 or any successor provisions) of the amount of any additional taxes that would be incurred by you if the Eliminated Payments (determined without regard to this sentence) were paid to you (including, state and federal income taxes on the

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Eliminated Payments, the excise tax imposed by Section 4999 of the Code payable with respect to all of the Contingent Compensation Payments in excess of your "base amount" (as defined in Section 280G(b)(3) of the Code), and any withholding taxes). The override of such reduction in Contingent Compensation Payments pursuant to this Section 8(b) shall be referred to as a "Section 8(b) Override." For purposes of this paragraph, if any federal or state income taxes would be attributable to the receipt of any Eliminated Payment, the amount of such taxes shall be computed by multiplying the amount of the Eliminated Payment by the maximum combined federal and state income tax rate provided by law.

- c. For purposes of this Section 8 the following terms shall have the following respective meanings:
  - (I) "Change in Ownership or Control" shall mean a change in the ownership or effective control of the Company or in the ownership of a substantial portion of the assets of the Company determined in accordance with Section 280G(b)(2) of the Code.
  - (II) "Contingent Compensation Payment" shall mean any payment (or benefit) in the nature of compensation that is made or made available (under this letter agreement or otherwise) to a "disqualified individual" (as defined in Section 280G(c) of the Code) and that is contingent (within the meaning of Section 280G(b)(2)(A)(i) of the Code) on a Change in Ownership or Control of the Company.
- d. Any payments or other benefits otherwise due to you following a Change in Ownership or Control that could reasonably be characterized (as determined by the Company) as Contingent Compensation Payments (the "Potential Payments") shall not be made until the dates provided for in this Section 8(d). Within 30 days after each date on which you first become entitled to receive (whether or not then due) a Contingent Compensation Payment relating to such Change in Ownership or Control, the Company shall determine and notify you (with reasonable detail regarding the basis for its determinations) (i) which Potential Payments constitute Contingent Compensation Payments, (ii) the Eliminated Amount and (iii) whether the Section 8(b) Override is applicable. Within 30 days after delivery of such notice to you, you shall deliver a response to the Company (the "Executive Response") stating either (A) that you agree with the Company's determination pursuant to the preceding sentence, or (B) that you disagree with such determination, in which case you shall set forth (i) which Potential Payments should be characterized as Contingent Compensation Payments, (ii) the Eliminated Amount, and (iii) whether the Section 8(b) Override is applicable. In the event that you fail to deliver an Executive Response on or before the required date, the Company's initial determination shall be final. If and to the extent that any Contingent Compensation Payments are required to be treated as Eliminated Payments pursuant to this Section 8, then the payments shall be reduced or eliminated, as determined by the Company, in the following order: (i) any cash payments, (ii) any taxable benefits, (iii) any nontaxable benefits, and (iv) any vesting of equity awards in each case in reverse order beginning with payments or benefits that are to be paid the farthest in time from the date that triggers the applicability of the excise tax, to the extent necessary to maximize the Eliminated Payments. If you state in the Executive Response that you agree with the Company's determination, the Company shall make the Potential Payments to you within three business days following delivery to the Company of the Executive Response (except for any Potential Payments which are not due to be made until after such date, which

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Potential Payments shall be made on the date on which they are due). If you state in the Executive Response that you disagree with the Company's determination, then, for a period of 60 days following delivery of the Executive Response, you and the Company shall use good faith efforts to resolve such dispute. If such dispute is not resolved within such 60-day period, such dispute shall be settled exclusively by arbitration in the Commonwealth of Massachusetts, in accordance with the rules of the American Arbitration Association then in effect. Judgment may be entered on the arbitrator's award in any court having jurisdiction. The Company shall, within three business days following delivery to the Company of the Executive Response, make to you those Potential Payments as to which there is no dispute between the Company and you regarding whether they should be made (except for any such Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). The balance of the Potential Payments shall be made within three business days following the resolution of such dispute. Subject to the limitations contained in Sections 8(a) and 8(b) hereof, the amount of any payments to be made to you following the resolution of such dispute shall be increased by the amount of the accrued interest thereon computed at the prime rate announced from time to time by The Wall Street Journal, compounded monthly from the date that such payments originally were due.

- e. The provisions of this Section 8 are intended to apply to any and all payments or benefits available to you under this letter agreement or any other agreement or plan of the Company under which you may receive Contingent Compensation Payments.
- 9. <u>Restrictive Covenants/Absence of Restrictions</u>. You acknowledge that your Inventions, Non-Disclosure, Non-Competition and Non-Solicitation Agreement dated June 23, 2017 (the "<u>Restrictive Covenant Agreement</u>") remains in full force and effect and unaltered in all respects. You represent that you are not bound by any employment contract, restrictive covenant or other restriction preventing (or that purports to prevent) you from entering into employment with or carrying out your responsibilities for the Company, or which is in any way inconsistent with the terms of this Letter Agreement.
- 10. <u>At-Will Employment</u>. This Letter Agreement shall not be construed as an agreement, either expressed or implied, to employ you for any stated term, and shall in no way alter the Company's policy of employment at will, under which both you and the Company remain free to terminate the employment relationship, with or without cause, at any time, with or without notice. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at-will" nature of your employment may only be changed by a written agreement signed by you and the Chief Executive Officer, which expressly states the intention to modify the at-will nature of your employment. Similarly, nothing in this Letter Agreement shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company, except to the extent explicitly set forth in Section 7 hereof.
- 11. <u>Company Premises and Property</u>. The Company's premises, including all workspaces, furniture, documents, and other tangible materials, and all information technology resources of the Company (including computers, data and other electronic files, and all internet and email) are subject to oversight and inspection by the Company at any time. Company employees should have no expectation of privacy with regard to any Company premises, materials, resources, or information.

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12. Entire Agreement/Governing Law. This Letter Agreement is your formal offer of employment and supersedes any and all prior or contemporaneous agreements (including, but not limited to, the Original Offer Letter), discussions and understandings, whether written or oral, relating to the subject matter of this Letter Agreement; provided, however, and for the avoidance of doubt, nothing herein shall be deemed to supersede the Restrictive Covenant Agreement, which remains in full force and effect. This Letter Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts (without reference to the conflict of laws provisions thereof). Any action, suit or other legal proceeding arising under or relating to any provision of this Letter Agreement shall be commenced only in a court of the Commonwealth of Massachusetts (or, if appropriate, a federal court located within the Commonwealth of Massachusetts), and the Company and you each consents to the jurisdiction of such a court.

If you would like to accept this offer of continued employment on the terms set forth herein as of the Effective Date, please sign and return this Letter Agreement on or before 5:00pm ET, Wednesday, July 1, 2020.

We look forward to you continuing to be part of the Inozyme team and helping to build what we hope will be an exceptional organization.

Very Truly Yours,

/s/ Axel Bolte By:

Name: Axel Bolte

Title: Chief Executive Officer

The foregoing correctly sets forth the terms of my employment by Inozyme Pharma, Inc. I am not relying on any representations other than those set forth above.

/s/ Henric Bjarke Date: July 1, 2020

Name: Henric Bjarke



#### APPENDIX A

## **Payments Subject to Section 409A**

- 1. Subject to this Appendix A, any severance payments that may be due under the Letter Agreement to which it is attached shall begin only upon the date of your "separation from service" (determined as set forth below) which occurs on or after the termination of your employment. The following rules shall apply with respect to distribution of the severance payments, if any, to be provided to you under the Letter Agreement, as applicable:
  - (a) It is intended that each installment of the severance payments under the Letter Agreement shall be treated as a separate "payment" for purposes of Section 409A of the Internal Revenue Code and the guidance issued thereunder ("Section 409A"). Neither the Company nor you shall have the right to accelerate or defer the delivery of any such payments except to the extent specifically permitted or required by Section 409A.
  - (b) If, as of the date of your "separation from service" from the Company, you are not a "specified employee" (within the meaning of Section 409A), then each installment of the severance payments shall be made on the dates and terms set forth in the Letter Agreement.
  - (c) If, as of the date of your "separation from service" from the Company, you are a "specified employee" (within the meaning of Section 409A), then:
    - (i) Each installment of the severance payments due under the Letter Agreement that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when your separation from service occurs, be paid within the short-term deferral period (as defined under Section 409A) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A and shall be paid on the dates and terms set forth in the Letter Agreement; and
    - (ii) Each installment of the severance payments due under the Letter Agreement that is not described in this Appendix A, Section 1(c)(i) and that would, absent this subsection, be paid within the six-month period following your "separation from service" from the Company shall not be paid until the date that is six months and one day after such separation from service (or, if earlier, your death) (the "New Payment Date"), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the New Payment Date and any subsequent installments, if any, being paid in accordance with the dates and terms set forth herein; provided, however, that the preceding provisions of this sentence shall not apply to any installment of

Henric Bjarke Appendix A of Letter Agreement Page 2 of 2

payments if and to the maximum extent that such installment is deemed to be paid under a separation pay plan that does not provide for a deferral of compensation by reason of the application of Treasury Regulation 1.409A-1(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-1(b)(9)(iii) must be paid no later than the last day of your second taxable year following the taxable year in which the separation from service occurs.

- 2. The determination of whether and when your separation from service from the Company has occurred shall be made in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h). Solely for purposes of this Appendix A, Section 2, "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Internal Revenue Code.
- 3. All reimbursements and in-kind benefits provided under the Letter Agreement shall be made or provided in accordance with the requirements of Section 409A to the extent that such reimbursements or in-kind benefits are subject to Section 409A, including, where applicable, the requirements that (i) any reimbursement is for expenses incurred during your lifetime (or during a shorter period of time specified in the Letter Agreement), (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred and (iv) the right to reimbursement is not subject to set off or liquidation or exchange for any other benefit.
- 4. The Company makes no representation or warranty and shall have no liability to you or to any other person if any of the provisions of the Letter Agreement (including this Appendix) are determined to constitute deferred compensation subject to Section 409A but that do not satisfy an exemption from, or the conditions of, that section.



June 30, 2020

Steven Jungles

Dear Steve:

This letter (the "Letter Agreement") amends and restates the terms and conditions of your employment with Inozyme Pharma, Inc. ("Inozyme" or the "Company"), as initially set forth in the offer letter dated April 18, 2017 and as amended if applicable (the "Original Offer Letter"), and will be effective as of the date on which the registration statement relating to the Company's initial public offering is effective (the "Effective Date"), provided that you remain employed by the Company as of the Effective Date. Until the Effective Date, the Original Offer Letter will remain in full force and effect and continue to govern your employment with the Company. This Letter Agreement contains the following terms:

- 1. <u>Position and Duties</u>. You will continue to be employed to serve as the Company's Senior Vice President and Chief Technical Operations Officer. You will be employed on a full time basis, and you will report to the Company's Chief Executive Officer and have such duties and responsibilities as are customary for such position. You agree to devote your best efforts, skill, knowledge, attention and energies to the advancement of the Company's business and interests and to the performance of your duties and responsibilities as an employee of the Company. You agree to abide by the rules, regulations, personnel practices and policies of the Company and any changes therein that may be adopted from time to time by the Company. You shall have the flexibility to work remotely from your home as your duties permit, but at the request of the Chief Executive Officer and/or as necessitated by business needs you shall also work out of the Company's office in Boston, Massachusetts (current expectation is up to two weeks per month but may vary in the Company's discretion based on business needs) and travel to other locations; provided, however, that the primary location where you perform work shall become Boston should the Board of Directors (the "Board") so determine at any time on or after the date that is 24 months following the Effective Date with 90 days' notice.
- 2. <u>Base Salary</u>. Your base salary will be at the rate of sixteen thousand ninety one dollars and sixty seven cents (\$16,091.67) per regular semimonthly pay period (annualized rate of three hundred eight six thousand two hundred dollars (\$386,200), subject to tax and other withholdings as required by law, and will be paid in accordance with the Company's regularly established payroll procedure. Such base salary may be adjusted from time to time in accordance with normal business practice and in the sole discretion of the Company.
- 3. <u>Discretionary Bonus</u>. Following the end of each calendar year, and subject to the approval of the Board (or a committee thereof), you will be eligible for a discretionary retention and performance bonus, targeted at forty percent (40%) of your gross base salary for the applicable calendar year, based on your individual performance and the Company's performance during the

Steven Jungles Letter Agreement Page 2 of 9

applicable calendar year, as determined by the Company in its sole discretion (the "<u>Discretionary Bonus</u>"). You must be an active employee of the Company on the date any bonus is distributed in order to be eligible for and to earn any bonus award, as it also serves as an incentive to remain employed by the Company. Any bonus hereunder will be awarded and paid before March 15<sup>th</sup> of the calendar year following that to which such bonus relates, and will be subject to tax and other withholdings as required by law.

#### 4. Benefits and Expenses.

- a. You may continue to participate in any and all benefit programs that the Company establishes and makes available to its employees from time to time, provided you are eligible under (and subject to all provisions of) the plan documents governing those programs. The benefit programs made available by the Company, and the rules, terms and conditions for participation in such benefit programs, may be changed by the Company at any time without advance notice (other than as required by such programs or under law).
- b. All reasonable business expenses that are documented by you and incurred in the ordinary course of business will be reimbursed in accordance with the Company's standard policies and procedures. Notwithstanding the foregoing, unless the Board otherwise determines (i) for up to 24 months following the Effective Date travel expenses for travel between your home and the Company's Boston area headquarters will be reimbursed in accordance with the Company's Travel and Expense Policy and (ii) beginning 24 months following the Effective Date, the Company will no longer reimburse you for travel expenses for travel between your home and the Company's Boston area headquarters.
- 5. Vacation. You will continue to be eligible for paid vacation time in accordance with Company policy.
- 6. <u>Severance Benefits</u>. Effective on the date of the closing of the Company's initial public offering (the "Closing Date"), provided that you remain employed by the Company as of the Closing Date, you shall be eligible to receive the following severance benefits in accordance with the terms and conditions set forth below:
  - a. **Termination by the Company without Cause or by You for Good Reason Not In Connection with a Change In Control.** If your employment is terminated by the Company without Cause or you terminate your employment for Good Reason (each as defined below) and such termination does not take place during the twelve (12) month period following a Change in Control (as defined below), and provided you execute and allow to become effective (within 60 days following the termination or such shorter period as may be directed by the Company) a separation and release of claims agreement in a form to be provided by the Company on or about the termination (which will include, at a minimum, a release of all releasable claims, non-disparagement and cooperation obligations, a reaffirmation of your continuing obligations under any existing restrictive covenant agreements, and an agreement not to compete with the Company for twelve (12) months following your separation from employment) (a "Release Agreement"), the Company will provide you with the following severance benefits (subject to the terms of Appendix A hereto):

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- i. The Company will pay you as severance pay an amount equivalent to nine (9) months of your then current base salary, less all applicable taxes and withholdings, which severance pay will be paid in installments in accordance with the Company's regular payroll practices beginning in the Company's first regular payroll cycle after the Release Agreement becomes effective; provided, however, that if the 60th day referenced above occurs in the calendar year following the date of your termination, then the severance payments shall begin no earlier than January 1 of such subsequent calendar year.
- ii. Should you timely elect and be eligible to continue receiving group medical coverage pursuant to the "COBRA" law, and so long as the Company can provide such benefit without violating the nondiscrimination requirements of applicable law, the Company will continue to pay the share of the premium for such coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage until the earlier of (x) nine (9) months following your termination date, or (y) the date upon which you commence full-time employment (or employment that provides you with eligibility for healthcare benefits substantially comparable to those provided by the Company) with an entity other than the Company. If applicable, the remaining balance of any premium costs shall timely be paid by you on a monthly basis for as long as, and to the extent that, you remain eligible for COBRA continuation.
- b. **Termination by the Company without Cause or by You for Good Reason In Connection with a Change In Control.** If your employment is terminated by the Company without Cause or you terminate your employment for Good Reason and such termination takes place during the twelve (12) month period following a Change in Control (as defined below), and provided you execute and allow to become effective a Release Agreement, the Company will provide you with the following severance benefits (subject to the terms of Appendix A hereto):
  - i. The Company will pay you as severance pay an amount equivalent to twelve (12) months of your then current base salary, less all applicable taxes and withholdings, which severance pay will be paid in installments in accordance with the Company's regular payroll practices beginning in the Company's first regular payroll cycle after the Release Agreement becomes effective; provided, however, that if the 60th day referenced above occurs in the calendar year following the date of your termination, then the severance payments shall begin no earlier than January 1 of such subsequent calendar year.
  - ii. Should you timely elect and be eligible to continue receiving group medical coverage pursuant to the "COBRA" law, and so long as the Company can provide such benefit without violating the nondiscrimination requirements of applicable law, the Company will continue to pay the share of the premium for such coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage until the earlier of (x) twelve (12) months following your termination date, or (y) the date upon which you commence full-time employment (or employment that

Steven Jungles Letter Agreement Page 4 of 9

- provides you with eligibility for healthcare benefits substantially comparable to those provided by the Company) with an entity other than the Company. If applicable, the remaining balance of any premium costs shall timely be paid by you on a monthly basis for as long as, and to the extent that, you remain eligible for COBRA continuation.
- iii. The Company will pay you 100% of your annual target Discretionary Bonus, less all applicable taxes and withholdings, for the year in which your termination occurs in a lump sum on the date the first installment of severance pay is paid. For the avoidance of doubt, for purposes of calculating the amount due under this Section 6(b)(iii), your target Discretionary Bonus shall be equal to the percent of your annualized base salary at the time of your termination that is set forth in Section 3.
- iv. All outstanding and unvested stock options and other equity awards in each case that vest solely based on continued service that are then held by you shall become fully vested and exercisable and, with respect to any stock options then held by you, those options shall remain exercisable for the period of time set forth in the applicable grant agreement.
- c. Definitions. For purposes of this Letter Agreement:
  - i. "Cause" means any of: (a) your conviction of, or plea of guilty or nolo contendere to, any crime involving dishonesty or moral turpitude or any felony; (b) a good faith finding by the Company that you have (i) engaged in dishonesty, willful misconduct or gross negligence, (ii) committed an act that materially injures or would reasonably be expected to materially injure the reputation, business or business relationships of the Company, (iii) materially breached the terms of any agreement between you and the Company, including without limitation this Letter Agreement, the Restrictive Covenant Agreement (as defined below) or any other restrictive covenant or confidentiality agreement with the Company; or (iv) failed or refused to comply in any material respect with the Company's material policies or procedures
  - ii. "Good Reason" means the occurrence, without your prior written consent, of any of the following events: (a) a material reduction in your authority, duties, or responsibilities; (b) the relocation of the principal place at which you provide services to the Company by at least 50 miles and to a location such that your daily commuting distance is increased, other than in connection with a decision by the Board at any time on or after the date that is 24 months following the Effective Date that your primary place of work will become Boston; (c) a material reduction of your base salary (except for across the board pay cuts of all management level employees of the Company); or (d) a material breach by the Company of its obligations under this Letter Agreement. No resignation will be treated as a resignation for Good Reason unless (i) you have given written notice to the Company of your intention to terminate your employment for Good Reason, describing the grounds for such action, no later than 90 days after the first occurrence of such circumstances, (ii) you have provided the Company with at least 30 days in which to cure the circumstances, and (iii) if the Company is not successful in curing the circumstances, you end your employment within 30 days following the cure period in (ii).

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- iii. "<u>Change of Control</u>" means any of the following events provided that such event also constitutes a "change in control event" within the meaning of Treasury Regulation Section 1.409A-3(i)(5):
- (a) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act) (a "Person") of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 under the Exchange Act) 50% or more of either (x) the then-outstanding shares of common stock of the Company (the "Outstanding Company Common Stock") or (y) the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors (the "Outstanding Company Voting Securities"); provided, however, that for purposes of this subsection (A), the following acquisitions shall not constitute a Change in Control Event: (1) any acquisition directly from the Company (excluding an acquisition pursuant to the exercise, conversion or exchange of any security exercisable for, convertible into or exchangeable for common stock or voting securities of the Company, unless the Person exercising, converting or exchanging such security acquired such security directly from the Company or an underwriter or agent of the Company), (2) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlled by the Company, or (3) any acquisition by any corporation pursuant to a Business Combination (as defined below) which complies with clauses (x) and (y) of subsection (C) of this definition; or
- (b) a change in the composition of the Board that results in the Continuing Directors (as defined below) no longer constituting a majority of the Board (or, if applicable, the Board of Directors of a successor corporation to the Company), where the term "Continuing Director" means at any date a member of the Board (x) who was a member of the Board on the date of the initial adoption of the Plan by the Board or (y) who was nominated or elected subsequent to such date by at least a majority of the directors who were Continuing Directors at the time of such nomination or election or whose election to the Board was recommended or endorsed by at least a majority of the directors who were Continuing Directors at the time of such nomination or election; *provided*, *however*, that there shall be excluded from this clause (y) any individual whose initial assumption of office occurred as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents, by or on behalf of a person other than the Board: or
- (c) the consummation of a merger, consolidation, reorganization, recapitalization or share exchange involving the Company or a sale or other disposition of all or substantially all of the assets of the Company (a "Business Combination"), unless, immediately following such Business Combination, each of the following two conditions is satisfied: (x) all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Common Stock and Outstanding Company Voting Securities

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immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the then-outstanding shares of common stock and the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one or more subsidiaries) (such resulting or acquiring corporation is referred to herein as the "Acquiring Corporation") in substantially the same proportions as their ownership of the Outstanding Company Common Stock and Outstanding Company Voting Securities, respectively, immediately prior to such Business Combination and (y) no Person (excluding any employee benefit plan (or related trust) maintained or sponsored by the Company or by the Acquiring Corporation) beneficially owns, directly or indirectly, 50% or more of the then-outstanding shares of common stock of the Acquiring Corporation, or of the combined voting power of the then-outstanding securities of such corporation entitled to vote generally in the election of directors (except to the extent that such ownership existed prior to the Business Combination); or

(d) the liquidation or dissolution of the Company.

For the avoidance of doubt, you will not be eligible for, nor shall you have a right to receive, any payments or benefits from the Company following your termination from employment other than as set forth in this Section 6; provided, however, that if your employment terminates between the Effective Date and the Closing Date under circumstances that would have entitled you to severance under the Original Offer Letter, then such severance will be paid on the terms and subject to the conditions described in the Original Offer Letter.

# 7. Section 280G.

a. Notwithstanding any other provision of this Letter Agreement, except as set forth in Section 7(b), in the event that the Company undergoes a "Change in Ownership or Control" (as defined below), the Company shall not be obligated to provide to you a portion of any "Contingent Compensation Payments" (as defined below) that you would otherwise be entitled to receive to the extent necessary to eliminate any "excess parachute payments" (as defined in Code Section 280G(b)(1)) for you. For purposes of this Section 7, the Contingent Compensation Payments so eliminated shall be referred to as the "Eliminated Payments" and the aggregate amount (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-30 or any successor provision) of the Contingent Compensation Payments so eliminated shall be referred to as the "Eliminated Amount."

b. Notwithstanding the provisions of 7(a), no such reduction in Contingent Compensation Payments shall be made if the Eliminated Amount (computed without regard to this sentence) exceeds 100% of the aggregate present value (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-31 and Q/A-32 or any successor provisions) of the amount of any additional taxes that would be incurred by you if the Eliminated Payments (determined without regard to this sentence) were paid to you (including, state and federal income taxes on the Eliminated Payments, the excise tax imposed by Section 4999 of the Code payable with respect to all of the Contingent Compensation Payments in excess of your "base amount" (as defined in Section 280G(b)(3) of the Code), and any withholding taxes). The override of such reduction in

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Contingent Compensation Payments pursuant to this Section 7(b) shall be referred to as a "Section 7(b) Override." For purposes of this paragraph, if any federal or state income taxes would be attributable to the receipt of any Eliminated Payment, the amount of such taxes shall be computed by multiplying the amount of the Eliminated Payment by the maximum combined federal and state income tax rate provided by law.

- c. For purposes of this Section 7 the following terms shall have the following respective meanings:
  - (I) "Change in Ownership or Control" shall mean a change in the ownership or effective control of the Company or in the ownership of a substantial portion of the assets of the Company determined in accordance with Section 280G(b)(2) of the Code.
  - (II) "Contingent Compensation Payment" shall mean any payment (or benefit) in the nature of compensation that is made or made available (under this letter agreement or otherwise) to a "disqualified individual" (as defined in Section 280G(c) of the Code) and that is contingent (within the meaning of Section 280G(b)(2)(A)(i) of the Code) on a Change in Ownership or Control of the Company.
- d. Any payments or other benefits otherwise due to you following a Change in Ownership or Control that could reasonably be characterized (as determined by the Company) as Contingent Compensation Payments (the "Potential Payments") shall not be made until the dates provided for in this Section 7(d). Within 30 days after each date on which you first become entitled to receive (whether or not then due) a Contingent Compensation Payment relating to such Change in Ownership or Control, the Company shall determine and notify you (with reasonable detail regarding the basis for its determinations) (i) which Potential Payments constitute Contingent Compensation Payments, (ii) the Eliminated Amount and (iii) whether the Section 7(b) Override is applicable. Within 30 days after delivery of such notice to you, you shall deliver a response to the Company (the "Executive Response") stating either (A) that you agree with the Company's determination pursuant to the preceding sentence, or (B) that you disagree with such determination, in which case you shall set forth (i) which Potential Payments should be characterized as Contingent Compensation Payments, (ii) the Eliminated Amount, and (iii) whether the Section 7(b) Override is applicable. In the event that you fail to deliver an Executive Response on or before the required date, the Company's initial determination shall be final. If and to the extent that any Contingent Compensation Payments are required to be treated as Eliminated Payments pursuant to this Section 7, then the payments shall be reduced or eliminated, as determined by the Company, in the following order: (i) any cash payments, (ii) any taxable benefits, (iii) any nontaxable benefits, and (iv) any vesting of equity awards in each case in reverse order beginning with payments or benefits that are to be paid the farthest in time from the date that triggers the applicability of the excise tax, to the extent necessary to maximize the Eliminated Payments. If you state in the Executive Response that you agree with the Company's determination, the Company shall make the Potential Payments to you within three business days following delivery to the Company of the Executive Response (except for any Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). If you state in the Executive Response that you disagree with the Company's determination, then, for a period of 60 days following delivery of the Executive Response, you and the Company shall use good faith efforts to

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resolve such dispute. If such dispute is not resolved within such 60-day period, such dispute shall be settled exclusively by arbitration in the Commonwealth of Massachusetts, in accordance with the rules of the American Arbitration Association then in effect. Judgment may be entered on the arbitrator's award in any court having jurisdiction. The Company shall, within three business days following delivery to the Company of the Executive Response, make to you those Potential Payments as to which there is no dispute between the Company and you regarding whether they should be made (except for any such Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). The balance of the Potential Payments shall be made within three business days following the resolution of such dispute. Subject to the limitations contained in Sections 7(a) and 7(b) hereof, the amount of any payments to be made to you following the resolution of such dispute shall be increased by the amount of the accrued interest thereon computed at the prime rate announced from time to time by The Wall Street Journal, compounded monthly from the date that such payments originally were due.

- e. The provisions of this Section 7 are intended to apply to any and all payments or benefits available to you under this letter agreement or any other agreement or plan of the Company under which you may receive Contingent Compensation Payments.
- 8. Restrictive Covenants/Absence of Restrictions. You acknowledge that your Inventions, Non-Disclosure, Non-Competition and Non-Solicitation Agreement dated April 18, 2017 (the "Restrictive Covenant Agreement") remains in full force and effect and unaltered in all respects. You represent that you are not bound by any employment contract, restrictive covenant or other restriction preventing (or that purports to prevent) you from entering into employment with or carrying out your responsibilities for the Company, or which is in any way inconsistent with the terms of this Letter Agreement.
- 9. <u>At-Will Employment</u>. This Letter Agreement shall not be construed as an agreement, either expressed or implied, to employ you for any stated term, and shall in no way alter the Company's policy of employment at will, under which both you and the Company remain free to terminate the employment relationship, with or without cause, at any time, with or without notice. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at-will" nature of your employment may only be changed by a written agreement signed by you and the Chief Executive Officer, which expressly states the intention to modify the at-will nature of your employment. Similarly, nothing in this Letter Agreement shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company, except to the extent explicitly set forth in Section 6 hereof.
- 10. <u>Company Premises and Property</u>. The Company's premises, including all workspaces, furniture, documents, and other tangible materials, and all information technology resources of the Company (including computers, data and other electronic files, and all internet and email) are subject to oversight and inspection by the Company at any time. Company employees should have no expectation of privacy with regard to any Company premises, materials, resources, or information.

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11. Entire Agreement/Governing Law. This Letter Agreement is your formal offer of employment and supersedes any and all prior or contemporaneous agreements (including, but not limited to, the Original Offer Letter), discussions and understandings, whether written or oral, relating to the subject matter of this Letter Agreement; provided, however, and for the avoidance of doubt, nothing herein shall be deemed to supersede the Restrictive Covenant Agreement, which remains in full force and effect. This Letter Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts (without reference to the conflict of laws provisions thereof). Any action, suit or other legal proceeding arising under or relating to any provision of this Letter Agreement shall be commenced only in a court of the Commonwealth of Massachusetts (or, if appropriate, a federal court located within the Commonwealth of Massachusetts), and the Company and you each consents to the jurisdiction of such a court.

\* \* \*

If you would like to accept this offer of continued employment on the terms set forth herein as of the Effective Date, please sign and return this Letter Agreement on or before 5:00pm ET, Wednesday, July 1, 2020.

We look forward to you continuing to be part of the Inozyme team and helping to build what we hope will be an exceptional organization.

Very Truly Yours,

By: /s/ Axel Bolte

Name: Axel Bolte Title: Chief Executive Officer

The foregoing correctly sets forth the terms of my employment by Inozyme Pharma, Inc. I am not relying on any representations other than those set forth above.

/s/ Steven Jungles Date: July 1, 2020

Name: Steven Jungles



#### APPENDIX A

## **Payments Subject to Section 409A**

- 1. Subject to this Appendix A, any severance payments that may be due under the Letter Agreement to which it is attached shall begin only upon the date of your "separation from service" (determined as set forth below) which occurs on or after the termination of your employment. The following rules shall apply with respect to distribution of the severance payments, if any, to be provided to you under the Letter Agreement, as applicable:
  - (a) It is intended that each installment of the severance payments under the Letter Agreement shall be treated as a separate "payment" for purposes of Section 409A of the Internal Revenue Code and the guidance issued thereunder ("Section 409A"). Neither the Company nor you shall have the right to accelerate or defer the delivery of any such payments except to the extent specifically permitted or required by Section 409A.
  - (b) If, as of the date of your "separation from service" from the Company, you are not a "specified employee" (within the meaning of Section 409A), then each installment of the severance payments shall be made on the dates and terms set forth in the Letter Agreement.
  - (c) If, as of the date of your "separation from service" from the Company, you are a "specified employee" (within the meaning of Section 409A), then:
    - (i) Each installment of the severance payments due under the Letter Agreement that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when your separation from service occurs, be paid within the short-term deferral period (as defined under Section 409A) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A and shall be paid on the dates and terms set forth in the Letter Agreement; and
    - (ii) Each installment of the severance payments due under the Letter Agreement that is not described in this Appendix A, Section 1(c)(i) and that would, absent this subsection, be paid within the six-month period following your "separation from service" from the Company shall not be paid until the date that is six months and one day after such separation from service (or, if earlier, your death) (the "New Payment Date"), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the New Payment Date and any subsequent installments, if any, being paid in accordance with the dates and terms set forth herein; provided, however, that the preceding provisions of this sentence shall not apply to any installment of

Steven Jungles Appendix A of Letter Agreement Page 2 of 2

payments if and to the maximum extent that such installment is deemed to be paid under a separation pay plan that does not provide for a deferral of compensation by reason of the application of Treasury Regulation 1.409A-1(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-1(b)(9)(iii) must be paid no later than the last day of your second taxable year following the taxable year in which the separation from service occurs.

- 2. The determination of whether and when your separation from service from the Company has occurred shall be made in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h). Solely for purposes of this Appendix A, Section 2, "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Internal Revenue Code.
- 3. All reimbursements and in-kind benefits provided under the Letter Agreement shall be made or provided in accordance with the requirements of Section 409A to the extent that such reimbursements or in-kind benefits are subject to Section 409A, including, where applicable, the requirements that (i) any reimbursement is for expenses incurred during your lifetime (or during a shorter period of time specified in the Letter Agreement), (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred and (iv) the right to reimbursement is not subject to set off or liquidation or exchange for any other benefit.
- 4. The Company makes no representation or warranty and shall have no liability to you or to any other person if any of the provisions of the Letter Agreement (including this Appendix) are determined to constitute deferred compensation subject to Section 409A but that do not satisfy an exemption from, or the conditions of, that section.



June 30, 2020

Pedro Huertas, MD, PhD

Dear Pedro:

This letter (the "Letter Agreement") amends and restates the terms and conditions of your employment with Inozyme Pharma, Inc. ("Inozyme" or the "Company"), as initially set forth in the offer letter dated September 11, 2019 and as amended if applicable (the "Original Offer Letter"), and will be effective as of the date on which the registration statement relating to the Company's initial public offering is effective (the "Effective Date"), provided that you remain employed by the Company as of the Effective Date. Until the Effective Date, the Original Offer Letter will remain in full force and effect and continue to govern your employment with the Company. This Letter Agreement contains the following terms:

- 1. <u>Position and Duties</u>. You will continue to be employed to serve as the Company's Senior Vice President and Chief Medical Officer. You will be employed on a full time basis, and you will report to the Company's Chief Executive Officer and have such duties and responsibilities as are customary for such position. You agree to devote your best efforts, skill, knowledge, attention and energies to the advancement of the Company's business and interests and to the performance of your duties and responsibilities as an employee of the Company, and not to engage in any other business activities without prior approval from the Company. Notwithstanding the forgoing and anything in this Letter Agreement to the contrary, you may provide consulting services to other businesses of up to ten (10) hours per month so long as such services do not interfere with your duties to the Company or breach any terms or conditions of this Letter Agreement or the Restrictive Covenant Agreement (as defined below). You agree to abide by the rules, regulations, personnel practices and policies of the Company and any changes therein that may be adopted from time to time by the Company. You will be primarily located in the Company's Boston area offices and may be required to travel as directed by the Company and consistent with the Company's business needs.
- 2. <u>Base Salary</u>. Your base salary will be at the rate of seventeen thousand six hundred thirty three dollar and thirty four cents (\$17,633.34) per regular semi-monthly pay period (annualized rate of four hundred twenty three thousand two hundred dollars (\$423,200), subject to tax and other withholdings as required by law, and will be paid in accordance with the Company's regularly established payroll procedure. Such base salary may be adjusted from time to time in accordance with normal business practice and in the sole discretion of the Company.
- 3. <u>Discretionary Bonus</u>. Following the end of each calendar year, and subject to the approval of the Board (or a committee thereof), you will be eligible for a discretionary retention and performance bonus, targeted at forty percent (40%) of your gross base salary for the applicable calendar year, based on your individual performance and the Company's performance during the applicable calendar year, as determined by the Company in its sole discretion (the "<u>Discretionary</u>

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<u>Bonus</u>"). You must be an active employee of the Company on the date any bonus is distributed in order to be eligible for and to earn any bonus award, as it also serves as an incentive to remain employed by the Company. Any bonus hereunder will be awarded and paid before March 15<sup>th</sup> of the calendar year following that to which such bonus relates, and will be subject to tax and other withholdings as required by law.

### 4. Benefits and Expenses.

- a. You may continue to participate in any and all benefit programs that the Company establishes and makes available to its employees from time to time, provided you are eligible under (and subject to all provisions of) the plan documents governing those programs. The benefit programs made available by the Company, and the rules, terms and conditions for participation in such benefit programs, may be changed by the Company at any time without advance notice (other than as required by such programs or under law).
- b. All reasonable business expenses that are documented by you and incurred in the ordinary course of business will be reimbursed in accordance with the Company's standard policies and procedures.
- 5. <u>Vacation</u>. You will continue to be eligible for paid vacation time in accordance with Company policy.
- 6. <u>Equity.</u> You will be granted, in connection with the initial public offering and subject to Board approval, an option to acquire 328,453 shares of the Company's common stock at an exercise price equal to the price at which the underwriters sell shares to the public in the offering. The option is contingent on the occurrence of the initial public offering, will be granted under the Company's 2020 Stock Incentive Plan (the "<u>Plan</u>"), and will be subject to the Plan and such terms and conditions as are set forth in the applicable option agreement.
- 7. <u>Severance Benefits</u>. Effective on the date of the closing of the Company's initial public offering (the "Closing Date"), provided that you remain employed by the Company as of the Closing Date, you shall be eligible to receive the following severance benefits in accordance with the terms and conditions set forth below:
  - a. **Termination by the Company without Cause or by You for Good Reason Not In Connection with a Change In Control.** If your employment is terminated by the Company without Cause or you terminate your employment for Good Reason (each as defined below) and such termination does not take place during the twelve (12) month period following a Change in Control (as defined below), and provided you execute and allow to become effective (within 60 days following the termination or such shorter period as may be directed by the Company) a separation and release of claims agreement in a form to be provided by the Company on or about the termination (which will include, at a minimum, a release of all releasable claims, non-disparagement and cooperation obligations, a reaffirmation of your continuing obligations under any existing restrictive covenant agreements, and an agreement not to compete with the Company for twelve (12) months following your separation from employment) (a "Release Agreement"), the Company will provide you with the following severance benefits (subject to the terms of Appendix A hereto):

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- i. The Company will pay you as severance pay an amount equivalent nine (9) months of your then current base salary, less all applicable taxes and withholdings, which severance pay will be paid in installments in accordance with the Company's regular payroll practices beginning in the Company's first regular payroll cycle after the Release Agreement becomes effective; provided, however, that if the 60th day referenced above occurs in the calendar year following the date of your termination, then the severance payments shall begin no earlier than January 1 of such subsequent calendar year.
- ii. Should you timely elect and be eligible to continue receiving group medical coverage pursuant to the "COBRA" law, and so long as the Company can provide such benefit without violating the nondiscrimination requirements of applicable law, the Company will continue to pay the share of the premium for such coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage until the earlier of (x) nine (9) months following your termination date, or (y) the date upon which you commence full-time employment (or employment that provides you with eligibility for healthcare benefits substantially comparable to those provided by the Company) with an entity other than the Company. If applicable, the remaining balance of any premium costs shall timely be paid by you on a monthly basis for as long as, and to the extent that, you remain eligible for COBRA continuation.
- b. **Termination by the Company without Cause or by You for Good Reason In Connection with a Change In Control.** If your employment is terminated by the Company without Cause or you terminate your employment for Good Reason and such termination takes place during the twelve (12) month period following a Change in Control (as defined below), and provided you execute and allow to become effective a Release Agreement, the Company will provide you with the following severance benefits (subject to the terms of Appendix A hereto):
  - i. The Company will pay you as severance pay an amount equivalent to twelve (12) months of your then current base salary, less all applicable taxes and withholdings, which severance pay will be paid in installments in accordance with the Company's regular payroll practices beginning in the Company's first regular payroll cycle after the Release Agreement becomes effective; provided, however, that if the 60th day referenced above occurs in the calendar year following the date of your termination, then the severance payments shall begin no earlier than January 1 of such subsequent calendar year.
  - ii. Should you timely elect and be eligible to continue receiving group medical coverage pursuant to the "COBRA" law, and so long as the Company can provide such benefit without violating the nondiscrimination requirements of applicable law, the Company will continue to pay the share of the premium for such coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage until the earlier of (x) twelve (12) months following your termination date, or (y) the date upon which you commence full-time employment (or employment that

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- provides you with eligibility for healthcare benefits substantially comparable to those provided by the Company) with an entity other than the Company. If applicable, the remaining balance of any premium costs shall timely be paid by you on a monthly basis for as long as, and to the extent that, you remain eligible for COBRA continuation.
- iii. The Company will pay you 100% of your annual target Discretionary Bonus, less all applicable taxes and withholdings, for the year in which your termination occurs in a lump sum on the date the first installment of severance pay is paid. For the avoidance of doubt, for purposes of calculating the amount due under this Section 7(b)(iii), your target Discretionary Bonus shall be equal to the percent of your annualized base salary at the time of your termination that is set forth in Section 3.
- iv. All outstanding and unvested stock options and other equity awards in each case that vest solely based on continued service that are then held by you shall become fully vested and exercisable and, with respect to any stock options then held by you, those options shall remain exercisable for the period of time set forth in the applicable grant agreement.
- c. Definitions. For purposes of this Letter Agreement:
  - i. "Cause" means any of: (a) your conviction of, or plea of guilty or nolo contendere to, any crime involving dishonesty or moral turpitude or any felony; (b) a good faith finding by the Company that you have (i) engaged in dishonesty, willful misconduct or gross negligence, (ii) committed an act that materially injures or would reasonably be expected to materially injure the reputation, business or business relationships of the Company, (iii) materially breached the terms of any agreement between you and the Company, including without limitation this Letter Agreement, the Restrictive Covenant Agreement (as defined below) or any other restrictive covenant or confidentiality agreement with the Company; or (iv) failed or refused to comply in any material respect with the Company's material policies or procedures.
  - ii. "Good Reason" means the occurrence, without your prior written consent, of any of the following events: (a) a material reduction in your authority, duties, or responsibilities; (b) the relocation of the principal place at which you provide services to the Company by at least 50 miles and to a location such that your daily commuting distance is increased; (c) a material reduction of your base salary (except for across the board pay cuts of all management level employees of the Company); or (d) a material breach by the Company of its obligations under this Letter Agreement. No resignation will be treated as a resignation for Good Reason unless (i) you have given written notice to the Company of your intention to terminate your employment for Good Reason, describing the grounds for such action, no later than 90 days after the first occurrence of such circumstances, (ii) you have provided the Company with at least 30 days in which to cure the circumstances, and (iii) if the Company is not successful in curing the circumstances, you end your employment within 30 days following the cure period in (ii).

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- iii. "<u>Change of Control</u>" means any of the following events provided that such event also constitutes a "change in control event" within the meaning of Treasury Regulation Section 1.409A-3(i)(5):
- (a) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act) (a "Person") of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 under the Exchange Act) 50% or more of either (x) the then-outstanding shares of common stock of the Company (the "Outstanding Company Common Stock") or (y) the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors (the "Outstanding Company Voting Securities"); provided, however, that for purposes of this subsection (A), the following acquisitions shall not constitute a Change in Control Event: (1) any acquisition directly from the Company (excluding an acquisition pursuant to the exercise, conversion or exchange of any security exercisable for, convertible into or exchangeable for common stock or voting securities of the Company, unless the Person exercising, converting or exchanging such security acquired such security directly from the Company or an underwriter or agent of the Company), (2) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlled by the Company, or (3) any acquisition by any corporation pursuant to a Business Combination (as defined below) which complies with clauses (x) and (y) of subsection (C) of this definition; or
- (b) a change in the composition of the Board that results in the Continuing Directors (as defined below) no longer constituting a majority of the Board (or, if applicable, the Board of Directors of a successor corporation to the Company), where the term "Continuing Director" means at any date a member of the Board (x) who was a member of the Board on the date of the initial adoption of the Plan by the Board or (y) who was nominated or elected subsequent to such date by at least a majority of the directors who were Continuing Directors at the time of such nomination or election or whose election to the Board was recommended or endorsed by at least a majority of the directors who were Continuing Directors at the time of such nomination or election; *provided*, *however*, that there shall be excluded from this clause (y) any individual whose initial assumption of office occurred as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents, by or on behalf of a person other than the Board: or
- (c) the consummation of a merger, consolidation, reorganization, recapitalization or share exchange involving the Company or a sale or other disposition of all or substantially all of the assets of the Company (a "Business Combination"), unless, immediately following such Business Combination, each of the following two conditions is satisfied: (x) all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Common Stock and Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the then-outstanding shares of common stock and the combined voting power of the then-outstanding securities entitled to vote generally in the election of

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directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one or more subsidiaries) (such resulting or acquiring corporation is referred to herein as the "Acquiring Corporation") in substantially the same proportions as their ownership of the Outstanding Company Common Stock and Outstanding Company Voting Securities, respectively, immediately prior to such Business Combination and (y) no Person (excluding any employee benefit plan (or related trust) maintained or sponsored by the Company or by the Acquiring Corporation) beneficially owns, directly or indirectly, 50% or more of the then-outstanding shares of common stock of the Acquiring Corporation, or of the combined voting power of the then-outstanding securities of such corporation entitled to vote generally in the election of directors (except to the extent that such ownership existed prior to the Business Combination); or

(d) the liquidation or dissolution of the Company.

For the avoidance of doubt, you will not be eligible for, nor shall you have a right to receive, any payments or benefits from the Company following your termination from employment other than as set forth in this Section 7; provided, however, that if your employment terminates between the Effective Date and the Closing Date under circumstances that would have entitled you to severance under the Original Offer Letter, then such severance will be paid on the terms and subject to the conditions described in the Original Offer Letter.

## 8. Section 280G.

- a. Notwithstanding any other provision of this Letter Agreement, except as set forth in Section 8(b), in the event that the Company undergoes a "Change in Ownership or Control" (as defined below), the Company shall not be obligated to provide to you a portion of any "Contingent Compensation Payments" (as defined below) that you would otherwise be entitled to receive to the extent necessary to eliminate any "excess parachute payments" (as defined in Code Section 280G(b)(1)) for you. For purposes of this Section 8, the Contingent Compensation Payments so eliminated shall be referred to as the "Eliminated Payments" and the aggregate amount (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-30 or any successor provision) of the Contingent Compensation Payments so eliminated shall be referred to as the "Eliminated Amount."
- b. Notwithstanding the provisions of 8(a), no such reduction in Contingent Compensation Payments shall be made if the Eliminated Amount (computed without regard to this sentence) exceeds 100% of the aggregate present value (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-31 and Q/A-32 or any successor provisions) of the amount of any additional taxes that would be incurred by you if the Eliminated Payments (determined without regard to this sentence) were paid to you (including, state and federal income taxes on the Eliminated Payments, the excise tax imposed by Section 4999 of the Code payable with respect to all of the Contingent Compensation Payments in excess of your "base amount" (as defined in Section 280G(b)(3) of the Code), and any withholding taxes). The override of such reduction in Contingent Compensation Payments pursuant to this Section 8(b) shall be referred to as a "Section 8(b) Override." For purposes of this paragraph, if any federal or state income taxes would be attributable to the receipt of any Eliminated Payment, the amount of such taxes shall be computed by multiplying the amount of the Eliminated Payment by the maximum combined federal and state income tax rate provided by law.

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- c. For purposes of this Section 8 the following terms shall have the following respective meanings:
  - (I) "Change in Ownership or Control" shall mean a change in the ownership or effective control of the Company or in the ownership of a substantial portion of the assets of the Company determined in accordance with Section 280G(b)(2) of the Code.
  - (II) "Contingent Compensation Payment" shall mean any payment (or benefit) in the nature of compensation that is made or made available (under this letter agreement or otherwise) to a "disqualified individual" (as defined in Section 280G(c) of the Code) and that is contingent (within the meaning of Section 280G(b)(2)(A)(i) of the Code) on a Change in Ownership or Control of the Company.
- d. Any payments or other benefits otherwise due to you following a Change in Ownership or Control that could reasonably be characterized (as determined by the Company) as Contingent Compensation Payments (the "Potential Payments") shall not be made until the dates provided for in this Section 8(d). Within 30 days after each date on which you first become entitled to receive (whether or not then due) a Contingent Compensation Payment relating to such Change in Ownership or Control, the Company shall determine and notify you (with reasonable detail regarding the basis for its determinations) (i) which Potential Payments constitute Contingent Compensation Payments, (ii) the Eliminated Amount and (iii) whether the Section 8(b) Override is applicable. Within 30 days after delivery of such notice to you, you shall deliver a response to the Company (the "Executive Response") stating either (A) that you agree with the Company's determination pursuant to the preceding sentence, or (B) that you disagree with such determination, in which case you shall set forth (i) which Potential Payments should be characterized as Contingent Compensation Payments, (ii) the Eliminated Amount, and (iii) whether the Section 8(b) Override is applicable. In the event that you fail to deliver an Executive Response on or before the required date, the Company's initial determination shall be final. If and to the extent that any Contingent Compensation Payments are required to be treated as Eliminated Payments pursuant to this Section 8, then the payments shall be reduced or eliminated, as determined by the Company, in the following order: (i) any cash payments, (ii) any taxable benefits, (iii) any nontaxable benefits, and (iv) any vesting of equity awards in each case in reverse order beginning with payments or benefits that are to be paid the farthest in time from the date that triggers the applicability of the excise tax, to the extent necessary to maximize the Eliminated Payments. If you state in the Executive Response that you agree with the Company's determination, the Company shall make the Potential Payments to you within three business days following delivery to the Company of the Executive Response (except for any Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). If you state in the Executive Response that you disagree with the Company's determination, then, for a period of 60 days following delivery of the Executive Response, you and the Company shall use good faith efforts to resolve such dispute. If such dispute is not resolved within such 60-day period, such dispute shall be settled exclusively by arbitration in the Commonwealth of Massachusetts, in accordance with the rules of the American Arbitration Association then in effect. Judgment may be entered on the

Pedro Huertas, MD, PhD Letter Agreement Page 8 of 9

arbitrator's award in any court having jurisdiction. The Company shall, within three business days following delivery to the Company of the Executive Response, make to you those Potential Payments as to which there is no dispute between the Company and you regarding whether they should be made (except for any such Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). The balance of the Potential Payments shall be made within three business days following the resolution of such dispute. Subject to the limitations contained in Sections 8(a) and 8(b) hereof, the amount of any payments to be made to you following the resolution of such dispute shall be increased by the amount of the accrued interest thereon computed at the prime rate announced from time to time by The Wall Street Journal, compounded monthly from the date that such payments originally were due.

- e. The provisions of this Section 8 are intended to apply to any and all payments or benefits available to you under this letter agreement or any other agreement or plan of the Company under which you may receive Contingent Compensation Payments.
- 9. Restrictive Covenants/Absence of Restrictions. In exchange for your continued employment with the Company pursuant to the terms and conditions herein and, with respect to the non-competition provision, the grant of equity described in Section 6, you hereby agree to execute the enclosed Inventions, Non-Disclosure, Non-Competition and Non-Solicitation Agreement (the "Restrictive Covenant Agreement"). By executing this Letter Agreement, you acknowledge that your eligibility for the grant of equity set forth in Section 6 of this Letter Agreement is contingent upon your agreement to the non-competition provisions set forth in the Restrictive Covenant Agreement. You further acknowledge that such consideration was mutually agreed upon by you and the Company and is fair and reasonable in exchange for your compliance with such non-competition obligations and that you were provided at least ten (10) business days to review the Restrictive Covenant Agreement.
- 10. <u>At-Will Employment</u>. This Letter Agreement shall not be construed as an agreement, either expressed or implied, to employ you for any stated term, and shall in no way alter the Company's policy of employment at will, under which both you and the Company remain free to terminate the employment relationship, with or without cause, at any time, with or without notice. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at-will" nature of your employment may only be changed by a written agreement signed by you and the Chief Executive Officer, which expressly states the intention to modify the at-will nature of your employment. Similarly, nothing in this Letter Agreement shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company, except to the extent explicitly set forth in Section 7 hereof.
- 11. <u>Company Premises and Property.</u> The Company's premises, including all workspaces, furniture, documents, and other tangible materials, and all information technology resources of the Company (including computers, data and other electronic files, and all internet and email) are subject to oversight and inspection by the Company at any time. Company employees should have no expectation of privacy with regard to any Company premises, materials, resources, or information.

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12. Entire Agreement/Governing Law. This Letter Agreement is your formal offer of employment and supersedes any and all prior or contemporaneous agreements (including, but not limited to, the Original Offer Letter), discussions and understandings, whether written or oral, relating to the subject matter of this Letter Agreement. This Letter Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts (without reference to the conflict of laws provisions thereof). Any action, suit or other legal proceeding arising under or relating to any provision of this Letter Agreement shall be commenced only in a court of the Commonwealth of Massachusetts (or, if appropriate, a federal court located within the Commonwealth of Massachusetts), and the Company and you each consents to the jurisdiction of such a court.

\* \* \*

If you would like to accept this offer of continued employment on the terms set forth herein as of the Effective Date, please sign and return this Letter Agreement on or before 5:00pm ET, Wednesday, July 1, 2020.

We look forward to you continuing to be part of the Inozyme team and helping to build what we hope will be an exceptional organization.

Very Truly Yours,

By: /s/ Axel Bolte
Name: Axel Bolte

Title: Chief Executive Officer

The foregoing correctly sets forth the terms of my employment by Inozyme Pharma, Inc. I am not relying on any representations other than those set forth above.

/s/ Pedro Huertas Date: 1 July 2020

Name: Pedro Huertas, MD, PhD



#### APPENDIX A

## **Payments Subject to Section 409A**

- 1. Subject to this Appendix A, any severance payments that may be due under the Letter Agreement to which it is attached shall begin only upon the date of your "separation from service" (determined as set forth below) which occurs on or after the termination of your employment. The following rules shall apply with respect to distribution of the severance payments, if any, to be provided to you under the Letter Agreement, as applicable:
  - (a) It is intended that each installment of the severance payments under the Letter Agreement shall be treated as a separate "payment" for purposes of Section 409A of the Internal Revenue Code and the guidance issued thereunder ("Section 409A"). Neither the Company nor you shall have the right to accelerate or defer the delivery of any such payments except to the extent specifically permitted or required by Section 409A.
  - (b) If, as of the date of your "separation from service" from the Company, you are not a "specified employee" (within the meaning of Section 409A), then each installment of the severance payments shall be made on the dates and terms set forth in the Letter Agreement.
  - (c) If, as of the date of your "separation from service" from the Company, you are a "specified employee" (within the meaning of Section 409A), then:
    - (i) Each installment of the severance payments due under the Letter Agreement that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when your separation from service occurs, be paid within the short-term deferral period (as defined under Section 409A) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A and shall be paid on the dates and terms set forth in the Letter Agreement; and
    - (ii) Each installment of the severance payments due under the Letter Agreement that is not described in this Appendix A, Section 1(c)(i) and that would, absent this subsection, be paid within the six-month period following your "separation from service" from the Company shall not be paid until the date that is six months and one day after such separation from service (or, if earlier, your death) (the "New Payment Date"), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the New Payment Date and any subsequent installments, if any, being paid in accordance with the dates and terms set forth herein; provided, however, that the preceding provisions of this sentence shall not apply to any installment of

Pedro Huertas, MD, PhD Appendix A of Letter Agreement Page 2 of 2

payments if and to the maximum extent that such installment is deemed to be paid under a separation pay plan that does not provide for a deferral of compensation by reason of the application of Treasury Regulation 1.409A-1(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-1(b)(9)(iii) must be paid no later than the last day of your second taxable year following the taxable year in which the separation from service occurs.

- 2. The determination of whether and when your separation from service from the Company has occurred shall be made in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h). Solely for purposes of this Appendix A, Section 2, "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Internal Revenue Code.
- 3. All reimbursements and in-kind benefits provided under the Letter Agreement shall be made or provided in accordance with the requirements of Section 409A to the extent that such reimbursements or in-kind benefits are subject to Section 409A, including, where applicable, the requirements that (i) any reimbursement is for expenses incurred during your lifetime (or during a shorter period of time specified in the Letter Agreement), (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred and (iv) the right to reimbursement is not subject to set off or liquidation or exchange for any other benefit.
- 4. The Company makes no representation or warranty and shall have no liability to you or to any other person if any of the provisions of the Letter Agreement (including this Appendix) are determined to constitute deferred compensation subject to Section 409A but that do not satisfy an exemption from, or the conditions of, that section.



June 30, 2020

Stephen Basso

Dear Stephen:

This letter (the "Letter Agreement") amends and restates the terms and conditions of your employment with Inozyme Pharma, Inc. ("Inozyme" or the "Company"), as initially set forth in the offer letter dated September 20, 2017 and as amended if applicable (the "Original Offer Letter"), and will be effective as of the date on which the registration statement relating to the Company's initial public offering is effective (the "Effective Date"), provided that you remain employed by the Company as of the Effective Date. Until the Effective Date, the Original Offer Letter will remain in full force and effect and continue to govern your employment with the Company. This Letter Agreement contains the following terms:

- 1. <u>Position and Duties</u>. You will continue to be employed to serve as the Company's Senior Vice President, Finance. You will be employed on a full time basis, and you will report to the Company's Chief Executive Officer and have such duties and responsibilities as are customary for such position. You agree to devote your best efforts, skill, knowledge, attention and energies to the advancement of the Company's business and interests and to the performance of your duties and responsibilities as an employee of the Company. You agree to abide by the rules, regulations, personnel practices and policies of the Company and any changes therein that may be adopted from time to time by the Company. You will be primarily located in the Company's Boston area offices and may be required to travel as directed by the Company and consistent with the Company's business needs.
- 2. <u>Base Salary</u>. Your base salary will be at the rate of twelve thousand seven hundred eight dollars and thirty four cents (\$12,708.34) per regular semi-monthly pay period (annualized rate of three hundred five thousand dollars (\$305,000), subject to tax and other withholdings as required by law, and will be paid in accordance with the Company's regularly established payroll procedure. Such base salary may be adjusted from time to time in accordance with normal business practice and in the sole discretion of the Company.
- 3. <u>Discretionary Bonus</u>. Following the end of each calendar year, and subject to the approval of the Board (or a committee thereof), you will be eligible for a discretionary retention and performance bonus, targeted at forty percent (40%) of your gross base salary for the applicable calendar year, based on your individual performance and the Company's performance during the applicable calendar year, as determined by the Company in its sole discretion (the "<u>Discretionary Bonus</u>"). You must be an active employee of the Company on the date any bonus is distributed in order to be eligible for and to earn any bonus award, as it also serves as an incentive to remain employed by the Company. Any bonus hereunder will be awarded and paid before March 15th of the calendar year following that to which such bonus relates, and will be subject to tax and other withholdings as required by law.

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# 4. Benefits and Expenses.

- a. You may continue to participate in any and all benefit programs that the Company establishes and makes available to its employees from time to time, provided you are eligible under (and subject to all provisions of) the plan documents governing those programs. The benefit programs made available by the Company, and the rules, terms and conditions for participation in such benefit programs, may be changed by the Company at any time without advance notice (other than as required by such programs or under law).
- b. All reasonable business expenses that are documented by you and incurred in the ordinary course of business will be reimbursed in accordance with the Company's standard policies and procedures. Notwithstanding the foregoing, unless the Board otherwise determines (i) for up to 24 months following the Effective Date travel expenses for travel between your home and the Company's Boston area headquarters will be reimbursed in accordance with the Company's Travel and Expense Policy and (ii) beginning 24 months following the Effective Date, the Company will no longer reimburse you for travel expenses for travel between your home and the Company's Boston area headquarters.
- 5. <u>Vacation</u>. You will continue to be eligible for paid vacation time in accordance with Company policy.
- 6. <u>Equity.</u> You will be granted, in connection with the initial public offering and subject to Board approval, an option to acquire 205,012 shares of the Company's common stock at an exercise price equal to the price at which the underwriters sell shares to the public in the offering. The option is contingent on the occurrence of the initial public offering, will be granted under the Company's 2020 Stock Incentive Plan (the "<u>Plan</u>"), and will be subject to the Plan and such terms and conditions as are set forth in the applicable option agreement.
- 7. <u>Severance Benefits</u>. Effective on the date of the closing of the Company's initial public offering (the "Closing Date"), provided that you remain employed by the Company as of the Closing Date, you shall be eligible to receive the following severance benefits in accordance with the terms and conditions set forth below:
  - a. **Termination by the Company without Cause or by You for Good Reason Not In Connection with a Change In Control.** If your employment is terminated by the Company without Cause or you terminate your employment for Good Reason (each as defined below) and such termination does not take place during the twelve (12) month period following a Change in Control (as defined below), and provided you execute and allow to become effective (within 60 days following the termination or such shorter period as may be directed by the Company) a separation and release of claims agreement in a form to be provided by the Company on or about the termination (which will include, at a minimum, a release of all releasable claims, non-disparagement and cooperation obligations, a reaffirmation of your continuing obligations under any existing restrictive covenant agreements, and an agreement not to compete with the Company for twelve (12)

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months following your separation from employment) (a "Release Agreement"), the Company will provide you with the following severance benefits (subject to the terms of Appendix A hereto):

- i. The Company will pay you as severance pay an amount equivalent to nine (9) months of your then current base salary, less all applicable taxes and withholdings, which severance pay will be paid in installments in accordance with the Company's regular payroll practices beginning in the Company's first regular payroll cycle after the Release Agreement becomes effective; provided, however, that if the 60th day referenced above occurs in the calendar year following the date of your termination, then the severance payments shall begin no earlier than January 1 of such subsequent calendar year.
- ii. Should you timely elect and be eligible to continue receiving group medical coverage pursuant to the "COBRA" law, and so long as the Company can provide such benefit without violating the nondiscrimination requirements of applicable law, the Company will continue to pay the share of the premium for such coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage until the earlier of (x) nine (9) months following your termination date, or (y) the date upon which you commence full-time employment (or employment that provides you with eligibility for healthcare benefits substantially comparable to those provided by the Company) with an entity other than the Company. If applicable, the remaining balance of any premium costs shall timely be paid by you on a monthly basis for as long as, and to the extent that, you remain eligible for COBRA continuation.
- b. **Termination by the Company without Cause or by You for Good Reason In Connection with a Change In Control.** If your employment is terminated by the Company without Cause or you terminate your employment for Good Reason and such termination takes place during the twelve (12) month period following a Change in Control (as defined below), and provided you execute and allow to become effective a Release Agreement, the Company will provide you with the following severance benefits (subject to the terms of Appendix A hereto):
  - i. The Company will pay you as severance pay an amount equivalent to twelve (12) months of your then current base salary, less all applicable taxes and withholdings, which severance pay will be paid in installments in accordance with the Company's regular payroll practices beginning in the Company's first regular payroll cycle after the Release Agreement becomes effective; provided, however, that if the 60th day referenced above occurs in the calendar year following the date of your termination, then the severance payments shall begin no earlier than January 1 of such subsequent calendar year.
  - ii. Should you timely elect and be eligible to continue receiving group medical coverage pursuant to the "COBRA" law, and so long as the Company can provide such benefit without violating the nondiscrimination requirements of applicable law, the Company

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will continue to pay the share of the premium for such coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage until the earlier of (x) twelve (12) months following your termination date, or (y) the date upon which you commence full-time employment (or employment that provides you with eligibility for healthcare benefits substantially comparable to those provided by the Company) with an entity other than the Company. If applicable, the remaining balance of any premium costs shall timely be paid by you on a monthly basis for as long as, and to the extent that, you remain eligible for COBRA continuation.

- iii. The Company will pay you 100% of your annual target Discretionary Bonus, less all applicable taxes and withholdings, for the year in which your termination occurs in a lump sum on the date the first installment of severance pay is paid. For the avoidance of doubt, for purposes of calculating the amount due under this Section 7(b)(iii), your target Discretionary Bonus shall be equal to the percent of your annualized base salary at the time of your termination that is set forth in Section 3.
- iv. All outstanding and unvested stock options and other equity awards in each case that vest solely based on continued service that are then held by you shall become fully vested and exercisable and, with respect to any stock options then held by you, those options shall remain exercisable for the period of time set forth in the applicable grant agreement.

## c. Definitions. For purposes of this Letter Agreement:

- i. "Cause" means any of: (a) your conviction of, or plea of guilty or nolo contendere to, any crime involving dishonesty or moral turpitude or any felony; (b) a good faith finding by the Company that you have (i) engaged in dishonesty, willful misconduct or gross negligence, (ii) committed an act that materially injures or would reasonably be expected to materially injure the reputation, business or business relationships of the Company, (iii) materially breached the terms of any agreement between you and the Company, including without limitation this Letter Agreement, the Restrictive Covenant Agreement (as defined below) or any other restrictive covenant or confidentiality agreement with the Company; or (iv) failed or refused to comply in any material respect with the Company's material policies or procedures.
- ii. "Good Reason" means the occurrence, without your prior written consent, of any of the following events: (a) a material reduction in your authority, duties, or responsibilities; (b) the relocation of the principal place at which you provide services to the Company by at least 50 miles and to a location such that your daily commuting distance is increased; (c) a material reduction of your base salary (except for across the board pay cuts of all management level employees of the Company); or (d) a material breach by the Company of its obligations under this Letter Agreement. No resignation will be treated as a resignation for Good Reason unless (i) you have given written notice to the Company of your intention to terminate your employment for Good Reason, describing the grounds for such action, no later than 90 days after the

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- first occurrence of such circumstances, (ii) you have provided the Company with at least 30 days in which to cure the circumstances, and (iii) if the Company is not successful in curing the circumstances, you end your employment within 30 days following the cure period in (ii).
- iii. "<u>Change of Control</u>" means any of the following events provided that such event also constitutes a "change in control event" within the meaning of Treasury Regulation Section 1.409A-3(i)(5):
- (a) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act) (a "Person") of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 under the Exchange Act) 50% or more of either (x) the then-outstanding shares of common stock of the Company (the "Outstanding Company Common Stock") or (y) the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors (the "Outstanding Company Voting Securities"); provided, however, that for purposes of this subsection (A), the following acquisitions shall not constitute a Change in Control Event: (1) any acquisition directly from the Company (excluding an acquisition pursuant to the exercise, conversion or exchange of any security exercisable for, convertible into or exchangeable for common stock or voting securities of the Company, unless the Person exercising, converting or exchanging such security acquired such security directly from the Company or an underwriter or agent of the Company), (2) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlled by the Company, or (3) any acquisition by any corporation pursuant to a Business Combination (as defined below) which complies with clauses (x) and (y) of subsection (C) of this definition; or
- (b) a change in the composition of the Board that results in the Continuing Directors (as defined below) no longer constituting a majority of the Board (or, if applicable, the Board of Directors of a successor corporation to the Company), where the term "Continuing Director" means at any date a member of the Board (x) who was a member of the Board on the date of the initial adoption of the Plan by the Board or (y) who was nominated or elected subsequent to such date by at least a majority of the directors who were Continuing Directors at the time of such nomination or election or whose election to the Board was recommended or endorsed by at least a majority of the directors who were Continuing Directors at the time of such nomination or election; *provided*, *however*, that there shall be excluded from this clause (y) any individual whose initial assumption of office occurred as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents, by or on behalf of a person other than the Board; or
- (c) the consummation of a merger, consolidation, reorganization, recapitalization or share exchange involving the Company or a sale or other disposition of all or substantially all of the assets of the Company (a "<u>Business Combination</u>"), unless, immediately following such Business Combination, each of the following two conditions is satisfied: (x) all or

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substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Common Stock and Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the then-outstanding shares of common stock and the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one or more subsidiaries) (such resulting or acquiring corporation is referred to herein as the "Acquiring Corporation") in substantially the same proportions as their ownership of the Outstanding Company Common Stock and Outstanding Company Voting Securities, respectively, immediately prior to such Business Combination and (y) no Person (excluding any employee benefit plan (or related trust) maintained or sponsored by the Company or by the Acquiring Corporation) beneficially owns, directly or indirectly, 50% or more of the then-outstanding shares of common stock of the Acquiring Corporation, or of the combined voting power of the then-outstanding securities of such corporation entitled to vote generally in the election of directors (except to the extent that such ownership existed prior to the Business Combination); or

(d) the liquidation or dissolution of the Company.

For the avoidance of doubt, you will not be eligible for, nor shall you have a right to receive, any payments or benefits from the Company following your termination from employment other than as set forth in this Section 7; provided, however, that if your employment terminates between the Effective Date and the Closing Date under circumstances that would have entitled you to severance under the Original Offer Letter, then such severance will be paid on the terms and subject to the conditions described in the Original Offer Letter.

# 8. Section 280G.

- a. Notwithstanding any other provision of this Letter Agreement, except as set forth in Section 8(b), in the event that the Company undergoes a "Change in Ownership or Control" (as defined below), the Company shall not be obligated to provide to you a portion of any "Contingent Compensation Payments" (as defined below) that you would otherwise be entitled to receive to the extent necessary to eliminate any "excess parachute payments" (as defined in Code Section 280G(b)(1)) for you. For purposes of this Section 8, the Contingent Compensation Payments so eliminated shall be referred to as the "Eliminated Payments" and the aggregate amount (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-30 or any successor provision) of the Contingent Compensation Payments so eliminated shall be referred to as the "Eliminated Amount."
- b. Notwithstanding the provisions of 8(a), no such reduction in Contingent Compensation Payments shall be made if the Eliminated Amount (computed without regard to this sentence) exceeds 100% of the aggregate present value (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-31 and Q/A-32 or any successor provisions) of the amount of any additional taxes that would be incurred by you if the Eliminated Payments (determined without regard to this sentence) were paid to you (including, state and federal income taxes on the Eliminated Payments, the excise tax imposed by Section 4999 of the Code payable with respect to

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all of the Contingent Compensation Payments in excess of your "base amount" (as defined in Section 280G(b)(3) of the Code), and any withholding taxes). The override of such reduction in Contingent Compensation Payments pursuant to this Section 8(b) shall be referred to as a "Section 8(b) Override." For purposes of this paragraph, if any federal or state income taxes would be attributable to the receipt of any Eliminated Payment, the amount of such taxes shall be computed by multiplying the amount of the Eliminated Payment by the maximum combined federal and state income tax rate provided by law.

- c. For purposes of this Section 8 the following terms shall have the following respective meanings:
  - (I) "Change in Ownership or Control" shall mean a change in the ownership or effective control of the Company or in the ownership of a substantial portion of the assets of the Company determined in accordance with Section 280G(b)(2) of the Code.
  - (II) "Contingent Compensation Payment" shall mean any payment (or benefit) in the nature of compensation that is made or made available (under this letter agreement or otherwise) to a "disqualified individual" (as defined in Section 280G(c) of the Code) and that is contingent (within the meaning of Section 280G(b)(2)(A)(i) of the Code) on a Change in Ownership or Control of the Company.
- d. Any payments or other benefits otherwise due to you following a Change in Ownership or Control that could reasonably be characterized (as determined by the Company) as Contingent Compensation Payments (the "Potential Payments") shall not be made until the dates provided for in this Section 8(d). Within 30 days after each date on which you first become entitled to receive (whether or not then due) a Contingent Compensation Payment relating to such Change in Ownership or Control, the Company shall determine and notify you (with reasonable detail regarding the basis for its determinations) (i) which Potential Payments constitute Contingent Compensation Payments, (ii) the Eliminated Amount and (iii) whether the Section 8(b) Override is applicable. Within 30 days after delivery of such notice to you, you shall deliver a response to the Company (the "Executive Response") stating either (A) that you agree with the Company's determination pursuant to the preceding sentence, or (B) that you disagree with such determination, in which case you shall set forth (i) which Potential Payments should be characterized as Contingent Compensation Payments, (ii) the Eliminated Amount, and (iii) whether the Section 8(b) Override is applicable. In the event that you fail to deliver an Executive Response on or before the required date, the Company's initial determination shall be final. If and to the extent that any Contingent Compensation Payments are required to be treated as Eliminated Payments pursuant to this Section 8, then the payments shall be reduced or eliminated, as determined by the Company, in the following order: (i) any cash payments, (ii) any taxable benefits, (iii) any nontaxable benefits, and (iv) any vesting of equity awards in each case in reverse order beginning with payments or benefits that are to be paid the farthest in time from the date that triggers the applicability of the excise tax, to the extent necessary to maximize the Eliminated Payments. If you state in the Executive Response that you agree with the Company's determination, the Company shall make the Potential Payments to you within three business days following delivery to the Company of the Executive Response (except for any Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). If you state in the Executive

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Response that you disagree with the Company's determination, then, for a period of 60 days following delivery of the Executive Response, you and the Company shall use good faith efforts to resolve such dispute. If such dispute is not resolved within such 60-day period, such dispute shall be settled exclusively by arbitration in the Commonwealth of Massachusetts, in accordance with the rules of the American Arbitration Association then in effect. Judgment may be entered on the arbitrator's award in any court having jurisdiction. The Company shall, within three business days following delivery to the Company of the Executive Response, make to you those Potential Payments as to which there is no dispute between the Company and you regarding whether they should be made (except for any such Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). The balance of the Potential Payments shall be made within three business days following the resolution of such dispute. Subject to the limitations contained in Sections 8(a) and 8(b) hereof, the amount of any payments to be made to you following the resolution of such dispute shall be increased by the amount of the accrued interest thereon computed at the prime rate announced from time to time by The Wall Street Journal, compounded monthly from the date that such payments originally were due.

- e. The provisions of this Section 8 are intended to apply to any and all payments or benefits available to you under this letter agreement or any other agreement or plan of the Company under which you may receive Contingent Compensation Payments.
- 9. <u>Restrictive Covenants/Absence of Restrictions</u>. You acknowledge that your Inventions, Non-Disclosure, Non-Competition and Non-Solicitation Agreement dated September 21, 2017 (the "<u>Restrictive Covenant Agreement</u>") remains in full force and effect and unaltered in all respects. You represent that you are not bound by any employment contract, restrictive covenant or other restriction preventing (or that purports to prevent) you from entering into employment with or carrying out your responsibilities for the Company, or which is in any way inconsistent with the terms of this Letter Agreement.
- 10. <u>At-Will Employment</u>. This Letter Agreement shall not be construed as an agreement, either expressed or implied, to employ you for any stated term, and shall in no way alter the Company's policy of employment at will, under which both you and the Company remain free to terminate the employment relationship, with or without cause, at any time, with or without notice. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at-will" nature of your employment may only be changed by a written agreement signed by you and the Chief Executive Officer, which expressly states the intention to modify the at-will nature of your employment. Similarly, nothing in this Letter Agreement shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company, except to the extent explicitly set forth in Section 7 hereof.
- 11. <u>Company Premises and Property.</u> The Company's premises, including all workspaces, furniture, documents, and other tangible materials, and all information technology resources of the Company (including computers, data and other electronic files, and all internet and email) are subject to oversight and inspection by the Company at any time. Company employees should have no expectation of privacy with regard to any Company premises, materials, resources, or information.

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12. Entire Agreement/Governing Law. This Letter Agreement is your formal offer of employment and supersedes any and all prior or contemporaneous agreements (including, but not limited to, the Original Offer Letter), discussions and understandings, whether written or oral, relating to the subject matter of this Letter Agreement; provided, however, and for the avoidance of doubt, nothing herein shall be deemed to supersede the Restrictive Covenant Agreement, which remains in full force and effect. This Letter Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts (without reference to the conflict of laws provisions thereof). Any action, suit or other legal proceeding arising under or relating to any provision of this Letter Agreement shall be commenced only in a court of the Commonwealth of Massachusetts (or, if appropriate, a federal court located within the Commonwealth of Massachusetts), and the Company and you each consents to the jurisdiction of such a court.

\* \* \*

If you would like to accept this offer of continued employment on the terms set forth herein as of the Effective Date, please sign and return this Letter Agreement on or before 5:00pm ET, Wednesday, July 1, 2020.

We look forward to you continuing to be part of the Inozyme team and helping to build what we hope will be an exceptional organization.

Very Truly Yours,

By: /s/ Axel Bolte
Name: Axel Bolte

Title: Chief Executive Officer

The foregoing correctly sets forth the terms of my employment by Inozyme Pharma, Inc. I am not relying on any representations other than those set forth above.

/s/ Stephen Basso Date: July 1, 2020

Name: Stephen Basso



#### APPENDIX A

## **Payments Subject to Section 409A**

- 1. Subject to this Appendix A, any severance payments that may be due under the Letter Agreement to which it is attached shall begin only upon the date of your "separation from service" (determined as set forth below) which occurs on or after the termination of your employment. The following rules shall apply with respect to distribution of the severance payments, if any, to be provided to you under the Letter Agreement, as applicable:
  - (a) It is intended that each installment of the severance payments under the Letter Agreement shall be treated as a separate "payment" for purposes of Section 409A of the Internal Revenue Code and the guidance issued thereunder ("Section 409A"). Neither the Company nor you shall have the right to accelerate or defer the delivery of any such payments except to the extent specifically permitted or required by Section 409A.
  - (b) If, as of the date of your "separation from service" from the Company, you are not a "specified employee" (within the meaning of Section 409A), then each installment of the severance payments shall be made on the dates and terms set forth in the Letter Agreement.
  - (c) If, as of the date of your "separation from service" from the Company, you are a "specified employee" (within the meaning of Section 409A), then:
    - (i) Each installment of the severance payments due under the Letter Agreement that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when your separation from service occurs, be paid within the short-term deferral period (as defined under Section 409A) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A and shall be paid on the dates and terms set forth in the Letter Agreement; and
    - (ii) Each installment of the severance payments due under the Letter Agreement that is not described in this Appendix A, Section 1(c)(i) and that would, absent this subsection, be paid within the six-month period following your "separation from service" from the Company shall not be paid until the date that is six months and one day after such separation from service (or, if earlier, your death) (the "New Payment Date"), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the New Payment Date and any subsequent installments, if any, being paid in accordance with the dates and terms set forth herein; provided, however, that the preceding provisions of this sentence shall not apply to any installment of

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payments if and to the maximum extent that such installment is deemed to be paid under a separation pay plan that does not provide for a deferral of compensation by reason of the application of Treasury Regulation 1.409A-1(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-1(b)(9)(iii) must be paid no later than the last day of your second taxable year following the taxable year in which the separation from service occurs.

- 2. The determination of whether and when your separation from service from the Company has occurred shall be made in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h). Solely for purposes of this Appendix A, Section 2, "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Internal Revenue Code.
- 3. All reimbursements and in-kind benefits provided under the Letter Agreement shall be made or provided in accordance with the requirements of Section 409A to the extent that such reimbursements or in-kind benefits are subject to Section 409A, including, where applicable, the requirements that (i) any reimbursement is for expenses incurred during your lifetime (or during a shorter period of time specified in the Letter Agreement), (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred and (iv) the right to reimbursement is not subject to set off or liquidation or exchange for any other benefit.
- 4. The Company makes no representation or warranty and shall have no liability to you or to any other person if any of the provisions of the Letter Agreement (including this Appendix) are determined to constitute deferred compensation subject to Section 409A but that do not satisfy an exemption from, or the conditions of, that section.

# Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated May 8, 2020, except for Note 13(d), as to which the date is July 20, 2020, in Amendment No. 1 to the Registration Statement (Form S-1 No. 333-239648) and related Prospectus of Inozyme Pharma, Inc. dated July 20, 2020 for the registration of shares of its common stock.

/s/ Ernst & Young LLP

Boston, Massachusetts July 20, 2020