Table of Contents

Filed Pursuant to Rule 424(b)(4)
Registration No. 333-239648
Registration No. 333-240063

PROSPECTUS

7,000,000 Shares

Common Stock

This is Inozyme Pharma, Inc.'s initial public offering. We are selling 7,000,000 shares of our common stock.

The public offering price is $16.00 per share. Currently, no public market exists for the shares. The shares have been approved for listing on the Nasdaq Global Select 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	$16.00	$112,000,000
Underwriting discount(1)	$1.12	$7,840,000
Proceeds, before expenses, to us	$14.88	$104,160,000

(1) We refer you to "Underwriting" beginning on page 208 of this prospectus for additional information regarding underwriting compensation.

The underwriters may also exercise their option to purchase up to an additional 1,050,000 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 July 28, 2020.

BofA Securities **Cowen** **Piper Sandler**

Wedbush PacGrow

The date of this prospectus is July 23, 2020.

TABLE OF CONTENTS

PROSPECTUS SUMMARY	1
RISK FACTORS	12
CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA	79
USE OF PROCEEDS	81
DIVIDEND POLICY	82
CAPITALIZATION	83
DILUTION	85
SELECTED CONSOLIDATED FINANCIAL DATA	88
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	90
BUSINESS	110
MANAGEMENT	161
EXECUTIVE COMPENSATION	168
TRANSACTIONS WITH RELATED PERSONS	185
PRINCIPAL STOCKHOLDERS	191
DESCRIPTION OF CAPITAL STOCK	195
SHARES ELIGIBLE FOR FUTURE SALE	201
MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF COMMON STOCK	204
UNDERWRITING	208
LEGAL MATTERS	217
EXPERTS	217
WHERE YOU CAN FIND MORE INFORMATION	217
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS	F-1

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 ® and ™ 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.

PROGRAM	ASSET	STAGE OF DEVELOPMENT				NEXT ANTICIPATED MILESTONE
		Research	IND Enabling	Phase 1/2	Phase 2/3	
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 third-party 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 comparable to 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	7,000,000 shares
Common stock to be outstanding immediately following this offering	22,314,851 shares
Option to purchase additional shares	We have granted the underwriters an option for a period of 30 days to purchase up to 1,050,000 additional shares of our common stock.
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $100.9 million (or approximately $116.5 million if the underwriters exercise their option to purchase additional shares in full), based on the initial public offering price of $16.00 per share, after deducting 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.
Risk Factors	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.
Nasdaq Global Select 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 available for future issuance under our new 2020 Stock Incentive Plan, 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 available for future issuance under our new 2020 Employee Stock Purchase Plan.

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

- assumes no exercise by the underwriters of their option to purchase 1,050,000 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 Ended December 31,		Three Months Ended March 31,	
	2018	2019	2019	2020
	(in thousands, except share and per share data)			
Consolidated Statements of Operations Data:				
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)		15,136,994		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.

	March 31, 2020		
	Actual	Pro Forma(1)	Pro Forma As Adjusted(2)
		(in thousands)	
Consolidated Balance Sheet Data:			
Cash, cash equivalents and short-term investments	$ 40,840	$ 74,540	$ 175,400
Working capital(3)	36,354	70,054	170,914
Total assets	42,036	75,736	176,596
Convertible preferred stock	77,927	—	—
Accumulated deficit	(42,390)	(60,149)	(60,149)
Total stockholders' (deficit) equity	(40,800)	70,827	171,687

(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 a fair value of $2.14 per share for the 8,294,360 shares of our Series A-2 Convertible Preferred Stock issued to Alexion, based upon an as converted estimated value per common share of $16.00, which is the initial public offering price per share. The shares of Series A-2 Convertible Preferred Stock issued to Alexion 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 in our consolidated financial statements for the three months ended September 30, 2020 because we will use them in our research and development activities and believe they have no alternative future uses. Based on the assumed fair value described above, this would result in an expense of approximately $17.8 million at the date of acquisition. For a further description of our intellectual property asset acquisition from Alexion, see "Business—Alexion Intellectual Property Asset Acquisition."

(2) The pro forma as adjusted balance sheet data give further effect to our issuance and sale of 7,000,000 shares of our common stock in this offering at the initial public offering price of $16.00 per share, after deducting 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.

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 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. 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 a significant number of recent business

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 patent laws in the United States and other countries may diminish the value of our patents and our ability to obtain, protect, maintain, defend and enforce our patent rights, narrow the scope of our patent protection and, more generally, could affect the value or narrow the scope of our patent rights.

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 curtailment of our operations.

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 59% 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 is 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 the initial public offering price of $16.00 per share, you will experience immediate dilution of $8.25 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 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 was determined through negotiations with the underwriters. Although our common stock has been approved for listing on the Nasdaq Global Select 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 loses 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 22,314,851 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 Select 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,” “predict,” “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 7,000,000 shares of our common stock in this offering will be approximately $100.9 million, based on the initial public offering price of $16.00 per share, after deducting 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 $116.5 million.

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 7,000,000 shares of our common stock in this offering at the initial public offering price of $16.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma balance information assumes a fair value of $2.14 per share for the 8,294,360 shares of our Series A-2 Convertible Preferred Stock issued to Alexion, based upon an as converted estimated value per common share of $16.00, which is the initial public offering price per share. The shares of Series A-2 Convertible Preferred Stock issued to Alexion 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 in our consolidated financial statements for the three months ended September 30, 2020 because we will use them in our research and development activities and believe they have no alternative future uses. Based on the assumed fair value described above, this would result in an expense of approximately $17.8 million at the date of acquisition. For a further description of our intellectual property asset acquisition from Alexion, see “Business—Alexion Intellectual Property Asset Acquisition.”

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	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share and per share data)		
Cash, cash equivalents and short-term investments	$ 40,840	$ 74,540	$ 175,400
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; 200,000,000 shares authorized, 22,161,157 shares issued and outstanding, pro forma as adjusted	—	1	2
Additional paid in-capital	1,562	130,947	231,806
Accumulated other comprehensive income	28	28	28
Accumulated deficit	(42,390)	(60,149)	(60,149)
Total stockholders' equity	(40,800)	70,827	171,687
Total capitalization	$ 37,127	$ 70,827	$ 171,687

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 available for future issuance under our new 2020 Stock Incentive Plan, 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 available for future issuance under our new 2020 Employee Stock Purchase Plan.

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 a fair value of $2.14 per share of our Series A-2 Convertible Preferred Stock, based upon an as converted estimated value per common share of $16.00, which is the initial public offering price per share, 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 7,000,000 shares of our common stock in this offering at the initial public offering price of $16.00 per share, and after deducting 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 $171.7 million, or $7.75 per share. This represents an immediate increase in pro forma as adjusted net tangible book value per share of $3.08 to existing stockholders and immediate dilution of $8.25 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 initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Initial public offering price per share		$16.00
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	3.08	
Pro forma as adjusted net tangible book value per share immediately after this offering		$ 7.75
Dilution per share to new investors purchasing shares of our common stock in this offering		$ 8.25

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 $8.07, representing an immediate increase in pro forma as adjusted net tangible book value per share of $3.40 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, based on the initial public offering price of $16.00 per share, and after deducting 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 the initial public offering price of $16.00 per share, before deducting 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 Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percentage	
Existing stockholders	14,051,247	67%	$116,328,210	51%	$ 8.28
Investors purchasing shares of our common stock in this offering	7,000,000	33%	$112,000,000	49%	$ 16.00
Total	21,051,247	100%	$228,328,210	100%	

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 64% 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 36% 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 a fair value of $2.14 per share of our Series A-2 Convertible Preferred Stock, based upon an as converted estimated value per common share of $16.00, which is the initial public offering price per share, 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 available for future issuance under our new 2020 Stock Incentive Plan, 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 available for future issuance under our new 2020 Employee Stock Purchase Plan.

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 31,	
	2018	2019	2019	2020
	(in thousands, except share and per share data)			
Consolidated Statements of Operations Data:				
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)		15,136,994		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, 2018	As of December 31, 2019	As of March 31, 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)

(1) 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 common stock.

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 December 31,		Three Months Ended March 31,	
	2018	2019	2019	2020
Risk-free interest rate	2.35% to 3.01%	1.63% to 2.51%	2.51%	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 December 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)	Per Share Fair Value of Common Stock on Grant Date(2)	Per Share Estimated Fair Value of Award(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

(1) 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.

(2) 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 Months Ended March 31,	
	2018	2019	2019	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,		Increase (Decrease)
	2019	2020	
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 Ended December 31,		
	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):

	December 31, 2018	December 31, 2019	March 31, 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):

	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 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.

PROGRAM	ASSET	STAGE OF DEVELOPMENT				NEXT ANTICIPATED MILESTONE
		Research	IND Enabling	Phase 1/2	Phase 2/3	
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

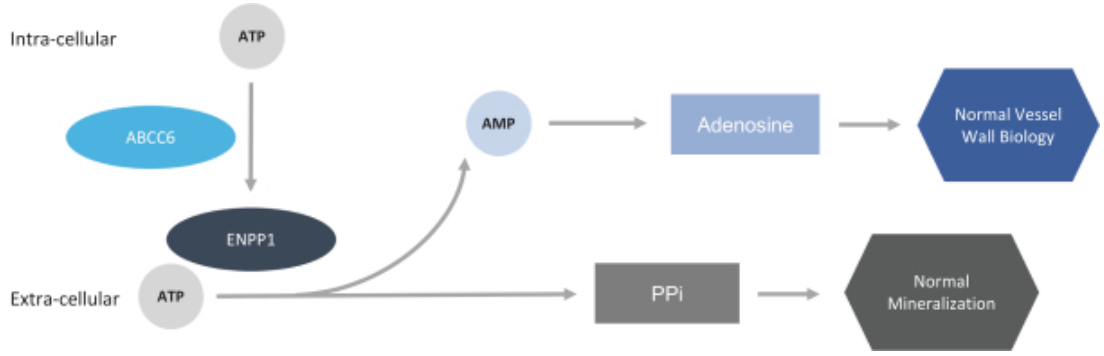
Mineralization is a biological process during which an organism deposits calcium salt crystals, typically calcium polyphosphates, onto an organic extracellular matrix that gives rise to essential structures, such as bone and teeth in humans. In human development, this normal mineralization process begins 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.

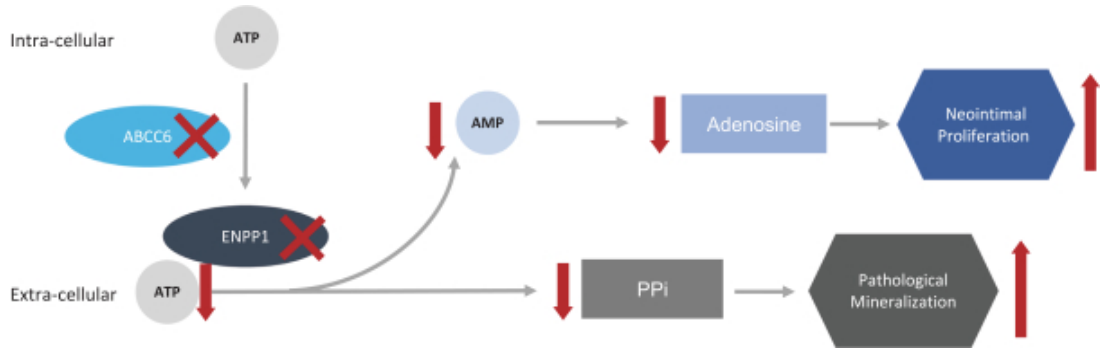


Pathology of Diseases of Abnormal Mineralization

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

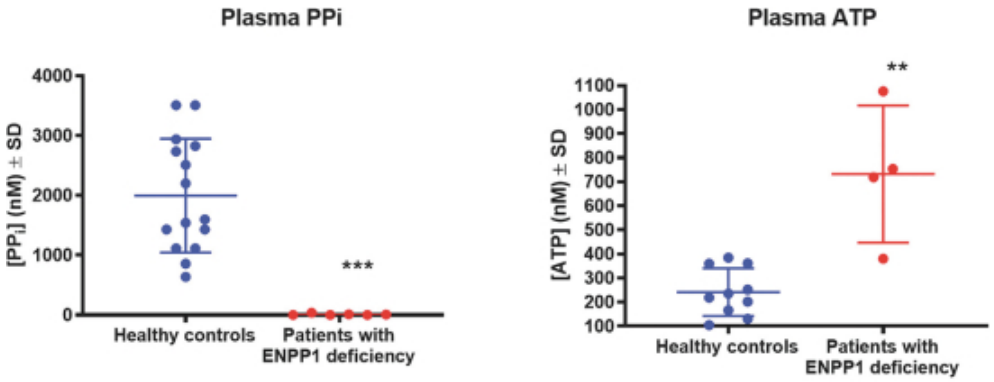
ENPP1 deficiency is a rare, inherited, genetic inborn error of metabolism caused by mutations in the ENPP1 gene. The condition is inherited as a recessive trait in which mutations in the ENPP1 gene result in decreased or absent activity of the ENPP1 enzyme. ENPP1 deficiency results in low plasma levels 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.

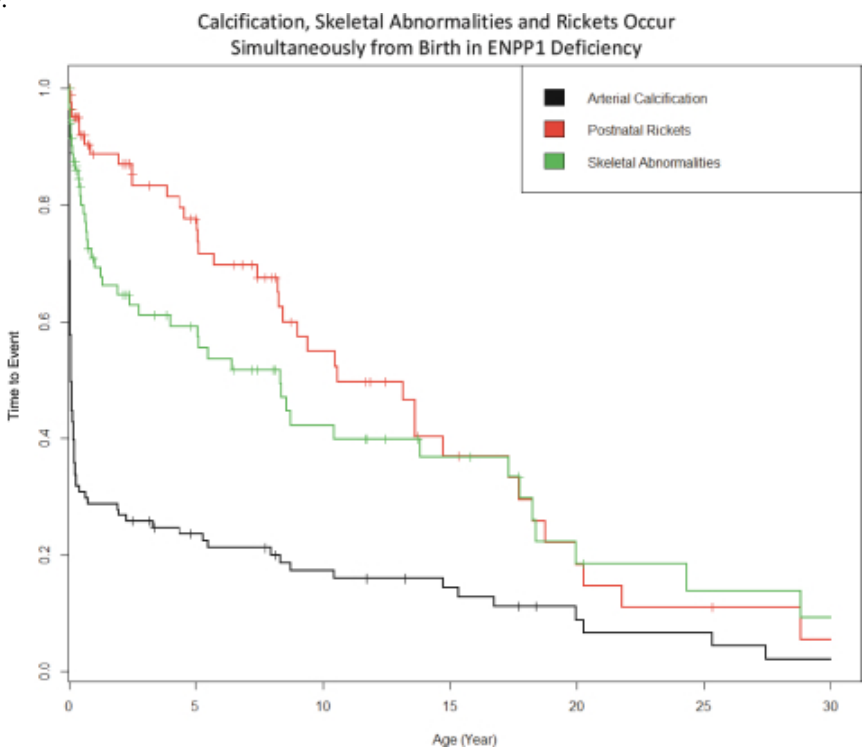
The graphs below, adapted from a third-party study, show that patients with ENPP1 deficiency have decreased levels of PPi and elevated levels of ATP in the plasma. This study measured plasma levels of PPi and plasma levels of ATP in healthy volunteers between 19 and 40 years of age and in patients with 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.



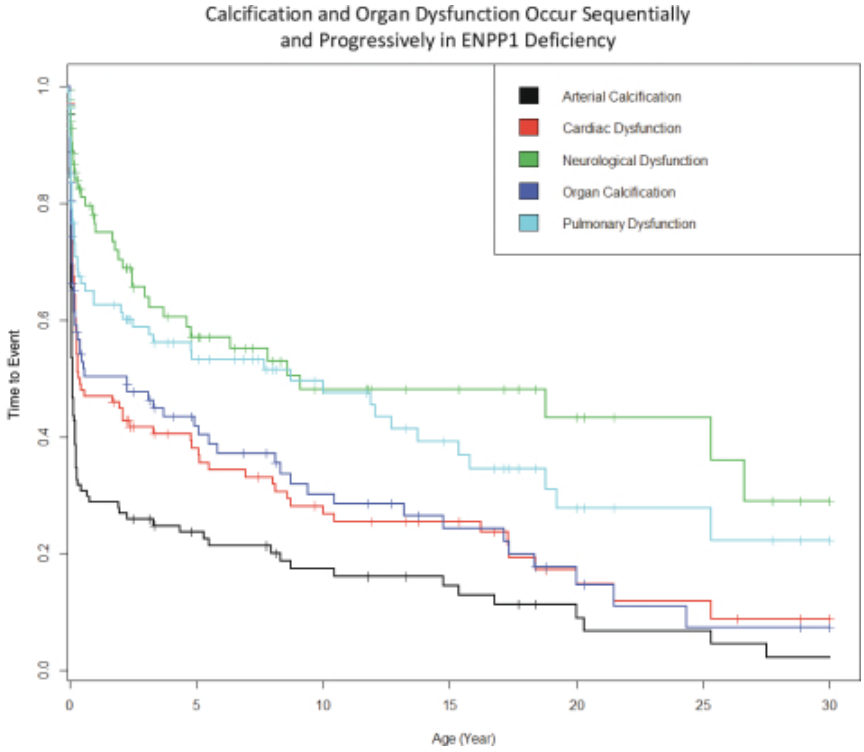
Retrospective Natural History Study

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

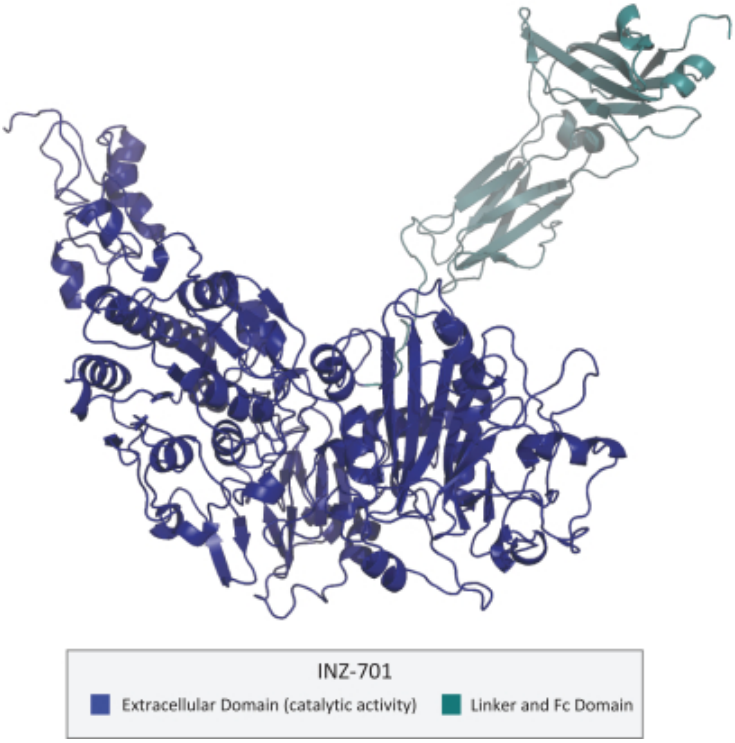
Abnormal mineralization and neointimal proliferation may also manifest in non-genetic diseases, such as calciphylaxis. Calciphylaxis, a manifestation of CKD, is associated with low levels of PPi and is characterized by pathological calcification of the vasculature in the skin and fat leading to blood 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

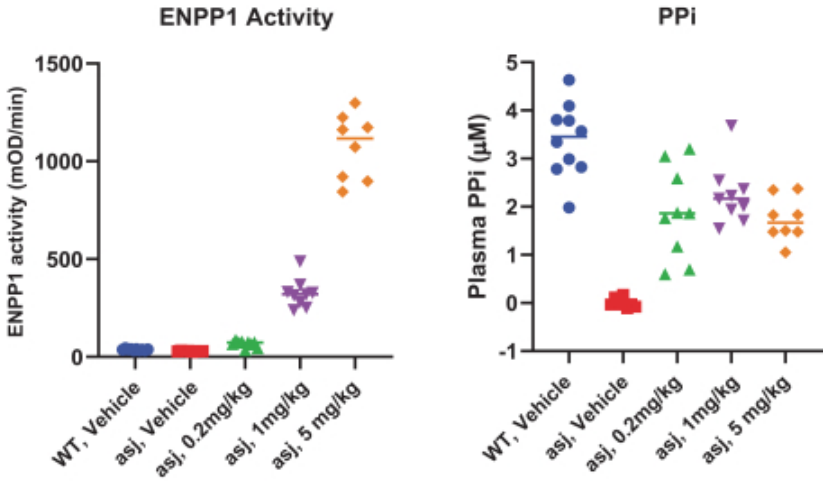
We determined preclinical proof of concept for INZ-701 using multiple mouse models containing inactivated genes for ENPP1. In these ENPP1-deficient mouse models, the animals have an increased propensity for vascular calcification and replicate key aspects of human disease due to ENPP1 deficiency. For 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.



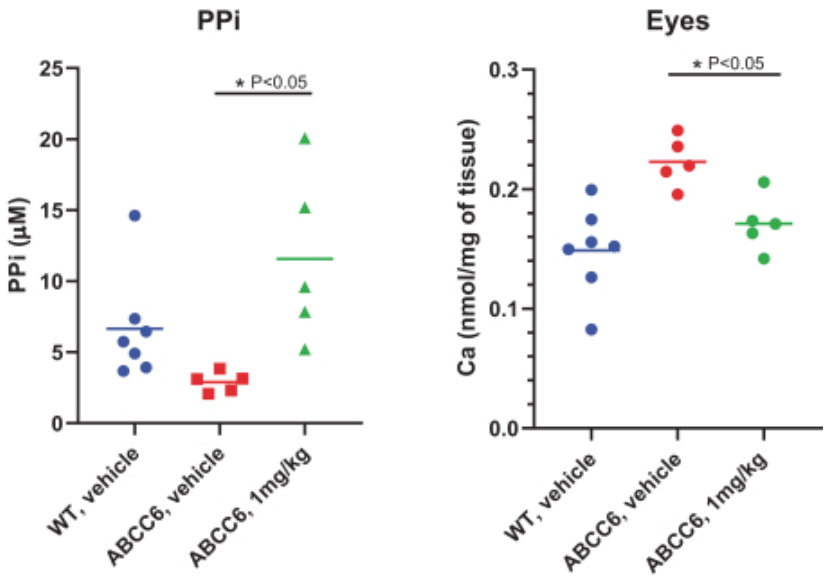
In addition to its ability to increase PPi levels in ENPP1-deficient mice, these initial studies showed that it is possible to administer doses of INZ-701 that normalized PPi levels in mice. We believe that increasing the amount of ENPP1 enzymatic activity by administration of INZ-701 could lead to further 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

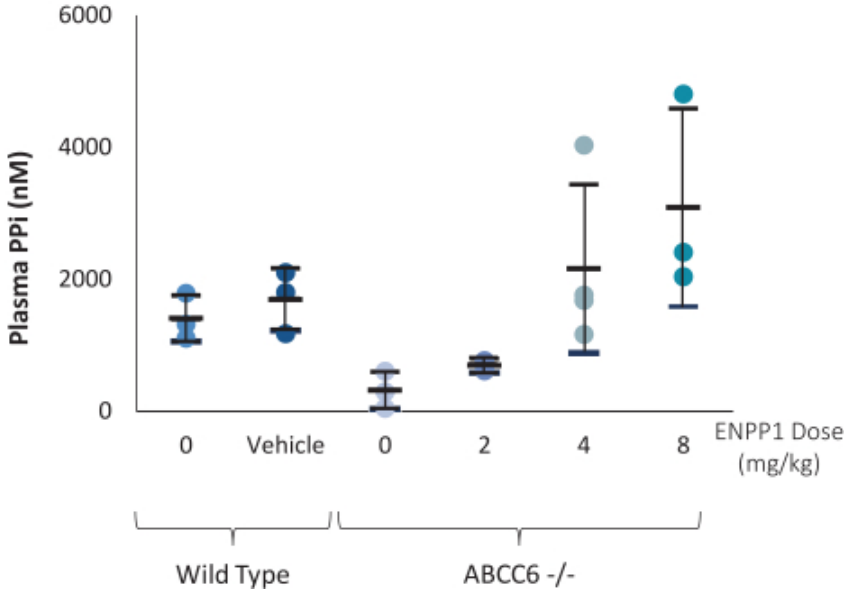
ABCC6 deficiency. Individuals with PXE have dysfunctional ABCC6 and decreased levels of plasma PPi due to deficiencies in exporting ATP from within the cell. In studies in mice with defects in the ABCC6 gene, plasma PPi levels are significantly reduced from wild-type mice but still higher than those 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.

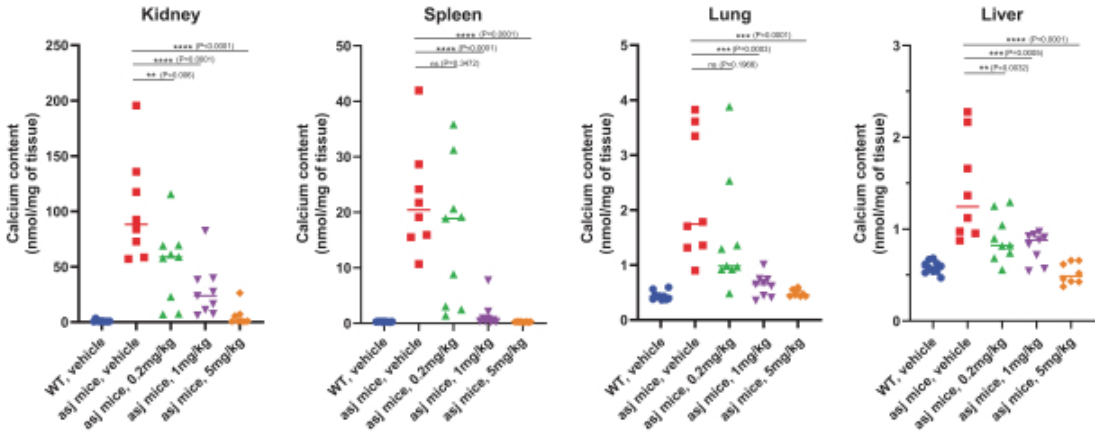


The above findings in ABCC6-deficient mice were also observed in another study, as shown in the graph below, where doses of mENPP1-Fc, a research version of INZ-701 containing a mouse Fc domain, ranging from 2 mg/kg to 8 mg/kg increased plasma PPi levels to wild-type levels. We believe that the data 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.

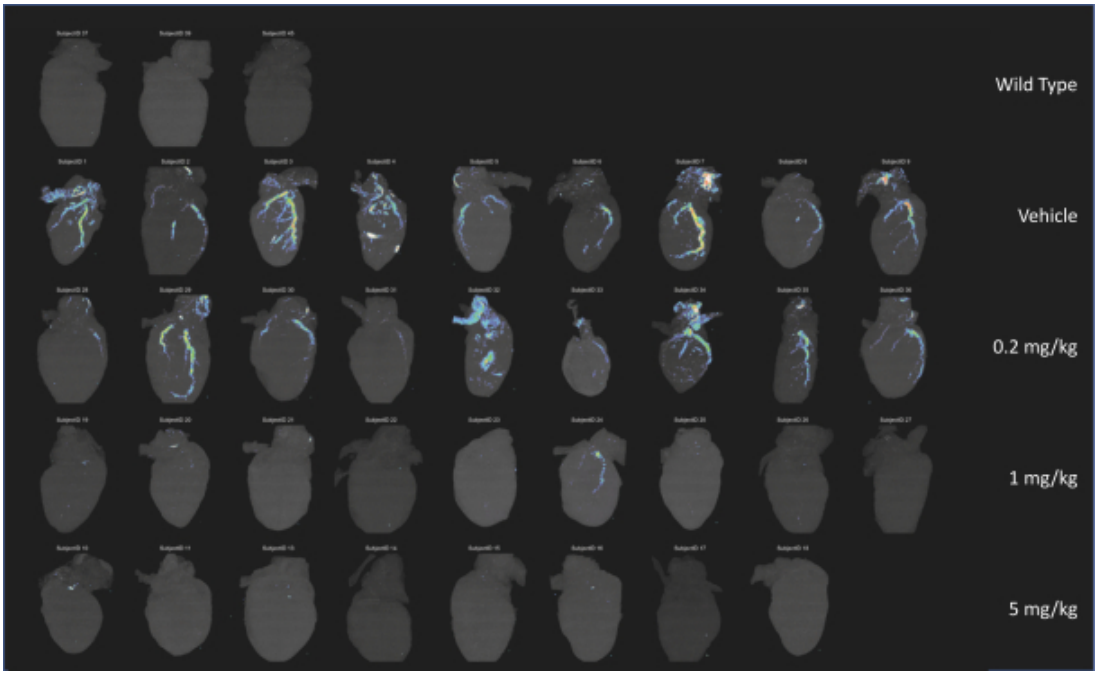


Reduction of Calcification

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.

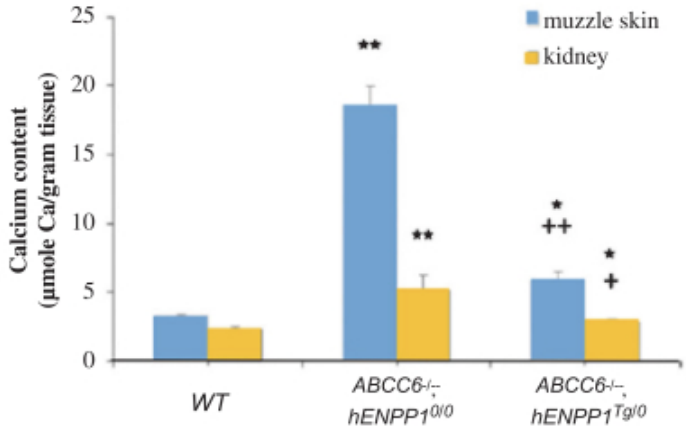


We obtained evidence of changes in vascular calcification in *asj* mice on the acceleration diet by carrying out scans of the heart and aorta using a technique known as high resolution micro computed tomography, or micro CT. All nine *asj* mice dosed with vehicle control showed variable but extensive 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.



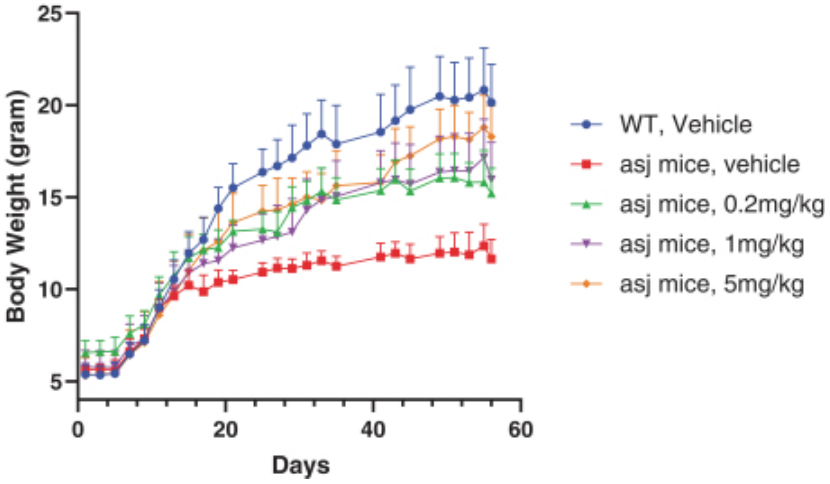
To investigate whether increasing plasma PPi levels would prevent ectopic calcification in ABCC6-deficient mice, ABCC6-deficient mice were crossed with a transgenic mouse with ubiquitous overexpression of human ENPP1 (the ABCC6 $^{-/-}$ hENPP1$^{tg/0}$ group in the graph below) and the results were compared to mice without overexpression of ENPP1 (the ABCC6$^{-/-}$ hENPP1$^{0/0}$ 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 0.05 from wild-type, the symbol ++ represents a p-value of less than 0.01 from the ABCC6$_{-/-}$ hENPP1$_{0/0}$ group and the symbol + represents a p-value of less than 0.01.



Overall Health and Survival

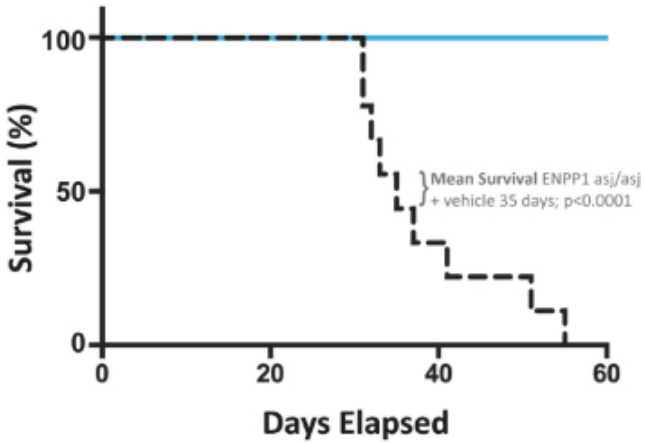
In addition to the measured changes in calcium deposition, treatment of *asj* mice with 0.2 mg/kg, 1 mg/kg or 5 mg/kg of INZ-701 and vehicle control every other day also led to improvements in overall health. Mice treated with INZ-701 had a dose-dependent increase in body weight compared to mice treated 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).

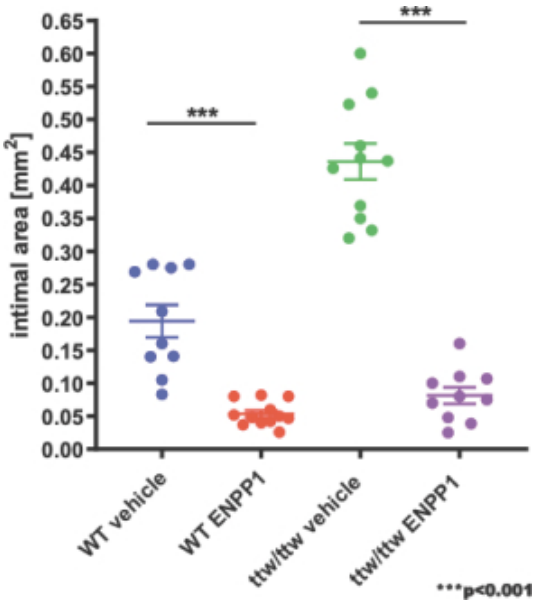


In another experiment, we treated *asj* mice with 0.2 mg/kg, 1 mg/kg or 5 mg/kg of INZ-701 and vehicle control for 56 days to analyze by micro CT the femora and tibiae bones and measure both trabecular number and cortical thickness, which are two important contributors of a bone's strength. The strength 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. Importantly, INZ-701 also 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, 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 pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries.

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 drug-pricing 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.

Name	Age	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 currently consists of eight members. Our board of directors is currently authorized to have nine members and following the closing of this offering will be authorized to have 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 or otherwise be an affiliated person of 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. Our audit committee's responsibilities 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 meets 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. Our compensation committee's responsibilities 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 meets 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. Our nominating and corporate governance committee's responsibilities 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 meets 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 have posted 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.

(2) 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 is $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, is 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 were 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.

	Option Awards			
Name	Number of securities underlying unexercised options (#) exercisable	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.

(3) 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 became 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 became 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 became 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; 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 became 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. The number of shares of our common stock reserved for issuance under the 2020 Plan is 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 remained 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 are 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) 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, 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 became 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 ESPP.

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.

Name	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 became 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:

	Member Annual Fee	Chair 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

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, 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:

Purchaser(1)	Date	Shares of Series A Convertible Preferred Stock	Aggregate Cash Purchase 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

(1) See the “Principal Stockholders” section of this prospectus for additional information about shares held by these entities and individuals.
(2) 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.
(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.
(5) 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:

Purchaser(1)	Shares of Series A Convertible Preferred Stock	Aggregate Cash Purchase 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 Preferred Stock	Aggregate Purchase Price
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:

Purchaser(1)	Shares of Series A-2 Convertible Preferred Stock	Aggregate Purchase Price
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
Sofinnova Venture Partners X, L.P.	5,944,056	$8,500,000
Pivotal bioVenture Partners Fund I, L.P.	5,244,755	$7,500,000
Entities affiliated with RA Capital Management, L.P.(2)	5,244,755	$7,500,000
Entities affiliated with Cowen Healthcare Investments(3)	3,146,853	$4,500,000

(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	Principal Stockholder
Sarah Bhagat	Sofinnova Venture Partners X, L.P.
Reinaldo Diaz	Longitude Venture Partners III, L.P.
Martin Edwards	Novo Holdings A/S
Robert Hopfner	Pivotal bioVenture Partners Fund I, L.P.
Edward Mathers	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 became 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 22,314,851 shares of our common stock to be outstanding after this offering, including the 7,000,000 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.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering (%)	After Offering (%)
5% Stockholders			
Longitude Venture Partners III, L.P.(1)	2,194,379	14.3	9.8
Entities affiliated with New Enterprise Associates(2)	2,194,379	14.3	9.8
Novo Holdings A/S(3)	2,194,379	14.3	9.8
Sofinnova Venture Partners X, L.P.(4)	1,590,808	10.4	7.1
Pivotal bioVenture Partners Fund I, L.P.(5)	1,403,654	9.2	6.3
Entities affiliated with RA Capital Management, L.P.(6)	1,403,653	9.2	6.3
Alexion Pharmaceuticals, Inc.(7)	1,109,910	7.2	5.0
Entities affiliated with Cowen Healthcare Investments(8)	842,191	5.5	3.8
Directors and Named Executive Officers			
Axel Bolte(9)	459,810	3.0	2.0
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	6.3
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	9.5

* Less than 1%

(1) 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.

(2) 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 is Computershare Trust Company, N.A.

Nasdaq Global Select Market

Our common stock has been approved for listing on the Nasdaq Global Select 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 22,314,851 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 7,000,000 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 223,149 shares immediately after this offering; and
- the average weekly trading volume in our common stock on the Nasdaq Global Select 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, 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 Rights” section 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.	2,800,000
Cowen and Company, LLC	2,065,000
Piper Sandler & Co.	1,575,000
Wedbush Securities Inc.	560,000
Total	7,000,000

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 $0.672 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	$16.00	$112,000,000	$128,800,000
Underwriting discount	$1.12	$7,840,000	$9,016,000
Proceeds, before expenses, to us	$14.88	$104,160,000	$119,784,000

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 1,050,000 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 Select Market Listing

Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol “INZY.”

Before this offering, there has been no public market for our common stock. The initial public offering price was determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors considered in determining the initial public offering price were:

- 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 Select 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.

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 activities 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, or any person pursuant to Section 275(1A) 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; (ii) which 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.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	Page
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2018 and 2019 and as of March 31, 2020 (unaudited) actual and pro forma	F-3
Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2018 and 2019 and the three months ended March 31, 2019 and 2020 (unaudited)	F-4
Consolidated Statements of Convertible Preferred Stock and Stockholders' (Deficit) Equity for the years ended December 31, 2018 and 2019 and the three months ended March 31, 2019 and 2020 (unaudited) actual and pro forma	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2018 and 2019 and the three months ended March 31, 2019 and 2020 (unaudited)	F-6
Notes to Consolidated Financial Statements	F-7

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)

	December 31, 2018	December 31, 2019	March 31, 2020 (unaudited)	Pro Forma March 31, 2020 (unaudited)
Assets				
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	130,947
Accumulated other comprehensive income (loss)	(2)	5	28	28
Accumulated deficit	(14,928)	(34,652)	(42,390)	(60,149)
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)

	Year Ended December 31,		Three Months Ended March 31,	
	2018	2019	2019 (unaudited)	2020 (unaudited)
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)
Other comprehensive income:				
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 Convertible Preferred Stock		Series A-2 Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
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 Preferred tranche liability	—	172	—	—	—	—	—	—	—	—
Issuance of Series A-2 Convertible Preferred Stock, net of issuance costs of $0.3 million	—	—	7,482,515	10,372	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	444	—	—	444
Comprehensive income:										
Unrealized gain on investments	—	—	—	—	—	—	—	16	—	16
Net loss	—	—	—	—	—	—	—	—	(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)
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:										
Unrealized gain on investments	—	—	—	—	—	—	—	7	—	7
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)	—	—	—	—	—	—	129	—	—	129
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)
Balance at March 31, 2020 (unaudited)	48,850,000	44,657	23,566,431	33,270	1,207,307	—	1,562	28	(42,390)	(40,800)
Issuance of Series A-2 Convertible Preferred Stock (unaudited)	—	—	31,860,791	51,459	—	—	—	—	—	—
Write-off of acquired in-process research and development (unaudited)	—	—	—	—	—	—	—	—	(17,759)	(17,759)
Conversion of convertible preferred stock into common stock (unaudited)	(48,850,000)	(44,657)	(55,427,222)	(84,729)	13,953,850	1	129,385	—	—	129,386
Pro forma balance at March 31, 2020 (unaudited)	—	$ —	—	$ —	15,161,157	$ 1	$ 130,947	$ 28	$ (60,149)	$ 70,827
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 $0.1 million (unaudited)	—	—	16,083,916	22,898	—	—	—	—	—	—
Stock-based compensation (unaudited)	—	—	—	—	—	—	41	—	—	41
Exercise of stock options (unaudited)	—	—	—	—	35,460	—	34	—	—	34
Comprehensive income:										
Unrealized gain on investments (unaudited)	—	—	—	—	—	—	—	2	—	2
Net loss (unaudited)	—	—	—	—	—	—	—	—	(4,971)	(4,971)
Balance at March 31, 2019 (unaudited)	48,850,000	$ 44,657	23,566,431	$ 33,270	1,170,475	$ —	$ 1,130	$ —	$ (19,899)	$ (18,769)

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,		Three Months Ended March 31,	
	2018	2019	2019 (unaudited)	2020 (unaudited)
Operating activities				
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	$ —	$ —	$ —	$ 191

The accompanying 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 a fair value of $2.14 per share, based upon an as converted estimated value per common share of $16.00, 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 estimated value of the acquired intellectual property assets of $17.8 million has been reflected as a non-recurring charge to the Company’s pro forma accumulated deficit, reflecting the non-recurring write-off of

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.

4. Balance Sheet Details

Short-term investments consisted of the following (dollar amounts in thousands):

		December 31, 2018			
Description	Maturity	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper	1 year or less	$ 3,980	$ —	$ (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	$ —	$ (2)	$ 7,197

		December 31, 2019			
Description	Maturity	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper	1 year or less	$ 10,903	$ 3	$ —	$ 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	$ —	$ 15,527

		March 31, 2020 (unaudited)			
Description	Maturity	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper	1 year or less	$ 10,195	$ 16	$ —	$ 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):

		December 31, 2018	
Description	Maturity	Fair Value	Unrealized 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	Unrealized 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 December 31,		At March 31,
	2018	2019	2020 (unaudited)
Interest receivable	$ 31	$ 104	$ 44
Prepaid seminars	—	—	116
Prepaid insurance	21	47	26
Prepaid taxes	—	42	42
Prepaid other	52	135	195
Total	$ 104	$ 328	$ 423

Property and equipment consisted of the following (dollar amounts in thousands):

	At December 31, 2018	At December 31, 2019	At March 31, 2020 (unaudited)
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 December 31, 2018	At December 31, 2019	At March 31, 2020 (unaudited)
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):

Description	December 31, 2018	Fair Value Measurements at Reporting Date Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 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	—	—
Total assets	$ 11,174	$ 3,479	$ 7,695	$ —

Description	December 31, 2019	Fair Value Measurements at Reporting Date Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds (included in cash and cash equivalents)	$ 11,709	$ 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	—	—
Total assets	$ 31,417	$ 12,959	$ 18,458	$ —

Description	March 31, 2020	Fair Value Measurements at Reporting Date Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	(unaudited)			
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 1 year	1-3 years	3-5 years	More than 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				
Description	Preferred stock authorized	Preferred stock issued and outstanding	Carrying value	Liquidation preference	Common 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

	December 31, 2019				
Description	Preferred stock authorized	Preferred stock issued and outstanding	Carrying value	Liquidation preference	Common 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	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

Description	March 31, 2020 (unaudited) Preferred stock authorized	Preferred stock issued and outstanding	Carrying value	Liquidation preference	Common 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	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)	Aggregate Intrinsic Value (in thousands)
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 December 31,		Three Months Ended March 31,	
	2018	2019	2019 (unaudited)	2020 (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 Ended 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):

	December 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)	$ —	$ —

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 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 in its consolidated financial statements for the three months ended September 30, 2020 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 August 17, 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.

7,000,000 Shares

Common Stock

PROSPECTUS

BofA Securities

Cowen

Piper Sandler

Wedbush PacGrow

July 23, 2020