UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2021

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-39397

INOZYME PHARMA, INC.
(Exact name of registrant as specified in its charter)

Delaware	**38-4024528**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
321 Summer Street, Suite 400 Boston, Massachusetts	**02210**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (857) 330-4340

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	INZY	Nasdaq Global Select Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of May 7, 2021, the registrant had 23,483,093 shares of common stock, $0.0001 par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance. All statements, other than statements of historical fact, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “outlook,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would,” and the negative version of these words and other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such forward-looking statements are subject to various risks and uncertainties. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. We believe these factors include but are not limited to those described in the “Risk Factors” section in our most recent Annual Report on Form 10-K and include, among other things:

- 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, enrollment and completion of the clinical trials and the period during which the results of the clinical trials will become available;
- the timing of our additional planned clinical trial applications for INZ-701 for ENPP1 Deficiency;
- our plan to file an investigational new drug application amendment for INZ-701 for ABCC6 Deficiency;
- 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 and long-term investments;
- 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 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 Jumpstart our Business Startups Act of 2012.

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 our most recent Annual Report on Form 10-K, 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 Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q are made as of the date of this Quarterly Report on Form 10-Q, 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.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

INOZYME PHARMA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(amounts in thousands, except share and per share data)
(Unaudited)

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 16,486	$ 28,040
Short-term investments	128,600	119,657
Prepaid expenses and other current assets	2,955	3,282
Total current assets	148,041	150,979
Property and equipment, net	2,688	2,648
Right-of-use assets	2,341	—
Restricted cash	354	354
Long-term investments	2,548	12,199
Prepaid expenses, net of current portion	2,943	3,183
Total assets	$ 158,915	$ 169,363
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,709	$ 3,069
Accrued expenses	4,451	6,904
Operating lease liabilities	672	—
Total current liabilities	6,832	9,973
Operating lease liabilities, net of current portion	3,194	1,287
Total liabilities	10,026	11,260
Stockholders' equity:		
Preferred Stock, $0.0001 par value – 5,000,000 shares authorized at March 31, 2021 and December 31, 2020; No shares issued and outstanding at March 31, 2021 or December 31, 2020	—	—
Common Stock, $0.0001 par value – 200,000,000 shares authorized at March 31, 2021 and December 31, 2020; 23,473,703 shares issued and outstanding at March 31, 2021 and 23,384,969 shares issued and outstanding at December 31, 2020	2	2
Additional paid in-capital	251,001	249,175
Accumulated other comprehensive income	12	2
Accumulated deficit	(102,126)	(91,076)
Total stockholders' equity	148,889	158,103
Total liabilities and stockholders' equity	$ 158,915	$ 169,363

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

INOZYME PHARMA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(amounts in thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 6,603	$ 6,406
General and administrative	4,369	1,500
Total operating expenses	10,972	7,906
Loss from operations	(10,972)	(7,906)
Other income (expense):		
Interest income	63	171
Other expenses	(141)	(3)
Other income (expense), net	(78)	168
Net loss	$ (11,050)	$ (7,738)
Other comprehensive income:		
Unrealized gains on available-for-sale securities	10	23
Total other comprehensive income	10	23
Comprehensive loss	$ (11,040)	$ (7,715)
Net loss attributable to common stockholders—basic and diluted	$ (11,050)	$ (7,738)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.47)	$ (6.42)
Weighted-average common shares outstanding—basic and diluted	23,429,507	1,205,346

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

INOZYME PHARMA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(amounts in thousands, except share data)
(Unaudited)

	Series A Convertible Preferred Stock		Series A-2 Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Income	Deficit	(Deficit)
Balance at December 31, 2020	—	$ —	—	$ —	23,384,969	$ 2	$ 249,175	$ 2	$ (91,076)	$ 158,103
Stock-based compensation	—	—	—	—	—	—	1,577	—	—	1,577
Exercise of stock options	—	—	—	—	88,734	—	249	—	—	249
Comprehensive income:					—	—	—	—	—	—
Unrealized gain on investments	—	—	—	—	—	—	—	10	—	10
Net loss	—	—	—	—	—	—	—	—	(11,050)	(11,050)
Balance at March 31, 2021	—	$ —	—	$ —	23,473,703	$ 2	$ 251,001	$ 12	$ (102,126)	$ 148,889
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	—	—	—	—	—	—	129	—	—	129
Exercise of stock options	—	—	—	—	2,677	—	5	—	—	5
Comprehensive income:										
Unrealized gain on investments	—	—	—	—	—	—	—	23	—	23
Net loss	—	—	—	—	—	—	—	—	(7,738)	(7,738)
Balance at March 31, 2020	48,850,000	$ 44,657	23,566,431	$ 33,270	1,207,307	$ —	$ 1,562	$ 28	$ (42,390)	$ (40,800)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

INOZYME PHARMA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(amounts in thousands)
(Unaudited)

	Three Months Ended March 31,	
	2021	**2020**
Operating activities		
Net loss	$ (11,050)	$ (7,738)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	158	25
Stock-based compensation expense	1,577	129
Amortization of premiums and discounts on marketable securities	68	(46)
Reduction in the carrying value of right-of-use assets	90	—
Unrealized gains on available for sale securities	(10)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	327	(95)
Accounts payable	(1,373)	668
Accrued expenses	(2,272)	814
Operating lease liabilities	(131)	—
Prepaid expenses - noncurrent	240	—
Other assets	—	(22)
Net cash used in operating activities	(12,376)	(6,265)
Investing activities		
Purchases of marketable securities	(38,549)	(13,408)
Maturities of marketable securities	39,210	10,101
Purchases of property and equipment	(88)	(101)
Net cash provided by (used in) investing activities	573	(3,408)
Financing activities		
Proceeds from exercise of stock options	249	5
Net cash provided by financing activities	249	5
Net decrease in cash, cash equivalents and restricted cash	(11,554)	(9,668)
Cash, cash equivalents and restricted cash at beginning of period	28,394	31,735
Cash, cash equivalents and restricted cash at end of period	$ 16,840	$ 22,067
Supplemental cash flow information:		
Cash and cash equivalents	$ 16,486	$ 21,937
Restricted cash	354	130
Cash, cash equivalents and restricted cash at end of period	$ 16,840	$ 22,067
Property and equipment unpaid at end of period	$ 110	$ —
Right-of-use asset at adoption of ASC 842	$ 2,431	$ —
Operating lease liabilities at adoption of ASC 842	$ 3,997	$ —
Deferred offering costs unpaid at end of period	$ —	$ 191

The accompanying notes are an integral part of these unaudited condensed consolidated financial statement.

1. Organization and Basis of Presentation

Inozyme Pharma, Inc. (the "Company") is a clinical-stage 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.

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 financial statements and footnotes to the financial statements have been prepared on the same basis as the most recently audited annual financial statements, except for disclosures related to the Company's adoption of ASU 2016-02, *Leases ("Topic 842")* as of January 1, 2021 as disclosed in Note 3 "Recent Accounting Pronouncements". In the opinion of management, the accompanying consolidated financial statements and footnotes to the financial statements reflect all normal recurring adjustments necessary for the fair presentation of the Company's financial position as of March 31, 2021 and the results of its operations and its cash flows for the three months ended March 31, 2021 and 2020. The results for the three months ended March 31, 2021 are not necessarily indicative of results to be expected for the year ending December 31, 2021, any other interim periods, or any future year or period. These consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2020 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 25, 2021 (the "Annual Report on Form 10-K").

Liquidity

Since the Company's incorporation in 2017 and through March 31, 2021, 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 $11.1 million in the three months ended March 31, 2021 and $56.4 million in the year ended December 31, 2020 and had an accumulated deficit of $102.1 million as of March 31, 2021. The Company had cash, cash equivalents, and short-term and long-term investments of $147.6 million as of March 31, 2021.

The accompanying condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets, and the satisfaction of liabilities and commitments in the ordinary course of business. The Company has incurred recurring losses and negative cash flows from operations since inception and has primarily funded its operations with proceeds from the issuance of convertible preferred stock, and the Company's initial public offering ("IPO") completed on July 28, 2020. The Company expects its operating losses and negative operating cash flows to continue into the foreseeable future as it continues to expand its research and development efforts.

The Company believes that its cash, cash equivalents, and short-term and long-term investments as of March 31, 2021 will be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months from the date of filing this Quarterly Report on Form 10-Q. The Company will need additional funding to support its planned operating activities. If the Company is unable to obtain additional funding, it would be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion, or commercialization efforts, which could adversely affect its business prospects.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany transactions and balances have been eliminated.

Summary of Significant Accounting Policies

The significant accounting policies and estimates used in the preparation of the accompanying consolidated financial statements are described in the Company's audited consolidated financial statements for the year ended December 31, 2020 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 25, 2021. Apart from the Company's adoption of Topic 842, there have been no material changes in the Company's significant accounting policies during the three months ended March 31, 2021.

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 and, for equity instruments issued prior to the completion of the Company's IPO, stock-based compensation expense, inclusive of the measurement of fair value of equity instruments. For equity instruments issued prior to the completion of the Company's IPO, 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 instruments. 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.

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, clinical trials, 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. Research and development costs also include the write-off of acquired in-process research and development assets with no alternative future use.

Net Loss Per Share

The Company follows the two-class method when computing net loss allocable to common securities per share as the Company had previously issued shares that meet the definition of participating securities, which include shares of: (i) Series A Convertible Preferred Stock; and (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 income 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, 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.

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).

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 and long-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 investments are comprised of U.S. Treasury and U.S. government agency debt 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.

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 February 2016, the FASB issued 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. On January 1, 2021, the Company adopted Topic 842 using the modified retrospective approach. The Company recorded operating lease assets (right-of-use assets) of $2.4 million and operating lease liabilities of $4.0 million and reversed a lease liability of $1.6 million related to straight-line rent and incentives. There was no impact to accumulated deficit upon adoption of Topic 842. The underlying assets of the Company's leases are primarily office and laboratory space.

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, with early adoption permitted. On January 1 2021, the Company adopted this standard and the adoption did not have a material impact on its consolidated financial statements.

Recently Issued Accounting Standards Not Yet Adopted

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 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 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 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):

		March 31, 2021			
Description	Maturity	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper	1 year or less	$ 101,881	$ 8	$ (4)	$ 101,885
U.S. Treasury securities	1 year or less	12,626	3	—	12,629
U.S. government agency debt securities	1 year or less	14,082	4	—	14,086
		$ 128,589	$ 15	$ (4)	$ 128,600

		December 31, 2020			
Description	Maturity	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper	1 year or less	$ 94,873	$ 5	$ (6)	$ 94,872
U.S. Treasury securities	1 year or less	11,614	2	(1)	11,615
U.S. government debt securities	1 year or less	13,169	1	—	13,170
		$ 119,656	$ 8	$ (7)	$ 119,657

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

		March 31, 2021			
Description	Maturity	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. Treasury securities	After 1 year through 5 years	$ 2,547	$ 1	$ —	$ 2,548
		$ 2,547	$ 1	$ —	$ 2,548

Description	Maturity	December 31, 2020 Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. Treasury securities	After 1 year through 5 years	$ 5,126	$ —	$ —	$ 5,126
U.S. government agency debt securities	After 1 year through 5 years	7,072	1	—	7,073
		$ 12,198	$ 1	$ —	$ 12,199

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 March 31, 2021 and December 31, 2020. 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 March 31, 2021	At December 31, 2020
Interest receivable	$ 122	$ 155
Prepaid insurance	1,034	1,723
Prepaid research studies	1,260	804
Prepaid other	539	600
Total	$ 2,955	$ 3,282

Prepaid expenses, net of current portion consisted of the following (dollar amounts in thousands):

	At March 31, 2021	At December 31, 2020
Prepaid clinical trial and other	$ 2,943	$ 3,183
	$ 2,943	$ 3,183

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

	At March 31, 2021	At December 31, 2020
Laboratory equipment and manufacturing equipment	$ 522	$ 339
Furniture and fixtures	254	254
Computer equipment and software	302	287
Leasehold improvements	2,095	2,095
	3,173	2,975
Less accumulated depreciation	(485)	(327)
Total	$ 2,688	$ 2,648

Depreciation expense for the three months ended March 31, 2021 and 2020 was $158 thousand and $25 thousand, respectively.

Accrued expenses consisted of the following (dollar amounts in thousands):

	At March 31, 2021	At December 31, 2020
Payroll and related liabilities	$ 1,123	$ 2,296
Professional fees	418	454
Research and development costs	2,259	2,997
Deferred rent	—	279
Other	651	878
Total	$ 4,451	$ 6,904

5. Fair Value Measurement

The following table represents the Company's financial assets measured at fair value on a recurring basis and indicate the level of fair value hierarchy utilized to determine such fair values (in thousands):

		Fair Value Measurements at Reporting Date Using		
Description	March 31, 2021	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)	$ 1,524	$ 1,524	$ —	$ —
Commercial paper	101,884	—	101,884	—
U.S. Treasury securities	15,177	15,177	—	—
U.S. government agency debt securities	14,086	—	14,086	—
Total assets	$ 132,671	$ 16,701	$ 115,970	$ —

		Fair Value Measurements at Reporting Date Using		
Description	December 31, 2020	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)	$ 15,739	$ 15,739	$ —	$ —
Commercial paper	94,872	—	94,872	—
U.S. Treasury securities	16,741	16,741	—	—
U.S. government agency debt securities	20,243	—	20,243	—
Total assets	$ 147,595	$ 32,480	$ 115,115	$ —

There have been no transfers between fair value levels during the three months ended March 31, 2021.

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 March 31, 2021, the Company incurred a total of $99,000 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. The Company is not aware of any currently ongoing patent challenges.

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 $0.1 million and $0.2 million in the three months ended March 31, 2021 and 2020, respectively.

7. Commitments and Contingencies

Operating Leases

The Company adopted Topic 842 on January 1, 2021. Topic 842 allows the Company to elect a package of practical expedients, which provide that an entity need not reassess: (i) whether any expired or existing contracts are or contain leases; (ii) the lease classification for any expired or existing leases; and (iii) any initial direct costs for any existing leases. Another practical expedient allows the Company to use hindsight in determining the lease term when considering lessee options to extend or terminate the lease and to purchase the underlying asset. The Company has elected to utilize this package of practical expedients and has not elected the hindsight methodology in its implementation of Topic 842.

The Company elected to adopt this standard using the optional modified retrospective approach and recognized a cumulative-effect adjustment to the condensed consolidated balance sheet on the date of adoption. Comparative periods have not been restated. With the adoption of Topic 842, the Company's condensed consolidated balance sheet now contains the following line items: Right-of-use assets, Operating lease liabilities and Operating lease liabilities, net of current portion.

The Company determined that it held the following significant operating leases of office and laboratory space as of January 1, 2021:

- An operating lease for 8,499 square feet of office space in Boston, Massachusetts that expires in 2025, with an option to extend the term for five years; and
- An operating lease for 6,244 square feet of laboratory space in Boston, Massachusetts that expires in 2025.

In connection with the Company's lease of office space, 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 sheets as of March 31, 2021 and December 31, 2020.

The Company has elected to not recognize right-of-use assets and lease liabilities arising from short-term leases, which are leases that, at the commencement date, have a lease term of 12 months or less and do not include an option to purchase the underlying asset that the lessee is reasonably certain to exercise.

As all the existing leases subject to Topic 842 were previously classified as operating leases by the Company, they were similarly classified as operating leases under Topic 842. The Company has determined that the identified leases did not contain non-lease components and require no further allocation of the total lease cost. Additionally, the agreements in place did not contain information to determine the rate implicit in the lease. As such, the Company calculated the incremental borrowing rate based on the remaining lease terms as of January 1, 2021. At January 1, 2021 and March 31, 2021, the weighted average incremental borrowing rate and the weighted average remaining lease term for the operating leases held by the Company were 8.0% and 5.0 years, respectively.

As of March 31, 2021, right-of-use assets and liabilities arising from operating leases were $2.3 million and $3.9 million, respectively. During the three months ended March 31, 2021, cash paid for amounts included for the measurement of lease liabilities was $0.2 million and the Company recorded operating lease expense of $0.2 million.

Future lease payments under non-cancelable leases as of March 31, 2021 are as follows (dollar amounts in thousands):

Year Ending December 31,		
2021 (remaining 9 months)	$	709
2022		968
2023		992
2024		1,016
2025		944
Thereafter		—
	$	4,629

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters arising out of the relationship between such parties and the Company. In addition, the Company has entered into indemnification agreements with members of its board of directors and senior management that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and it has not accrued any liabilities related to such obligations as of March 31, 2021 or December 31, 2020.

Legal Proceedings

The Company is not currently a party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses the costs related to its legal proceedings as they are incurred. No such costs have been incurred during the three months ended March 31, 2021 and 2020.

8. Convertible Preferred Stock and Stockholders' Equity

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 Series A-2 Agreement provided for a second tranche closing, pursuant to which the investors were 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, 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 $33.6 million.

In July 2020, the Company increased the number of authorized shares of Series A-2 Convertible Preferred Stock from 47,132,862 to 55,427,222. In July 2020, the Company issued 8,294,360 shares of Series A-2 Convertible Preferred Stock to Alexion Pharmaceuticals, Inc. ("Alexion") in consideration for the sale and assignment to the Company of specified patent rights and other specified assets related to ENPP1.

In July 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. On July 28, 2020, upon the closing of the Company's IPO, all 104,277,222 shares of then outstanding preferred stock automatically converted into 13,953,850 shares of common stock.

In addition, on July 28, 2020, the Company amended and restated its certificate of incorporation to authorize 200,000,000 shares of common stock and 5,000,000 shares of preferred stock, which shares of preferred stock are currently undesignated. The Company does not have any outstanding preferred stock as of March 31, 2021.

There have been no dividends declared on preferred stock or common stock by the Company's board of directors as of March 31, 2021.

Equity Incentive Plans

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 "2017 Plan"), which provided 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. The maximum number of shares of common stock that were authorized for issuance under the 2017 Plan was 2,730,496.

On July 17, 2020, the Company's stockholders approved the 2020 Stock Incentive Plan (the "2020 Plan"), which became effective on July 23, 2020. The 2020 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The number of shares of the Company's common stock reserved for issuance under the 2020 Plan is 1,588,315 shares, plus the 426,065 shares of common stock remaining available for issuance under the 2017 Plan as of July 23, 2020. The number of shares reserved under the 2020 Plan will be annually increased on each January 1 through January 1, 2030 by the lower of (i) 4% of the number of shares of common stock outstanding on the first day of such fiscal year and (ii) an amount determined by the Company's board of directors. The number of shares available for grant under the 2020 Plan increased by 935,398 on January 1, 2021 due to this provision.

As of the effective date of the 2020 Plan, no further awards will be made under the 2017 Plan. Any options or awards outstanding under the 2017 Plan remain outstanding and effective and are governed by their existing terms. The shares of the Company's common stock subject to outstanding awards under the 2017 Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right will be added back to the shares of common stock available for issuance under the 2020 Plan. No more than 1,588,315 shares of the Company's common stock may be granted subject to incentive stock options under the 2020 Plan. As of March 31, 2021, 819,406 shares of common stock remain available for future issuance under the 2020 Plan.

For financial reporting purposes, the Company performed common stock valuations with the assistance of a third-party valuation specialist as of March 31, 2020, May 31, 2019, November 30, 2018, December 31, 2017 and April 30, 2017 to determine stock-based compensation expense for the stock options issued under the 2017 Plan prior to the IPO. Following the completion of the IPO, the fair value of the common stock underlying option grants is determined based on the closing price of the Company's common stock on the Nasdaq Global Select Market on the date of grant.

The following table summarizes stock option activity under the Company's equity incentive plans since December 31, 2020:

	Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (1) (in thousands)
Outstanding at December 31, 2020	3,064,457	$ 7.28	8.76	$ 41,680
Granted	746,185	20.47		
Exercised	(88,734)	2.80		
Forfeited	(198,322)	7.56		
Outstanding at March 31, 2021	3,523,586	$ 10.17	8.79	$ 35,270
Exercisable at March 31, 2021	1,001,661	$ 3.31	7.64	$ 16,522
Vested and expected to vest at March 31, 2021	3,523,586	$ 10.17	8.79	$ 35,270

(1) 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 weighted-average grant date fair value of options granted during the three months ended March 31, 2021 was $17.01 per share. The aggregate intrinsic value of stock options exercised during the three months ended March 31, 2021 was $0.2 million.

For purposes of calculating stock-based compensation expense, 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 participants using the Black-Scholes option-pricing were as follows:

	For the Three Months Ended March 31,	
	2021	2020
Risk-free interest rate range	0.48% to 1.05%	N/A
Dividend yield	0%	N/A
Expected term of options (years)	6.08 to 6.48	N/A
Volatility rate range	88.70% to 90.53%	N/A

The total compensation cost recognized in the statements of operations associated with all the stock-based compensation awards granted by the Company is as follows (in thousands):

	Three Months Ended March 31,	
	2021	2020
Research and development	$ 641	$ 85
General and administrative	936	44
Total	$ 1,577	$ 129

The total unrecognized compensation cost related to outstanding employee awards as of March 31, 2021 was $23.8 million, and is expected to be recognized over a weighted-average period of 2.6 years.

Employee Stock Purchase Plan

On July 17, 2020, the Company's stockholders approved the 2020 Employee Stock Purchase Plan (the "ESPP"), which became effective on July 23, 2020. The ESPP initially provides participating employees with the opportunity to purchase up to an aggregate of 198,539 shares of the Company's common stock. The number of shares of common stock reserved for issuance under the ESPP will automatically increase on each January 1 through January 1, 2031, in an amount equal to the lowest of (1) 397,079 shares of the Company's common stock, (2) 1% of the number of shares of the Company's common stock outstanding on the first day of such fiscal year and (3) an amount determined by the Company's board of directors. The number of shares available for grant under this plan increased by 233,849 on January 1, 2021 due to this provision. As of March 31, 2021, no shares have been purchased by employees under the ESPP.

9. Net Loss per Share

Net Loss per Share Attributable to Common Stockholders

For purposes of the diluted net loss per share calculation, stock options, 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 from the computation of diluted net loss per share attributable to common stockholders because including them would have had an anti-dilutive effect:

	Three Months Ended March 31,	
	2021	2020
Series A Convertible Preferred Stock (as converted to common stock)	—	6,536,856
Series A-2 Convertible Preferred Stock (as converted to common stock)	—	3,153,537
Options to purchase common stock	3,523,586	1,623,911
	3,523,586	11,314,304

10. 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. Employees can designate the investment of their 401(k) accounts into several mutual funds. Effective January 1, 2021, the Company implemented a matching policy under which the Company matches 50% of an employee's contributions to the 401(k) plan, up to a maximum of 6% of the employee's base salary and bonus paid during the year. For the three months ended March 31, 2021, the Company has made employer contributions to the 401(k) plan totaling $58 thousand.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and the related notes appearing elsewhere in the Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the Securities and Exchange Commission, or SEC, on March 25, 2021. 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 our most recent Annual Report on Form 10-K, 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 clinical-stage 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, INZ-701 achieved survival benefit in a mouse model of ENPP1 Deficiency. We plan to advance INZ-701 into two separate Phase 1/2 clinical trials in both the United States and in Europe, one in patients with ENPP1 Deficiency and another in patients with ABCC6 Deficiency. The U.S. Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA, have granted orphan drug designation to INZ-701 for the treatment of ENPP1 Deficiency. The FDA has also granted orphan drug designation to INZ-701 for the treatment of ABCC6 Deficiency. The FDA has also granted fast track designation for INZ-701 for the treatment of ENPP1 Deficiency, and rare pediatric disease designation for the treatment of ENPP1 Deficiency.

In December 2020, the FDA cleared our Investigational New Drug Application, or IND, for INZ-701 for the treatment of ENPP1 Deficiency, after our submission of a final study report for the three-month toxicology studies as recommended by the FDA and resolution of a previously imposed clinical hold, and the United Kingdom Medicines and Healthcare Products Regulatory Agency, or MHRA, authorized our Clinical Trial Application, or CTA, for a Phase 1/2 clinical trial evaluating INZ-701 in adults with ENPP1 Deficiency. We expect site activation in the United States for our Phase 1/2 clinical trial in June 2021 and enrollment of the first patient shortly thereafter. We plan to report preliminary safety and biomarker data from this trial in the second half of 2021. We also expect to file additional CTAs with regulatory authorities in the European Union in June 2021 to allow us to initiate clinical development in Europe outside the United Kingdom.

We recently filed a CTA in Europe for a Phase 1/2 clinical trial of INZ-701 for the treatment of ABCC6 Deficiency. We also are preparing to file with the FDA an amendment to our IND for INZ-701 to include ABCC6 Deficiency. Subject to receiving regulatory clearance, we expect site activation and enrollment of the first patient in our planned Phase 1/2 clinical trial in mid-2021. We plan to report preliminary safety and biomarker data from this trial by the end of 2021.

Subject to successfully completing clinical development of INZ-701 in ENPP1 and ABCC6 Deficiencies, 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, such as calciphylaxis. We are also exploring the potential for development of a gene therapy for ENPP1 Deficiency.

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. We have not yet initiated a clinical trial for INZ-701 or any other product candidate. To date, we have funded our operations primarily with proceeds from the sales of convertible preferred stock and sales of common stock in our initial public offering, or IPO. Through March 31, 2021, we had received net proceeds of $111.5 million from the sales of our convertible preferred stock and net proceeds of approximately $115.9 from the sale of our common stock in our IPO.

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 $56.4 million for the year ended December 31, 2020, and $11.1 million for the three months ended March 31, 2021. As of March 31, 2021, we had an accumulated deficit of $102.1 million.

Our operating expenses were $11.0 million for the three months ended March 31, 2021 and $57.0 million for the year ended December 31, 2020. 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. We have incurred and expect to continue 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. 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, 2021, we had cash, cash equivalents and short-term and long-term investments of approximately $147.6 million.

We believe that our existing cash, cash equivalents and short-term and long-term investments as of March 31, 2021 will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter 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.

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, including the write-off of acquired in-process research and development assets with no alternative future use;
- 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 we have not yet initiated a clinical trial for INZ-701. We expect site activation in the United States for our Phase 1/2 clinical trial of INZ-701 for the treatment of ENPP1 Deficiency in June 2021 and enrollment of the first patient shortly thereafter. We recently filed a CTA in Europe for a Phase 1/2 clinical trial of INZ-701 for the treatment of ABCC6 Deficiency. We also are preparing. to file with the FDA an amendment to our IND for INZ-701 to include ABCC6 Deficiency. Subject to receiving regulatory clearance, we expect site activation and enrollment of the first patient in our planned Phase 1/2 clinical trial of INZ-701 for the treatment of ABCC6 Deficiency in mid-2021. 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, 2021, we have incurred $63.2 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 our planned Phase 1/2 clinical trial of INZ-701 for ENPP1 Deficiency;
- filing and acceptance of our additional planned CTAs for INZ-701 by the regulatory authorities in the European Union to allow us to initiate Phase 1/2 clinical development of INZ-701 for ENPP1 Deficiency in Europe outside of the United Kingdom;
- acceptance of our CTA for INZ-701 by regulatory authorities in Europe to allow us to initiate Phase 1/2 clinical development of INZ-701 for ABCC6 Deficiency;
- filing and acceptance of our IND amendment for INZ-701 by the FDA in the United States to allow us to initiate Phase 1/2 clinical development of INZ-701 for ABCC6 Deficiency;
- 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 incur and anticipate that we will continue to 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 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 investments.

Other Income (Expense), net

Other income (expense), net primarily consists of foreign exchange gains or losses.

Results of Operations

Comparison of the Three Months Ended March 31, 2021 and 2020

The following table summarizes our results of operations for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,		Increase (Decrease)
	2021	2020	
Operating expenses:			
Research and development	$ 6,603	$ 6,406	$ 197
General and administrative	4,369	1,500	2,869
Total operating expenses	10,972	7,906	3,066
Loss from operations	(10,972)	(7,906)	3,066
Other income (expense):			
Interest income	63	171	(108)
Other expenses	(141)	(3)	(138)
Other income (expense), net	(78)	168	(246)
Net loss	$ (11,050)	$ (7,738)	$ 3,312

Research and Development Expense

Research and development expense increased by $0.2 million to $6.6 million for the three months ended March 31, 2021 from $6.4 million for the three months ended March 31, 2020. The increase in research and development expense was primarily attributable to the following:

- an increase of $1.1 million due to increased salaries and other employee-related costs to support the growth of the business;
- an increase of $0.9 million as a result of preclinical study costs and clinical preparation activities with our CRO;
- an increase of $0.6 million as a result of increased stock-based compensation expense following our IPO in July 2020;
- an increase of $0.1 million related to other activities such as travel;
- a decrease of $1.5 million due to decreases in manufacturing operations based on the timing of production runs; and
- a decrease of $1.0 million as a result of the timing of the completion of preclinical toxicology studies in support of our IND filing 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 indication or of additional product candidates.

General and Administrative Expense

General and administrative expense increased by $2.9 million to $4.4 million for the three months ended March 31, 2021 from $1.5 million for the three months ended March 31, 2020. 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 new contracts and operations as a public company, and generally higher fees in areas such as audit, tax and information technology to support our growth and support our operations as a public company. We expect that our general and administrative expenses 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 $0.1 million to $0.1 million for the three months ended March 31, 2021 from $0.2 million for the three months ended March 31, 2020. The decrease was primarily attributable to lower interest rates on investments during the three months ended March 31, 2021 as compared to the three months ended March 31, 2020.

Other Expenses

Other expenses, consisting primarily of foreign exchange gains and losses, increased by $0.1 million to $0.1 million for the three months ended March 31, 2021 from less than $0.1 million for the three months ended March 31, 2020. This increase was driven by cash balances we hold which are denominated in Euros and their related appreciation compared to the U.S. Dollar in the three months ended March 31, 2021 compared to the three months ended March 31, 2020.

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 and sales of common stock in our IPO. Through March 31, 2021, we had received net cash proceeds of $111.5 million from sales of our convertible preferred stock. In July 2020, we completed our IPO in which we received net proceeds, inclusive of the exercise by the underwriters of their option to purchase additional shares, of approximately $115.9 million, after deducting underwriting discounts and commissions and offering expenses. As of March 31, 2021, we had cash, cash equivalents and short-term and long-term investments of approximately $147.6 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 and long-term investments at March 31, 2021 and December 31, 2020 (in thousands):

	March 31, 2021	December 31, 2020
Cash and cash equivalents	$ 16,486	$ 28,040
Short-term investments	128,600	119,657
Long-term investments	2,548	12,199
Total cash, cash equivalents, and short-term and long-term investments	$ 147,634	$ 159,896

Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Net cash used in operating activities	$ (12,376)	$ (6,265)
Net cash provided by (used in) investing activities	573	(3,408)
Net cash provided by financing activities	249	5
Net decrease in cash, cash equivalents and restricted cash	$ (11,554)	$ (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 $12.4 million for the three months ended March 31, 2021 compared to $6.3 million for the three months ended March 31, 2020. The increase in cash used in operating activities of $6.1 million was primarily due to an increase in net loss adjusted for non-cash items of $1.5 million as well as an increase in the use of cash for accounts payable and accrued expenses.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $0.6 million for the three months ended March 31, 2021 compared to $3.4 million net cash used in investing activities for the three months ended March 31, 2020. For the three months ended March 31, 2021, we had maturities of marketable securities of $39.2 million, purchases of marketable securities of $38.6 million and purchases of property and equipment of $0.1 million. For the three months ended March 31, 2020 we had maturities of marketable securities of $10.1 million, purchases of marketable securities of $13.4 million and purchases of property and equipment of $0.1 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $0.2 million for the three months ended March 31, 2021 compared to less than $0.1 million for the three months ended March 31, 2020. The increase in net cash provided by financing activities of $0.2 million was primarily due to an increase in proceeds from stock option exercises.

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, as a result of our IPO, 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, 2021, we had cash, cash equivalents and short-term and long-term investments of approximately $147.6 million. We believe that our existing cash, cash equivalents and short-term and long-term investments as of March 31, 2021 will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter 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, the ownership interests of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. 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.

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.

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience 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. Actual results may differ from these estimates under different assumptions or conditions. During the three months ended March 31, 2021, there were no material changes to our critical accounting policies from those described in our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 25, 2021.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 3 to our consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012 permits an "emerging growth company" such as us 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 emerging growth company.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of March 31, 2021, our cash equivalents consisted of primarily of short-term money market funds. As of March 31, 2021, our short-term investments consisted of commercial paper, U.S. Treasury securities and U.S. government agency debt securities with maturities of less than one year. As of March 31, 2021, our long-term investments consisted of U.S. Treasury securities with maturities greater than one year but less than 18 months. 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 primarily 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 three months ended March 31, 2021 and 2020.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Senior Vice President, Finance (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2021. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2021, our Chief Executive Officer and Senior Vice President, Finance concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15(d)-15(f) under the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1A. Risk Factors.

There have been no material changes to the risk factors described in Part I, Item IA, Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 25, 2021.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Recent Sales of Unregistered Equity Securities

We did not issue any securities that were not registered under the Securities Act of 1933, as amended, or the Securities Act, during the three months ended March 31, 2021.

Use of Proceeds from Initial Public Offering

On July 28, 2020, we completed our IPO, pursuant to which we issued and sold 7,000,000 shares of our common stock at a public offering price of $16.00 per share, and on July 30, 2020, we sold an additional 1,050,000 shares of our common stock at a price of $16.00 per share pursuant to the exercise by the underwriters of their option to purchase additional shares.

The offer and sale of all of the shares of our common stock in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-239648), which was declared effective by the SEC on July 23, 2020. BofA Securities, Inc., Cowen and Company, LLC and Piper Sandler & Co. acted as joint book-running managers for our IPO. Wedbush Securities Inc. acted as lead manager for our IPO. The offering commenced on July 23, 2020 and did not terminate until the sale of all of the shares offered.

We received aggregate gross proceeds from our IPO, inclusive of the exercise by the underwriters of their option to purchase additional shares, of approximately $128.8 million, or aggregate net proceeds of approximately $115.9 million after deducting underwriting discounts and commissions and offering expenses. None of the underwriting discounts and commissions or offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

We had not used any of the net proceeds from the IPO as of March 31, 2021 as we have continued to fund our operations from proceeds received through our preferred stock financings. There has been no material change in our planned use of the net proceeds from our IPO as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on July 24, 2020.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-39397) filed with the Securities and Exchange Commission on July 28, 2020).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-39397) filed with the Securities and Exchange Commission on July 28, 2020).
10.1	Employment Contract, dated March 24, 2021, between Inozyme Pharma Switzerland GmbH and Axel Bolte (incorporated by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K (File No. 001-39397) filed with the Securities and Exchange Commission on March 25, 2021).
10.2	Amended and Restated Employment Agreement, dated March 24, 2021, by and between the Registrant and Stephen Basso (incorporated by reference to Exhibit 10.20 to the Registrant's Annual Report on Form 10-K (File No. 001-39397) filed with the Securities and Exchange Commission on March 25, 2021).
10.3	Employment Agreement, dated January 29, 2021, by and between the Registrant and Deborah Wenkert (incorporated by reference to Exhibit 10.21 to the Registrant's Annual Report on Form 10-K (File No. 001-39397) filed with the Securities and Exchange Commission on March 25, 2021).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1+	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2+	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

\+ Furnished herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

INOZYME PHARMA, INC.

Date: May 12, 2021 By: /s/ Axel Bolte

Axel Bolte
President and Chief Executive Officer, Director
(Principal Executive Officer)

Date: May 12, 2021 By: /s/ Stephen Basso

Stephen Basso
Senior Vice President, Finance
(Principal Financial
Officer and Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Axel Bolte, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Inozyme Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 12, 2021

By: /s/ Axel Bolte

Axel Bolte
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Stephen Basso, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Inozyme Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 12, 2021

By: /s/ Stephen Basso

Stephen Basso
Senior Vice President, Finance
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Inozyme Pharma, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 12, 2021

By: /s/ Axel Bolte

Axel Bolte
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Inozyme Pharma, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 12, 2021

By: /s/ Stephen Basso

Stephen Basso
Senior Vice President, Finance
(Principal Financial Officer and Principal Accounting Officer)