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 September 30, 2022

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 November 7, 2022, the registrant had 40,394,363 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 in this Quarterly Report on Form 10-Q and include, among other things:

- our ongoing Phase 1/2 clinical trials of INZ-701 for ENPP1 and ABCC6 Deficiencies, including statements regarding the timing of enrollment and completion of the clinical trials and the period during which the results of the clinical trials will become available;
- the timing and conduct of our planned later stage clinical trials of INZ-701 for patients with ENPP1 and ABCC6 Deficiencies;
- our plans to conduct research and preclinical testing of INZ-701 for additional indications;
- our plans to conduct research and preclinical testing of other product candidates;
- the timing of, and our ability to obtain and maintain, marketing approvals of INZ-701, and the ability of INZ-701 and our other product candidates to meet existing or future regulatory standards;
- our expectations regarding our ability to fund our operating expenses, capital expenditures, and debt service obligations with our cash, cash equivalents and short-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 and in this Quarterly Report on Form 10-Q, 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)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 44,044	$ 23,316
Short-term investments	97,408	88,485
Prepaid expenses and other current assets	4,474	3,541
Total current assets	145,926	115,342
Property and equipment, net	2,197	2,383
Other assets	354	354
Right-of-use assets	1,734	2,053
Prepaid expenses, net of current portion	3,810	3,409
Total assets	$ 154,021	$ 123,541
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,391	$ 2,394
Accrued expenses	10,948	8,508
Operating lease liabilities	794	731
Total current liabilities	13,133	11,633
Operating lease liabilities, net of current portion	2,035	2,640
Long term debt, net	4,073	—
Total liabilities	19,241	14,273
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred Stock, $0.0001 par value – 5,000,000 shares authorized at September 30, 2022 and December 31, 2021; No shares issued and outstanding at September 30, 2022 or December 31, 2021	—	—
Common Stock, $0.0001 par value – 200,000,000 shares authorized at September 30, 2022 and December 31, 2021; 40,394,363 shares issued and outstanding at September 30, 2022 and 23,668,747 shares issued and outstanding at December 31, 2021	4	2
Additional paid in-capital	331,470	256,948
Accumulated other comprehensive (loss) income	(477)	18
Accumulated deficit	(196,217)	(147,700)
Total stockholders' equity	134,780	109,268
Total liabilities and stockholders' equity	$ 154,021	$ 123,541

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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 12,191	$ 9,346	$ 34,012	$ 24,169
General and administrative	4,721	4,916	15,130	13,720
Total operating expenses	16,912	14,262	49,142	37,889
Loss from operations	(16,912)	(14,262)	(49,142)	(37,889)
Other income (expense):				
Interest income	737	47	1,118	168
Other expenses	(197)	(65)	(493)	(149)
Other income, net	540	(18)	625	19
Net loss	$ (16,372)	$ (14,280)	$ (48,517)	$ (37,870)
Other comprehensive (loss) income:				
Unrealized (losses) gains on available-for-sale securities	(60)	(6)	(417)	10
Foreign currency translation adjustment	(20)	(9)	(78)	(9)
Total other comprehensive (loss) income	(80)	(15)	(495)	1
Comprehensive loss	$ (16,452)	$ (14,295)	$ (49,012)	$ (37,869)
Net loss attributable to common stockholders—basic and diluted	$ (16,372)	$ (14,280)	$ (48,517)	$ (37,870)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.38)	$ (0.60)	$ (1.36)	$ (1.61)
Weighted-average common shares and pre-funded warrants outstanding—basic and diluted	43,657,718	23,643,494	35,755,695	23,521,981

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	23,668,747	$ 2	$ 256,948	$ 18	$ (147,700)	$ 109,268
Stock-based compensation	—	—	1,752	—	—	1,752
Exercise of stock options	149,664	—	240	—	—	240
Comprehensive loss:						
Unrealized loss on investments	—	—	—	(132)	—	(132)
Foreign currency translation adjustment	—	—	—	(15)	—	(15)
Net loss	—	—	—	—	(16,884)	(16,884)
Balance at March 31, 2022	23,818,411	$ 2	$ 258,940	$ (129)	$ (164,584)	$ 94,229
Stock-based compensation	—	—	2,185	—	—	2,185
Exercise of stock options	1,678	—	4	—	—	4
Issuance of common stock, net of issuance costs	16,276,987	2	56,135	—	—	56,137
Issuance of pre-funded warrants, net of issuance costs	—	—	12,150	—	—	12,150
Comprehensive loss:						
Unrealized loss on investments	—	—	—	(225)	—	(225)
Foreign currency translation adjustment	—	—	—	(43)	—	(43)
Net loss	—	—	—	—	(15,261)	(15,261)
Balance at June 30, 2022	40,097,076	$ 4	$ 329,414	$ (397)	$ (179,845)	$ 149,176
Stock-based compensation	—	—	1,849	—	—	1,849
Exercise of stock options	59,635	—	115	—	—	115
Exercise of pre-funded warrants	197,240	—	—	—	—	—
Shares purchased in Employee Stock Purchase Plan	40,412	—	92	—	—	92
Comprehensive loss:						
Unrealized loss on investments	—	—	—	(60)	—	(60)
Foreign currency translation adjustment	—	—	—	(20)	—	(20)
Net loss	—	—	—	—	(16,372)	(16,372)
Balance at September 30, 2022	40,394,363	$ 4	$ 331,470	$ (477)	$ (196,217)	$ 134,780
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
Stock-based compensation	—	—	1,813	—	—	1,813
Exercise of stock options	96,890	—	106	—	—	106
Comprehensive income:						
Unrealized gain on investments	—	—	—	6	—	6
Net loss	—	—	—	—	(12,540)	(12,540)
Balance at June 30, 2021	23,570,593	$ 2	$ 252,920	$ 18	$ (114,666)	$ 138,274
Stock-based compensation	—	—	1,752	—	—	1,752
Exercise of stock options	94,154	—	243	—	—	243
Comprehensive income:						
Unrealized loss on investments	—	—	—	(6)	—	(6)
Foreign currency translation adjustment	—	—	—	(9)	—	(9)
Net loss	—	—	—	—	(14,280)	(14,280)
Balance at September 30, 2021	23,664,747	$ 2	$ 254,915	$ 3	$ (128,946)	$ 125,974

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)

	Nine Months Ended September 30,	
	2022	**2021**
Operating activities		
Net loss	$ (48,517)	$ (37,870)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	546	492
Loss on disposal of fixed assets	4	—
Stock-based compensation expense	5,786	5,142
Amortization of premiums and discounts on marketable securities	(1,082)	146
Reduction in the carrying value of right-of-use assets	319	279
Non-cash interest expense and amortization of debt issuance costs	27	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(933)	(2,014)
Accounts payable	(1,003)	(2,482)
Accrued expenses	2,435	942
Operating lease liabilities	(542)	(457)
Prepaid expenses - noncurrent	(401)	1,113
Net cash used in operating activities	(43,361)	(34,709)
Investing activities		
Purchases of marketable securities	(126,007)	(104,994)
Maturities of marketable securities	117,750	138,660
Purchases of property and equipment	(364)	(357)
Net cash (used in) provided by investing activities	(8,621)	33,309
Financing activities		
Net proceeds from issuance of common stock	56,137	—
Net proceeds from issuance of pre-funded warrants	12,150	—
Net proceeds from issuance of long-term debt	4,050	—
Proceeds from exercise of stock options	359	598
Proceeds from issuance of common stock for cash under employee stock purchase plan	92	—
Net cash provided by financing activities	72,788	598
Net increase (decrease) in cash, cash equivalents and restricted cash	20,806	(802)
Effect of foreign currency exchange rate in cash	(78)	(9)
Cash, cash equivalents and restricted cash at beginning of period	23,670	28,394
Cash, cash equivalents and restricted cash at end of period	$ 44,398	$ 27,583
Supplemental cash flow information:		
Cash and cash equivalents	$ 44,044	$ 27,229
Restricted cash	354	354
Cash, cash equivalents and restricted cash at end of period	$ 44,398	$ 27,583
Property and equipment unpaid at end of period	$ —	$ 78
Right-of-use asset at adoption of Topic 842	$ —	$ 2,431
Operating lease liabilities at adoption of Topic 842	$ —	$ 3,997

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 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 pathway and that defects in these genes lead to pathologic mineralization and intimal proliferation. The Company is initially focused on developing a novel therapy to treat rare genetic diseases of ENPP1 Deficiency and ABCC6 Deficiency.

The Company's lead product candidate, INZ-701, is a soluble, recombinant, or genetically engineered, fusion protein that is designed to correct defects in a pathway involving ENPP1 and ABCC6 Deficiencies. This pathway is central to the regulation of calcium deposition throughout the body and is further associated with intimal proliferation leading to a narrowing of blood vessels.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") for interim financial information. Accordingly, these unaudited condensed consolidated financial statements do not include all of the information and note disclosures required by U.S. GAAP for audited year-end financial statements. The accompanying unaudited condensed consolidated financial statements reflect all normal recurring adjustments that are, in the opinion of management, necessary for a fair presentation of the interim period results. The results for the three and nine month periods ended September 30, 2022 are not necessarily indicative of results to be expected for the year ending December 31, 2022, any other interim periods, or any future year or period. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021. 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").

Liquidity, Capital Resources, and Going Concern

Since the Company's incorporation in 2017 and through September 30, 2022, the Company has devoted substantially all of its efforts to raising capital, building infrastructure, developing intellectual property and conducting research and development activities. The Company incurred net losses of $48.5 million in the nine months ended September 30, 2022 and $56.6 million in the year ended December 31, 2021 and had an accumulated deficit of $196.2 million as of September 30, 2022. The Company had cash, cash equivalents, and short-term investments of $141.5 million as of September 30, 2022.

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, offerings of common stock and pre-funded warrants and the Loan Agreement (see Note 8). 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 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 believes its available cash, cash equivalents, and short-term investments as of September 30, 2022 will be sufficient to fund its cash flow requirements for at least twelve months from the date of filing this Quarterly Report on Form 10-Q. Management's expectations with respect to its ability to fund current and long term planned operations are based on estimates that are subject to risks and uncertainties. If actual results are different from management's estimates, the Company may need to seek additional strategic or financing opportunities sooner than would otherwise be expected. However, there is no guarantee that any of these strategic or financing opportunities will be executed on favorable terms, or at all, and some could be dilutive to existing stockholders. If the Company is unable to obtain additional funding on a timely basis, it may be forced to delay, reduce or eliminate some or all of its research and development programs, portfolio expansion or commercialization efforts, which could adversely affect its business.

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, Inozyme Securities Corp., which is a Massachusetts subsidiary created to buy, sell, and hold securities, Inozyme Ireland Limited, and Inozyme Pharma Switzerland GmbH. 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, 2021 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021. The Company adopted a warrant accounting policy detailed below following the closing of the Company's underwritten offering in April 2022 and a debt and debt issuance costs accounting policy following the closing of the Loan Agreement in July 2022. Apart from these adoptions, there have been no material changes in the Company's significant accounting policies during the nine months ended September 30, 2022.

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. 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 condensed consolidated balance sheets and within research and development expense in the accompanying condensed 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.

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. 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 and pre-funded warrants 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 pre-funded warrants and potentially dilutive securities outstanding using the treasury-stock and if-converted methods. 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 investments and, from time to time, 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 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.

Debt and Debt Issuance Costs

Debt issuance costs and the Lender Expenses (see Note 8) are presented on the condensed consolidated balance sheet as a direct deduction from the related debt liability. Debt issuance costs represent legal and other direct costs incurred in connection with the Company's term loan under the Loan Agreement. These costs are amortized as a non-cash component of interest expense using the effective interest method over the term of the loan. Any final payments are included in the cash flows to determine the effective interest rate and are recognized using the effective interest method over the term of the loan.

Warrants

The Company determines the accounting classification of warrants that are issued, as either liability or equity, by first assessing whether the warrants meet liability classification in accordance with ASC 480-10, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*, and then in accordance with ASC 815-40, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*. Under ASC 480-10, warrants are considered liability classified if the warrants are mandatorily redeemable, obligate the issuer to settle the warrants or the underlying shares by paying cash or other assets, or must or may require settlement by issuing variable number of shares.

If warrants do not meet liability classification under ASC 480-10, the Company assesses the requirements under ASC 815-40, which states that contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. If the warrants do not require liability classification under ASC 815-40, in order to conclude equity classification, the Company assesses whether the warrants are indexed to its common stock and whether the warrants are classified as equity under ASC 815-40 or other applicable U.S.

GAAP. After all relevant assessments are made, the Company concludes whether the warrants are classified as liability or equity. Liability classified warrants are required to be accounted for at fair value both on the date of issuance and on subsequent accounting period ending dates, with all changes in fair value after the issuance date recorded in the statements of operations as a gain or loss. Equity classified warrants are accounted for at fair value on the issuance date with no changes in fair value recognized after the issuance date.

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 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 Company adopted this standard effective January 1, 2022. There was no material impact to the Company's financial statements upon adoption.

In August 2020, the FASB issued ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40)*. ASU 2020-06 simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The Company elected to early adopt this standard effective January 1, 2022. There was no material impact to the Company's financial statements upon adoption.

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 the Company 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.

4. Balance Sheet Details

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

		September 30, 2022			
Description	Maturity	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper	1 year or less	$ 74,935	$ —	$ (231)	$ 74,704
U.S. Treasury securities	1 year or less	22,887	—	(183)	$ 22,704
		$ 97,822	$ —	$ (414)	$ 97,408

		December 31, 2021			
Description	Maturity	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper	1 year or less	$ 78,456	$ 5	$ (3)	$ 78,458
U.S. Treasury securities	1 year or less	5,025	—	—	5,025
U.S. government agency debt securities	1 year or less	5,002	—	—	5,002
		$ 88,483	$ 5	$ (3)	$ 88,485

The Company concluded that the 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 September 30, 2022 and December 31, 2021. 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 September 30, 2022	At December 31, 2021
Interest receivable	$ 96	$ 62
Prepaid insurance	1,897	1,728
Prepaid research studies	1,643	1,190
Prepaid other	838	561
Total	$ 4,474	$ 3,541

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

	At September 30, 2022	At December 31, 2021
Prepaid clinical trial and other	$ 3,810	$ 3,409
	$ 3,810	$ 3,409

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

	At September 30, 2022	At December 31, 2021
Laboratory equipment and manufacturing equipment	$ 806	$ 591
Furniture and fixtures	258	258
Computer equipment and software	571	440
Leasehold improvements	2,095	2,095
	3,730	3,384
Less accumulated depreciation	(1,533)	(1,001)
Total	$ 2,197	$ 2,383

Depreciation expense for the three months ended September 30, 2022 and 2021 was $189 thousand and $167 thousand, respectively. Depreciation expense for the nine months ended September 30, 2022 and 2021 was $546 thousand and $492 thousand, respectively.

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

	At September 30, 2022	At December 31, 2021
Payroll and related liabilities	$ 2,263	$ 2,379
Professional fees	524	727
Research and development costs	7,649	5,066
Other	512	336
Total	$ 10,948	$ 8,508

The Company had $0.4 million of restricted cash at September 30, 2022 and September 30, 2021. This amount is included in the "other assets" line item on the balance sheets.

5. Fair Value Measurement

The following tables represent 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):

Description	September 30, 2022	Fair Value Measurements at Reporting Date Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds (included in cash and cash equivalents)	$ 38,936	$ 38,936	$ —	$ —
Commercial paper (including amounts in cash and cash equivalents)	77,688	—	77,688	—
U.S. Treasury securities	22,704	22,704	—	—
Total assets	$ 139,328	$ 61,640	$ 77,688	$ —

Description	December 31, 2021	Fair Value Measurements at Reporting Date Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds (included in cash and cash equivalents)	$ 14,302	$ 14,302	$ —	$ —
Commercial paper	78,457	—	78,457	—
U.S. Treasury securities	5,026	5,026	—	—
U.S. government agency debt securities	5,002	—	5,002	—
Total assets	$ 102,787	$ 19,328	$ 83,459	$ —

There have been no transfers between fair value levels during the three or nine months ended September 30, 2022.

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 $0.1 million 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 September 30, 2022, the Company incurred a total of $0.2 million in license maintenance fees to Yale. The Company is required to pay Yale up to $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 January 2022, the Company paid Yale an approximately $0.3 million milestone payment following dosing of the first patient in Company's Phase 1/2 clinical trial of INZ-701 in adult patients with ENPP1 Deficiency in November 2021. In March 2022, the Company paid Yale an approximately $0.3 million milestone payment following completion of the first cohort of the Company's Phase 1/2 clinical trial of INZ-701 in adult patients with ENPP1 Deficiency in January 2022. In addition, the Company is required to pay Yale an amount in the several hundreds of thousands of dollars, based on the achievement of a specified net product sales milestone or specified development and commercialization milestones, for each diagnostic licensed product developed. While the agreement remains in effect, the Company is required to pay Yale low single-digit percentage royalties on aggregate worldwide net sales of certain licensed products. Yale is guaranteed a minimum royalty payment amount (ranging in dollar amounts from the mid six figures to low seven figures) for each year after the first sale of a therapeutic or prophylactic licensed

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

In January 2017, the Company also entered into a corporate sponsored research agreement with Yale (the "Sponsored Research Agreement"), which was amended in February 2019, under which the Company agreed to provide research support funding in the aggregate amount of $2.4 million over the five year period from contract inception through December 2021. The Sponsored Research Agreement was amended in February 2022, under which the contract was extended through June 30, 2022 subject to the terms of the existing agreement. The Sponsored Research Agreement was amended again in May 2022, under which the contract was extended through April 2023 with approximately $0.1 million of Company-provided research support funding for such extended period. The Company recorded research and development expenses associated with this arrangement of less than $0.1 million and approximately $0.1 million in the three and nine months ended September 30, 2022, respectively, and $0.1 million and $0.4 million in the three and nine months ended September 30, 2021, respectively.

7. Commitments and Contingencies

Operating Leases

The Company held the following significant operating leases of office and laboratory space as of September 30, 2022:

- 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.

During the nine months ended September 30, 2022, cash paid for amounts included in the measurement of lease liabilities was $0.6 million and the Company recorded operating lease expense of $0.5 million.

Future lease payments under non-cancelable leases as of September 30, 2022 are as follows (dollar amounts in thousands):

Year Ending December 31,		
2022 (remaining 3 months)	$	243
2023		992
2024		1,016
2025		944
Thereafter		—
	$	3,195

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 September 30, 2022 or December 31, 2021.

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 and nine months ended September 30, 2022 and 2021.

8. Convertible Debt

Loan Agreement with K2 HealthVentures LLC

On July 25, 2022, the Company, as borrower, entered into a loan and security agreement (the "Loan Agreement") with K2 HealthVentures LLC ("K2HV", together with any other lender from time to time, the "Lenders"), K2HV, as administrative agent for the Lenders, and Ankura Trust Company, LLC, as collateral agent for the Lenders. The Loan Agreement provides up to $70.0 million principal in term loans, subject to certain customary conditions. The Company received $5.0 million from the first tranche commitment upon closing. The first tranche commitment contains an additional $20.0 million available to be drawn at the Company's option though March 31, 2023. Two subsequent tranche commitments totaling $20.0 million in the aggregate are available to be drawn at the Company's option during certain availability periods, subject to the achievement of certain clinical and regulatory milestones relating to INZ-701. A fourth tranche commitment of $25.0 million may be made available to be drawn down at the Company's option through August 31, 2025, subject to use of proceeds limitations and Lender's consent in its discretion. The fourth tranche commitment is subject to an additional 0.75% facility fee. As security for its obligations under the Loan Agreement, the Company granted the Lenders a first priority security interest on substantially all of the Company's assets (other than intellectual property), subject to certain exceptions.

The term loan matures on August 1, 2026 and the Company is obligated to make interest only payments for the first 36 months and then interest and equal principal payments through the maturity date. The term loan bears a variable interest rate equal to the greater of (i) 7.85%, and (ii) the sum of (A) the prime rate last quoted in The Wall Street Journal (or a comparable replacement rate if The Wall Street Journal ceases to quote such rate) and (B) 3.85%; provided that the interest rate cannot exceed 9.60%. The interest rate as of September 30, 2022, was 9.60% based upon an increase in the prime rate in September 2022. The Company has the option to prepay all, but not less than, the outstanding principal balance and all accrued and unpaid interest with respect to the principal balance being repaid of the term loans, subject to a prepayment premium to which the Lenders are entitled. The prepayment fee is 3% prior to the second anniversary of the July 25, 2022 funding date, 2% after the second anniversary but prior the third anniversary of the funding date, and 1% thereafter if prior to the maturity date. Upon final payment or prepayment of the loans, the Company must pay a final payment equal to 6.25% of the loans borrowed ("Final Fee"), which is being accrued as interest expense over the term of the loan using the effective interest method.

The Lenders may elect, prior to the full repayment of the term loans, to convert up to $5.0 million of outstanding principal of the term loans into shares of the Company's common stock, at a conversion price of $6.21 per share, subject to customary adjustments and 9.99% and 19.99% beneficial ownership limitations. The Company determined that the embedded conversion option was not required to be separated from the term loan. The embedded conversion option met the derivative accounting scope exception since the embedded conversion option is indexed to the Company's own common stock and qualifies for classification within stockholders' equity.

The Loan Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including covenants that limit or restrict the Company's ability to, among other things, dispose of assets, make changes to the Company's business, management, ownership or business locations, merge or consolidate, incur additional indebtedness, incur additional liens, pay dividends or other distributions or repurchase equity, make investments, and enter into certain transactions with affiliates, in each case subject to certain exceptions. Upon the occurrence of an event of default, a default interest rate of an additional 5.00% per annum may be applied to the outstanding loan balances, and the Lender may declare all outstanding obligations immediately due and payable and exercise all of its rights and remedies as set forth in the Loan Agreement and under applicable law. As of September 30, 2022, the Company was in compliance with all covenants under the Loan Agreement.

Subject to certain conditions, the Company granted the Lenders the right, prior to repayment of the term loans, to invest up to $5.0 million in the aggregate in future offerings of common stock, convertible preferred stock or other equity securities of the Company that are broadly marketed and offered to multiple investors, on the same terms, conditions and pricing afforded to others participating in any such financing.

The Company incurred debt issuance costs of $0.5 million in connection with the term loan. In addition, at the time of closing the Company paid to the Lenders a facility fee of $0.4 million, as well as $0.1 million of other expenses incurred by the Lenders and reimbursed by the Company ("Lender Expenses"). The debt issuance costs, Lender Expenses and the Final Fee are being amortized as additional interest expense over the term of the loan using the effective interest method. The Company recorded interest expense of $0.1 million during the three and nine months ended September 30, 2022. At September 30, 2022, the carrying value of the Loan Agreement approximates the fair value of the term loan, considering that it bears interest that is similar to prevailing market rates.

The following table summarizes the impact of the term loan, on the Company's condensed consolidated balance sheet at September 30, 2022:

	September 30, 2022
	(in thousands)
Gross proceeds	$ 5,000
Unamortized debt issuance costs	(927)
Carrying value	$ 4,073

Future principal payments, which include the Final Fee, in connection with the Loan Agreement as of September 30, 2022 are as follows (dollar amounts in thousands):

Fiscal Year	
2022 (remaining three months)	$ —
2023	—
2024	—
2025	1,617
2026	3,695
Total	$ 5,312

9. Stockholders' Equity

April 2022 Underwritten Offering

On April 14, 2022, the Company entered into an underwriting agreement with Jefferies LLC and Cowen and Company, LLC, relating to an underwritten offering of 16,276,987 shares of the Company's common stock (the "Shares") and, in lieu of common stock to certain investors, pre-funded warrants to purchase 3,523,013 shares of common stock. The closing of the offering took place on April 19, 2022. The offering price of the Shares was $3.69 per share and the offering price of the pre-funded warrants was $3.6899 per share underlying each pre-funded warrant. Warrants must be exercised by means of a cashless exercise. Net proceeds from the offering were approximately $68.3 million, after deducting underwriting discounts and commissions and offering expenses.

On June 10, 2022, the Company and each holder of the pre-funded warrants entered into amended and restated pre-funded warrants solely to eliminate the seven-year expiration date of the pre-funded warrants. Each amended and restated pre-funded warrant is now exercisable for $0.0001 per share of common stock from the original date of issuance until the date the pre-funded warrant is exercised in full. All other terms of the pre-funded warrants remain unchanged. The pre-funded warrants contain standard adjustment provisions if certain corporate events were to happen.

The pre-funded warrants are classified as a component of permanent equity and were recorded at the issuance date using a relative fair value allocation method. The pre-funded warrants are equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, and permit the holders to receive a fixed number of shares of common stock upon exercise. In addition, such pre-funded warrants do not provide any guarantee of value or return. As of September 30, 2022, 197,251 pre-funded warrants have been exercised by means of cashless exercise in exchange for the issuance of 197,240 shares of the Company's common stock.

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 was 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.

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 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. On January 1, 2022, the number of shares of common stock reserved under the 2020 Plan was increased by 946,749 shares. As of September 30, 2022, 333,216 shares of common stock remain available for future issuance under the 2020 Plan.

The following table summarizes stock option activity under the Company's equity incentive plans for the nine months ended September 30, 2022:

	Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (1) (in thousands)
Outstanding at December 31, 2021	3,582,613	$ 10.63	8.32	$ 7,428
Granted	1,740,069	4.92		
Exercised	(210,977)	1.70		
Forfeited	(304,196)	10.28		
Outstanding at September 30, 2022	4,807,509	$ 8.98	8.28	$ 831
Exercisable at September 30, 2022	1,967,985	$ 9.29	7.39	$ 741
Vested and expected to vest at September 30, 2022	4,807,509	$ 8.98	8.28	$ 831

(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 and nine months ended September 30, 2022 was $2.28 per share and $3.62 per share, respectively. The aggregate intrinsic value of stock options exercised during the three months ended September 30, 2022 was $0.1 million. The aggregate intrinsic value of stock options exercised during the nine months ended September 30, 2022 was $0.5 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 September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Risk-free interest rate range	2.63% to 4.04%	0.93% to 0.98%	1.58% to 4.04%	0.48% to 1.15%
Dividend yield	0%	0%	0%	0%
Expected term of options (years)	6.08 to 6.48	5.98 to 6.08	5.08 to 6.48	5.37 to 6.48
Volatility rate range	84.50% to 86.40%	88.57% to 89.25%	84.50% to 87.15%	88.57% to 91.19%

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	$ 931	$ 798	$ 2,923	$ 2,495
General and administrative	918	954	2,863	2,647
Total	$ 1,849	$ 1,752	$ 5,786	$ 5,142

The total unrecognized compensation cost related to outstanding employee awards as of September 30, 2022 was $14.9 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 236,687 on January 1, 2022 due to this provision. As of September 30, 2022, 40,412 shares have been purchased by employees under the ESPP.

The Company activated its first offering period under the ESPP on April 1, 2022. The offering period ended on September 30, 2022. A second offering period began on October 1, 2022 and will end on March 31, 2023. During the three and nine months ended September 30, 2022, the Company recorded less than $0.1 million of stock-based compensation expense under the ESPP. The Company did not record any stock-based compensation expense under the ESPP in the three and nine months ended September 30, 2021.

10. Net Loss per Share

Net Loss per Share Attributable to Common Stockholders

The following table sets forth the computation of basic and diluted net loss per share for the three months ended September 30, 2022 and 2021 (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net loss attributable to common stockholders—basic and diluted	$ (16,372)	$ (14,280)	$ (48,517)	$ (37,870)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.38)	$ (0.60)	$ (1.36)	$ (1.61)
Weighted-average common shares and pre-funded warrants outstanding—basic and diluted	43,657,718	23,643,494	35,755,695	23,521,981

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. Since the shares underlying the pre-funded warrants are issuable for little or no consideration, they are considered outstanding for both basic and diluted earnings per share from the date of issuance. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Options to purchase common stock	4,807,509	3,361,497	4,807,509	3,361,497
	4,807,509	3,361,497	4,807,509	3,361,497

11. Employee Benefit Plans

The Company established a defined contribution savings plan in 2018 for all eligible U.S. employees under Section 401(k) of the Internal Revenue Code. 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 and nine months ended September 30, 2022, the Company made employer contributions to the 401(k) plan totaling $60 thousand and $202 thousand, respectively.

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, 2021 filed with the Securities and Exchange Commission, or SEC, on March 15, 2022. 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 and in this Quarterly Report on Form 10-Q, 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 impacting the vasculature, soft tissue and skeleton. Through our in-depth understanding of a key biological pathway, 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 this critical pathway and that defects in these genes lead to pathologic mineralization and intimal proliferation. 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 defects in a pathway involving ENPP1 and ABCC6 Deficiencies. This pathway is central to the regulation of calcium deposition throughout the body and is further associated with intimal proliferation leading to a narrowing of blood vessels. We have generated robust proof of concept data in preclinical models demonstrating that INZ-701 prevented pathologic mineralization, led to improvements in overall health and survival and prevented intimal proliferation.

We are currently conducting Phase 1/2 clinical trials of INZ-701 for the treatment of ENPP1 Deficiency and ABCC6 Deficiency. These clinical trials are being conducted in both North America and in Europe. The U.S. Food and Drug Administration, or FDA, and the European Medicines Agency have granted orphan drug designation to INZ-701 for the treatment of ENPP1 Deficiency and 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 INZ-701 for the treatment of ENPP1 Deficiency.

In November 2021, we initiated our Phase 1/2 clinical trial of INZ-701 in adult patients with ENPP1 Deficiency. This trial is currently ongoing in North America and Europe. In the Phase 1 dose-escalation portion of the clinical trial, we are assessing INZ-701 for 32-days at doses of 0.2 mg/kg, 0.6 mg/kg, and 1.8 mg/kg administered via subcutaneous injection twice weekly, with three patients per dose cohort.

In April 2022, we announced preliminary biomarker, safety and pharmacokinetic, or PK, data from the 0.2 mg/kg cohort of this trial. At the 0.2 mg/kg dose level of INZ-701, all three patients showed rapid, significant, and sustained increases in plasma pyrophosphate, or PPi, levels. Preclinical findings demonstrated PPi being a key predictive biomarker of therapeutic benefit in ENPP1 Deficiency. The range of PPi levels across the three patients at screening was 132-333 nM. At the 0.2 mg/kg dose level of INZ-701, the mean PPi level observed during the 32-day dose evaluation period across the three patients was 1356 nM, an approximately 5-fold mean increase from screening across the three patients. The range of peak PPi levels observed during the 32-day dose evaluation period across the three patients was 1082-2416 nM, and was comparable to data from our study of healthy subjects (n=10), which showed PPi levels between 1002 nM and 2169 nM. Increased PPi levels observed after dosing of INZ-701 were associated with systemic exposure and activity of INZ-701. PK analysis showed INZ-701 nearing steady-state by Day 29 with an approximately 4-fold accumulation from Day 1, based on AUC_{0-72}. We believe that the half-life of INZ-701 observed in this trial suggests the potential for once-weekly dosing. All three patients from the first cohort enrolled in the open-label Phase 2 48-week extension portion of the trial. At Week 12, low titers of anti-drug antibodies were observed in two out of three patients. The significantly increased PPi levels observed during the 32-day dose evaluation period were sustained in all three patients through Week 12 of the extension portion of the trial. INZ-701 was generally well-tolerated, with no treatment-related serious adverse events reported, and otherwise exhibited a favorable initial safety profile.

We are currently dosing patients in the 1.8 mg/kg cohort and plan to report topline data from this trial in the fourth quarter of 2022. In November 2022, we announced the first self-administration of INZ-701 in the open-label Phase 2 48-week extension portion of the trial. We are also actively engaged in designing and planning a clinical trial of INZ-701 in pediatric patients with ENPP1 Deficiency.

In April 2022, we initiated our Phase 1/2 clinical trial of INZ-701 in adult patients with ABCC6 Deficiency. The trial is currently ongoing in the United States and Europe. In the Phase 1 dose-escalation portion of the clinical trial, we are assessing

INZ-701 for 32-days at doses of 0.2 mg/kg, 0.6 mg/kg, and 1.8 mg/kg administered via subcutaneous injection twice weekly, with three patients per dose cohort.

In July 2022, we announced preliminary biomarker, safety and PK data from the 0.2 mg/kg cohort of this trial. At the 0.2 mg/kg dose level of INZ-701, all three patients showed rapid and significant increases in PPi levels. Preclinical findings demonstrated PPi being a key predictive biomarker of therapeutic benefit in ABCC6 Deficiency. The mean PPi level across the three patients at baseline was 851 nM. At the 0.2 mg/kg dose level of INZ-701, the mean PPi level observed during the 32-day dose evaluation period across the three patients was 1057 nM, which was within the range observed in our study of healthy subjects (n=10), which showed PPi levels between 1002 nM and 2169 nM. The range of peak PPi levels observed across the three patients in the 32-day dose evaluation period was 2139-4090 nM. Preliminary PK and INZ-701 enzymatic activity remained consistent with data reported from our ongoing Phase 1/2 trial of INZ-701 in patients with ENPP1 Deficiency. INZ-701 continued to exhibit a favorable initial safety profile. INZ-701 was generally well-tolerated with no serious adverse events reported. Low titers of anti-drug antibodies were observed in one patient at day 32 of the trial, which had no impact on PK or ENPP1 activity. All three patients from the first cohort enrolled in the open-label Phase 2 48-week extension portion of the trial. We are currently dosing patients in the 1.8 mg/kg cohort and plan to report topline data from this trial in the first quarter of 2023.

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 pathologic mineralization and intimal proliferation, including those without a clear genetic basis, such as calciphylaxis and calcifications as a result of end stage kidney disease. Based on regulatory feedback, we plan to initiate a clinical trial in end stage kidney disease patients and we expect data from this trial to inform our development plans in calciphylaxis. We are also exploring the potential for development of a gene therapy for ENPP1 Deficiency.

Our Operations

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, including preclinical studies and early-stage clinical trials, establishing arrangements for the manufacture of INZ-701 and longer term planning for potential commercialization. To date, we have funded our operations primarily with proceeds from the sales of convertible preferred stock, offerings of common stock and pre-funded warrants and borrowings under our loan and security agreement, or the Loan Agreement, with K2 HealthVentures LLC, or K2HV.

Uncertainty remains as to the potential impact of COVID-19 on our future research and development activities and the potential for a material impact on the Company increases the longer the virus impacts certain aspects of economic activity around the world. The full extent to which COVID-19 will directly or indirectly impact our business, results of operations and financial condition, including our ability to fulfill our clinical trial enrollment needs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international markets, the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, the ultimate impact on financial markets and the global economy, the effectiveness of vaccines and vaccine distribution efforts and the effectiveness of other actions taken in the United States and other countries to contain and treat the disease.

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 $48.5 million for the nine months ended September 30, 2022 and $56.6 million for the year ended December 31, 2021. As of September 30, 2022, we had an accumulated deficit of $196.2 million.

Our operating expenses were $49.1 million for the nine months ended September 30, 2022 and $56.6 million for the year ended December 31, 2021. We expect to continue to incur significant expenses for the foreseeable future. We expect our expenses to increase substantially in connection with our ongoing and planned 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, other than under our Loan Agreement. Our ability to borrow under our Loan Agreement is

subject to our satisfaction of specified conditions and lender discretion. 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 September 30, 2022, we had cash, cash equivalents and short-term investments of approximately $141.5 million.

On April 14, 2022, we entered into an underwriting agreement with Jefferies LLC and Cowen and Company, LLC, relating to an underwritten offering of 16,276,987 shares of our common stock or the Shares, and, in lieu of common stock to certain investors, pre-funded warrants to purchase 3,523,013 shares of common stock. The closing of the offering took place on April 19, 2022. The offering price of the Shares was $3.69 per share and the offering price of the pre-funded warrants was $3.6899 per share underlying each pre-funded warrant. Net proceeds from the offering were approximately $68.3 million, after deducting underwriting discounts and commissions and offering expenses.

On July 25, 2022, we entered into a Loan Agreement with K2HV (together with any other lender from time to time party thereto, the "Lenders"), K2HV, as administrative agent for the Lenders, and Ankura Trust Company, LLC, as collateral agent for the Lenders. The Loan Agreement provides up to $70.0 million principal in term loans consisting of (subject to certain customary conditions): (i) a first tranche commitment of $25.0 million, of which $5.0 million was funded at closing and with the remainder available to be drawn at our option through March 31, 2023, or the First Tranche Commitment, (ii) two subsequent tranche commitments totaling $20.0 million in the aggregate to be drawn at our option during certain availability periods, subject to the achievement, as determined by the administrative agent in its sole discretion, of certain time-based, clinical and regulatory milestones relating to INZ-701, and (iii) a fourth tranche commitment of $25.0 million available to be drawn at our option through August 31, 2025, subject to use of proceeds limitations and Lender's consent in its discretion.

The facility carries a 48-month term with interest only payments for 36 months and then interest and equal principal payments for the next 12 months. The term loan will mature on August 1, 2026 and bears a variable interest rate equal to the greater of (i) 7.85% and (ii) the sum of (A) the prime rate last quoted in The Wall Street Journal (or a comparable replacement rate if The Wall Street Journal ceases to quote such rate) and (B) 3.85%; *provided* that the interest rate cannot exceed 9.60%. We may prepay, at our option, all, but not less than all, of the outstanding principal balance and all accrued and unpaid interest with respect to the principal balance being prepaid of the term loans, subject to a prepayment premium to which the Lenders are entitled and certain notice requirements. We paid the Lenders certain customary fees and expenses at closing and are required to pay the Lenders additional fees that may be due upon maturity or prepayment such as final payment fees and prepayment fees. As security for its obligations under the Loan Agreement, we granted the Lenders a first priority security interest on substantially all of our assets (other than intellectual property), subject to certain exceptions.

Subject to certain conditions, we granted the Lenders the right, prior to repayment of the term loans, to invest up to $5,000,000 in the aggregate in our future offerings of common stock, convertible preferred stock or other equity securities that are broadly marketed and offered to multiple investors, on the same terms, conditions and pricing afforded to others participating in any such financing.

We believe that our existing cash, cash equivalents and short-term investments as of September 30, 2022, together with the remainder of the First Tranche Commitment, will enable us to fund our cash flow requirements into the second quarter of 2024. 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:

- conduct our ongoing Phase 1/2 clinical trials of INZ-701 for ENPP1 Deficiency and 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;
- 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;
- 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;
- personnel-related expenses, including salaries, related benefits, travel and stock-based compensation expense for employees and consultants 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. We are currently conducting our Phase 1/2 clinical trials of INZ-701 for ENPP1 Deficiency and ABCC6 Deficiency. 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 September 30, 2022, we have incurred $128.3 million of research and development costs for INZ-701. We expect that our research and development costs will continue to increase substantially for the foreseeable future as we conduct the ongoing clinical trials of INZ-701, prepare for, initiate and conduct later stage clinical trials of INZ-701 for patients with ENPP1 and ABCC6 Deficiencies, further 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;
- 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 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 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 September 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended September 30, 2022 and 2021 (in thousands):

	Three Months Ended September 30,		
	2022	2021	Increase (Decrease)
Operating expenses:			
Research and development	$ 12,191	$ 9,346	$ 2,845
General and administrative	4,721	4,916	(195)
Total operating expenses	16,912	14,262	2,650
Loss from operations	(16,912)	(14,262)	2,650
Other income (expense):			
Interest income	737	47	690
Other expenses	(197)	(65)	132
Other income, net	540	(18)	558
Net loss	$ (16,372)	$ (14,280)	$ 2,092

Research and Development Expense

Research and development expense increased by $2.8 million to $12.2 million for the three months ended September 30, 2022 from $9.3 million for the three months ended September 30, 2021. The increase in research and development expense was primarily attributable to an increase in clinical trial costs due to the progression of the clinical trials of INZ-701 for ENPP1 Deficiency and ABCC6 Deficiency, manufacturing operations, and costs for consultants to support our ongoing trials.

We expect that our research and development expenses will increase for the foreseeable future as we conduct clinical trials of INZ-701, prepare for, initiate and conduct later stage clinical trials of INZ-701 for patients with ENPP1 and ABCC6

Deficiencies, further scale our manufacturing processes and advance development of INZ-701 for additional indications or potentially additional product candidates.

General and Administrative Expense

General and administrative expense decreased by $0.2 million to $4.7 million for the three months ended September 30, 2022 from $4.9 million for the three months ended September 30, 2021. The decrease in general and administrative expense was primarily attributable to a decrease in professional services and other administrative expenses partially offset by an increase in personnel costs. We expect that our general and administrative expenses will increase in future periods as we expand our operations and incur costs in connection with being a public company.

Interest Income

Interest income for the three months ended September 30, 2022 was approximately $0.7 million as a result of higher interest rates and a larger cash balance on which we are earning interest in the period compared to the three months ended September 30, 2021.

Other Expenses

Other expenses, consisting primarily of foreign exchange gains and losses, for the three months ended September 30, 2022 increased by $0.1 million as compared to the three months ended September 30, 2021. This increase was driven by cash balances we hold which are denominated in Euros and their related depreciation compared to the U.S. Dollar in the three months ended September 30, 2022 compared to the three months ended September 30, 2021.

Comparison of the Nine Months Ended September 30, 2022 and 2021

The following table summarizes our results of operations for the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine Months Ended September 30,		
	2022	2021	Increase (Decrease)
Operating expenses:			
Research and development	$ 34,012	$ 24,169	$ 9,843
General and administrative	15,130	13,720	1,410
Total operating expenses	49,142	37,889	11,253
Loss from operations	(49,142)	(37,889)	11,253
Other income (expense):			
Interest income	1,118	168	950
Other expenses	(493)	(149)	344
Other income, net	625	19	606
Net loss	$ (48,517)	$ (37,870)	$ 10,647

Research and Development Expense

Research and development expense increased by $9.8 million to $34.0 million for the nine months ended September 30, 2022 from $24.2 million for the nine months ended September 30, 2021. The increase in research and development expense was primarily attributable to an increase in clinical trial costs due to the progression of the clinical trials of INZ-701 for ENPP1 Deficiency and ABCC6 Deficiency, manufacturing operations, personnel costs, and consultants to support our ongoing trials partially offset by a decrease in research costs.

We expect that our research and development expenses will increase for the foreseeable future as we conduct clinical trials of INZ-701, prepare for, initiate and conduct later stage clinical trials of INZ-701 for patients with ENPP1 and ABCC6 Deficiencies, further scale our manufacturing processes and advance development of INZ-701 for additional indications or potentially additional product candidates.

General and Administrative Expense

General and administrative expense increased by $1.4 million to $15.1 million for the nine months ended September 30, 2022 from $13.7 million for the nine months ended September 30, 2021. The increase in general and administrative expense was attributable to an increase in personnel costs and consulting expenses partially offset by a decrease in professional services costs. We expect that our general and administrative expenses will increase in future periods as we expand our operations and incur costs in connection with being a public company.

Interest Income

Interest income for the nine months ended September 30, 2022 was approximately $1.1 million as a result of higher interest rates and a larger cash balance on which we are earning interest in the period compared to the nine months ended September 30, 2021.

Other Expenses

Other expenses, consisting primarily of foreign exchange gains and losses, for the nine months ended September 30, 2022 increased by $0.3 million as compared to the nine months ended September 30, 2021. This increase was driven by cash balances we hold which are denominated in Euros and their related depreciation compared to the U.S. Dollar in the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021.

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, offerings of common stock and pre-funded warrants and borrowings under our Loan Agreement. Through September 30, 2022, we had received net cash proceeds of approximately $299.8 million from sales of our convertible preferred stock, common stock and pre-funded warrants, after deducting underwriting discounts and commissions and offering expenses, and proceeds from the issuance of long-term debt, net of issuance costs. As of September 30, 2022, we had cash, cash equivalents and short-term investments of approximately $141.5 million.

On August 11, 2021, we filed a universal shelf registration statement on Form S-3, which was declared effective on August 23, 2021, or the Registration Statement. Under the Registration Statement, we may offer and sell up to $200.0 million of a variety of securities, including common stock, preferred stock, depositary shares, debt securities, warrants, subscription rights or units from time to time pursuant to one or more offerings at prices and terms to be determined at the time of the sale. In connection with the filing of the Registration Statement, we entered into an Open Market Sale Agreement with Jefferies LLC, as sales agent, pursuant to which we may offer and sell shares of our common stock with an aggregate offering price of up to $50.0 million under an "at-the-market" offering program. To date, we have not sold any securities pursuant to the Open Market Sale Agreement.

In April 2022, we closed an underwritten offering in which we sold 16,276,987 shares of common stock and pre-funded warrants to purchase 3,523,013 shares of common stock under the Registration Statement. Net proceeds from the offering were approximately $68.3 million, after deducting underwriting discounts and commissions and offering expenses.

In July 2022, we entered into a Loan Agreement with the Lenders, which provides up to $70.0 million principal in term loans consisting of (subject to certain customary conditions): (i) a First Tranche Commitment of $25.0 million, of which $5.0 million was funded at closing and with the remainder available to be drawn at our option through March 31, 2023, (ii) two subsequent tranche commitments totaling $20.0 million in the aggregate to be drawn at our option during certain availability periods, subject to the achievement, as determined by the administrative agent in its sole discretion, of certain time-based, clinical and regulatory milestones relating to INZ-701, and (iii) a fourth tranche commitment of $25.0 million available to be drawn at our option through August 31, 2025, subject to use of proceeds limitations and Lender's consent in its discretion. Additional information on the Loan Agreement is described in Note 8 to our consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Cash in excess of immediate requirements is invested primarily with a view to liquidity and capital preservation. The following table provides information regarding our total cash, cash equivalents and short-term investments at September 30, 2022 and December 31, 2021 (in thousands):

	September 30, 2022	December 31, 2021
Cash and cash equivalents	$ 44,044	$ 23,316
Short-term investments	97,408	88,485
Total cash, cash equivalents and short-term investments	$ 141,452	$ 111,801

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine Months Ended September 30,	
	2022	2021
Net cash used in operating activities	$ (43,361)	$ (34,709)
Net cash (used in) provided by investing activities	(8,621)	33,309
Net cash provided by financing activities	72,788	598
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 20,806	$ (802)

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 $43.4 million for the nine months ended September 30, 2022 compared to $34.7 million for the nine months ended September 30, 2021. The increase in cash used in operating activities of $8.7 million was primarily due to an increase in net loss adjusted for non-cash items of $11.1 million, offset by changes in operating assets and liabilities of $2.5 million.

Net Cash (Used in) Provided by Investing Activities

Net cash used in investing activities was $8.6 million for the nine months ended September 30, 2022 compared to net cash provided by investing activities of $33.3 million for the nine months ended September 30, 2021 as purchases of marketable securities surpassed maturities of marketable securities in the nine months ended September 30, 2022. For the nine months ended September 30, 2022, we had maturities of marketable securities of $117.8 million, purchases of marketable securities of $126.0 million and purchases of property and equipment of $0.4 million. For the nine months ended September 30, 2021, we had maturities of marketable securities of $138.7 million, purchases of marketable securities of $105.0 million and purchases of property and equipment of $0.4 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities of $72.8 million for the nine months ended September 30, 2022 reflects the cash proceeds from the issuance of common stock and pre-funded warrants in our underwritten offering in April 2022, proceeds from the issuance of long-term debt in July 2022, proceeds from the exercise of stock options, and proceeds from the issuance of common stock under the employee stock purchase plan. Net cash provided by financing activities of $0.6 million for the nine months ended September 30, 2021 reflects cash proceeds from the exercise of stock options.

Funding Requirements

We expect to devote substantial financial resources to our ongoing and planned activities, particularly as we conduct our ongoing Phase 1/2 clinical trials of INZ-701 for ENPP1 Deficiency and ABCC6 Deficiency, 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 and planned 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. 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 ongoing Phase 1/2 clinical trials of INZ-701 for ENPP1 Deficiency and ABCC6 Deficiency 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;

- 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 extent of our debt service obligations and our ability, if desired, to refinance any of our existing debt on terms that are more favorable to us;
- 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 September 30, 2022, we had cash, cash equivalents and short-term investments of approximately $141.5 million. We believe that our existing cash, cash equivalents and short-term investments as of September 30, 2022, together with the remainder of the First Tranche Commitment, will enable us to fund our cash flow requirements into the second quarter of 2024. 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.

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, other than under our Loan Agreement. Our ability to borrow under our Loan Agreement is subject to our satisfaction of specified conditions and lender discretion. To the extent that we raise additional capital through the sale of equity or convertible debt securities or to the extent the Lenders elect to convert a portion of their outstanding principal into shares of our common stock pursuant to the Loan Agreement, the ownership interests of our stockholders will be diluted, and the terms of any new 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 indebtedness, 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. The covenants under our Loan Agreement and the pledge of our assets as collateral limit our ability to take specific actions, including obtaining additional debt financing.

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.

Critical Accounting 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 and nine months ended September 30, 2022, there were no material changes to our critical accounting estimates from those described in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2021.

Contractual Obligations, Commitments and Contingencies

Except for the Loan Agreement entered into in July 2022 and described in Note 8 to our consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, during the nine months ended September 30, 2022, there were no material changes to our contractual obligations and commitments from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended December 31, 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 September 30, 2022, our cash equivalents consisted of primarily of short-term money market funds. As of September 30, 2022, our short-term investments consisted of commercial paper, and U.S. Treasury securities. 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. An immediate increase (decrease) of 100 basis points would result in an increase (decrease) in interest income of approximately $1.0 million annually.

As of September 30, 2022, the aggregate principal amount outstanding under the Loan Agreement was $5.0 million, which bears interest at a variable rate equal to the greater of (i) 7.85% and (ii) the sum of (A) the prime rate last quoted in The Wall Street Journal (or a comparable replacement rate if The Wall Street Journal ceases to quote such rate) and (B) 3.85%; provided that the interest rate cannot exceed 9.60%. The interest rate as of September 30, 2022, was 9.60%.

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 nine months ended September 30, 2022 and 2021.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2022. 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 September 30, 2022, our Chief Executive Officer and our Chief Financial Officer 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.

You should carefully consider the following risks and uncertainties and the risks and uncertainties discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10–K for the year ended December 31, 2021, together with all of the other information contained in this Quarterly Report on Form 10-Q, which could materially affect our business, financial condition or results of operations. The risk factors disclosure in our Annual Report on Form 10-K for the year ended December 31, 2021 is qualified by the information that is described in this Quarterly Report on Form 10-Q. The risks described below and in our Annual Report on Form 10–K for the year ended December 31, 2021 are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or future results.

Risks Related to Our Financial Position and Need for Additional Capital

We have a loan agreement that requires us to meet specified funding conditions and operating covenants and places restrictions on our operating and financial flexibility.

Under our Loan Agreement, we have $5.0 million of outstanding principal indebtedness, and we may in the future draw down up to $65.0 million of additional principal indebtedness under the Loan Agreement, subject to specified conditions and lender discretion. Our ability to draw down two tranche commitments totaling $20.0 million in the aggregate is subject to our achievement, as determined by the administrative agent in its sole discretion, of certain time-based, clinical and regulatory milestones relating to INZ-701. Our ability to draw down an additional tranche commitment of $25.0 million is subject to use of proceeds limitations and Lender's consent in its discretion. As security for its obligations under the Loan Agreement, we granted the Lenders a first priority security interest on substantially all of our assets (other than intellectual property), subject to certain exceptions. Because of the security interest, the Lender's rights to repayment from a liquidation of the assets subject to that security interest would be senior to the rights of other creditors.

The Loan Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including covenants that limit or restrict our ability to, among other things, dispose of assets, make changes to our business, management, ownership or business locations, merge or consolidate, incur additional indebtedness, incur additional liens, pay dividends or other distributions or repurchase equity, make investments, and enter into certain transactions with affiliates, in each case subject to certain exceptions.

We intend to satisfy our current and future debt service obligations with our existing cash and cash equivalents. However, we may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our outstanding debt. Funds from external sources may not be available on acceptable terms, if at all. In addition, a failure to comply with the conditions of our Loan Agreement, including a breach of any covenant, could result in an event of default thereunder. In the event of an acceleration of amounts due under our Loan Agreement as a result of an event of default, including upon the occurrence of an event or circumstance that could be expected to have a material adverse effect on our business, operations, properties, assets or financial condition or a failure to pay any amount due, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and the Lenders could seek to enforce security interests in the collateral securing such indebtedness. Any declaration by the Lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

In addition, our outstanding debt combined with our other financial obligations and contractual commitments could have significant adverse consequences, including:

- restricting the amount of our cash resources, after satisfaction of our debt service obligations, available to fund working capital, research and development efforts and other general corporate purposes;
- limiting our flexibility in planning for, or reacting to, changes in our business and our industry; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

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 September 30, 2022.

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.

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.

We have used approximately $50.9 million of the net proceeds from the IPO as of September 30, 2022 to fund clinical development of INZ-701, to fund our preclinical research and development activities, and for working capital and other general corporate purposes. 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†	Loan and Security Agreement, dated July 25, 2022, by and among the Registrant, K2 HealthVentures LLC, as lender, K2 HealthVentures LLC, as administrative agent, and Ankura Trust Company, LLC, as collateral agent (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39397) filed with the Securities and Exchange Commission on August 15, 2022).
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	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101).

* Filed herewith.

\+ Furnished herewith.

† Certain portions of this exhibit have been omitted because they are not material and contain information that the Registrant customarily and actually treats as private or confidential.

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: November 10, 2022

By: /s/ Axel Bolte

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

Date: November 10, 2022

By: /s/ Sanjay Subramanian

Sanjay Subramaniam
Chief Financial Officer
(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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (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: November 10, 2022

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, Sanjay Subramanian, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (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: November 10, 2022

By: /s/ Sanjay Subramanian

Sanjay Subramanian
Chief Financial Officer
(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 ended September 30, 2022 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: November 10, 2022

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 ended September 30, 2022 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: November 10, 2022

By: /s/ Sanjay Subramanian

Sanjay Subramanian
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)