UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2024

OR

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

For the transition period from _____ to _____

Commission File Number: 001-39397

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

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

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

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

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

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

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

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

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

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

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

As of May 2, 2024, the registrant had 61,855,509 shares of common stock, $0.0001 par value per share, outstanding.

CAUTIONARY NOTE REGARDING 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 adults with ENPP1 and ABCC6 Deficiencies, our ongoing Phase 1b clinical trial of INZ-701 for infants with ENPP1 Deficiency ("ENERGY-1"), our ongoing pivotal trial of INZ-701 in pediatric patients with ENPP1 Deficiency ("ENERGY-3"), and our ongoing Phase 1 clinical trial of INZ-701 in patients with end-stage kidney disease receiving hemodialysis ("SEAPORT-1"), 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, design, and conduct of our planned clinical trials of INZ-701 for patients with ENPP1 and ABCC6 Deficiencies, including our planned pivotal clinical trials of INZ-701 for infants ("ENERGY-2") and in adolescents and adults with ENPP1 Deficiency ("ENERGY-4"), and our planned pivotal clinical trial of INZ-701 for pediatric patients with ABCC6 Deficiency;
- our plans to conduct research, preclinical testing and clinical trials of INZ-701 for additional indications;
- our plans to conduct research, preclinical testing and clinical trials of other product candidates;
- our plans to engage in regulatory interactions with the U.S. Food and Drug Administration, the European Medicines Agency and other regulatory authorities;
- our plans with respect to regulatory filings;
- 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 cash flow requirements 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;
- 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;
- our ability to comply with the covenants under our loan agreement;
- 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)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 20,618	$ 34,588
Short-term investments	145,535	154,001
Prepaid expenses and other current assets	8,171	7,661
Total current assets	174,324	196,250
Property and equipment, net	1,316	1,466
Right-of-use assets	992	1,126
Restricted cash	311	311
Prepaid expenses, net of current portion	—	1,694
Total assets	$ 176,943	$ 200,847
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,166	$ 1,166
Accrued expenses	9,306	12,610
Operating lease liabilities	934	910
Total current liabilities	12,406	14,686
Operating lease liabilities, net of current portion	669	913
Long-term debt, net	45,032	44,769
Total liabilities	58,107	60,368
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred Stock, $0.0001 par value – 5,000,000 shares authorized at March 31, 2024 and December 31, 2023; no shares issued and outstanding at March 31, 2024 or December 31, 2023	—	—
Common Stock, $0.0001 par value – 200,000,000 shares authorized at March 31, 2024 and December 31, 2023; 61,816,509 shares issued and outstanding at March 31, 2024 and 61,768,771 shares issued and outstanding at December 31, 2023	6	6
Additional paid in-capital	428,212	426,362
Accumulated other comprehensive (loss) income	(105)	41
Accumulated deficit	(309,277)	(285,930)
Total stockholders' equity	118,836	140,479
Total liabilities and stockholders' equity	$ 176,943	$ 200,847

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 March 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 19,111	$ 11,857
General and administrative	5,234	6,512
Total operating expenses	24,345	18,369
Loss from operations	(24,345)	(18,369)
Other income (expense):		
Interest income	2,374	1,327
Interest expense	(1,325)	(328)
Other expense, net	(51)	(34)
Other income (expense), net	998	965
Net loss	$ (23,347)	$ (17,404)
Other comprehensive income (loss):		
Unrealized (losses) gains on available-for-sale securities	(156)	150
Foreign currency translation adjustment	10	19
Total other comprehensive (loss) income	(146)	169
Comprehensive loss	$ (23,493)	$ (17,235)
Net loss attributable to common stockholders—basic and diluted	$ (23,347)	$ (17,404)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.38)	$ (0.40)
Weighted-average common shares and pre-funded warrants outstanding—basic and diluted	61,772,279	43,720,578

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 (Loss) Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance at December 31, 2023	61,768,771	$ 6	$ 426,362	$ 41	$ (285,930)	$ 140,479
Stock-based compensation	—	—	1,691	—	—	1,691
Exercise of stock options	3,206	—	11	—	—	11
Shares purchased in Employee Stock Purchase Plan	44,532	—	148	—	—	148
Comprehensive loss:						
Unrealized loss on investments	—	—	—	(156)	—	(156)
Foreign currency translation adjustment	—	—	—	10	—	10
Net loss	—	—	—	—	(23,347)	(23,347)
Balance at March 31, 2024	61,816,509	$ 6	$ 428,212	$ (105)	$ (309,277)	$ 118,836
Balance at December 31, 2022	40,394,363	$ 4	$ 333,356	$ (205)	$ (214,761)	$ 118,394
Stock-based compensation	—	—	2,092	—	—	2,092
Exercise of pre-funded warrants	3,325,644	—	—	—	—	—
Shares purchased in Employee Stock Purchase Plan	45,478	—	96	—	—	96
Comprehensive loss:						
Unrealized gain on investments	—	—	—	150	—	150
Foreign currency translation adjustment	—	—	—	19	—	19
Net loss	—	—	—	—	(17,404)	(17,404)
Balance at March 31, 2023	43,765,485	$ 4	$ 335,544	$ (36)	$ (232,165)	$ 103,347

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

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

	Three Months Ended March 31,	
	2024	**2023**
Operating activities		
Net loss	$ (23,347)	$ (17,404)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	182	207
Stock-based compensation expense	1,691	2,092
Amortization of premiums and discounts on marketable securities	(2,116)	(746)
Reduction in the carrying value of right-of-use assets	134	117
Non-cash interest expense and amortization of debt issuance costs	263	80
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(510)	309
Accounts payable	1,000	(729)
Accrued expenses	(3,304)	(1,423)
Operating lease liabilities	(220)	(197)
Prepaid expenses, net of current portion	1,694	—
Other long-term liabilities	—	(78)
Net cash used in operating activities	(24,533)	(17,772)
Investing activities		
Purchases of marketable securities	(49,324)	(46,059)
Maturities of marketable securities	59,750	60,000
Purchases of property and equipment	(32)	(175)
Net cash provided by investing activities	10,394	13,766
Financing activities		
Net proceeds from issuance of long-term debt	—	20,000
Proceeds from exercise of stock options	11	—
Proceeds from issuance of common stock for cash under Employee Stock Purchase Plan	148	96
Net cash provided by financing activities	159	20,096
Net (decrease) increase in cash, cash equivalents, and restricted cash	(13,980)	16,090
Effect of foreign currency exchange rate on cash	10	19
Cash, cash equivalents, and restricted cash at beginning of period	34,899	33,269
Cash, cash equivalents, and restricted cash at end of period	$ 20,929	$ 49,378
Supplemental cash flow information:		
Cash and cash equivalents	$ 20,618	$ 49,024
Restricted cash	311	354
Cash, cash equivalents, and restricted cash at end of period	$ 20,929	$ 49,378
Property and equipment unpaid at end of period	$ —	$ 5

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

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.

Through the Company's in-depth understanding of a key biological pathway, the Company is pursuing the development of therapeutics that address pathologic mineralization and intimal proliferation, or smooth muscle cell overgrowth that leads to narrowing and the obstruction of blood vessels, to improve the underlying causes of these debilitating diseases. It is well established that low levels of plasma pyrophosphate ("PPi") drive pathologic mineralization and low levels of adenosine drive intimal proliferation in a number of rare diseases. The Company is initially focused on developing a novel therapy for diseases characterized by pathological calcification and intimal proliferation, including ENPP1 Deficiency and ABCC6 Deficiency as well as calciphylaxis.

The Company's lead product candidate, INZ-701, is a soluble, recombinant, or genetically engineered, fusion protein that is designed to cleave extracellular adenosine triphosphate to generate plasma PPi and adenosine monophosphate, which can be processed to phosphate and adenosine. This process is central to the regulation of calcium deposition throughout the body and is further associated with the inhibition of intimal proliferation.

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 month period ended March 31, 2024 are not necessarily indicative of results to be expected for the year ending December 31, 2024, 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, 2023.

Liquidity, Capital Resources, and Going Concern

Since the Company's incorporation in 2017 and through March 31, 2024, 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 $24.3 million for the three months ended March 31, 2024 and had an accumulated deficit of $309.3 million as of March 31, 2024. The Company had cash, cash equivalents, and short-term investments of $166.2 million as of March 31, 2024.

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 its loan and security agreement (the "Loan Agreement") with K2 HealthVentures LLC (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 March 31, 2024 will be sufficient to fund its cash flow requirements for at least 12 months from the filing date of 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 prospects.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying condensed 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 condensed consolidated financial statements are described in the Company's audited consolidated financial statements for the year ended December 31, 2023 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023. There have been no material changes in the Company's significant accounting policies during the three months ended March 31, 2024.

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.

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 currently composed of U.S. Treasury securities and U.S. government agency debt securities. The Company mitigates credit risk by maintaining a diversified portfolio and limiting the amount of investment exposure as to institution, maturity, and investment type.

The Company has no significant off-balance sheet risk such as foreign exchange contracts, option contracts, or other foreign hedging arrangements.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents. Cash and cash equivalents include cash in readily available checking accounts, money market accounts, and certain marketable securities. Cash is carried at cost, which approximates its fair value. Cash equivalents are carried at fair market value.

Restricted Cash

Restricted cash is composed of amounts held to collateralize the letter of credit related to the Company's lease arrangements. Restricted cash is classified as either current or non-current based on the terms of the underlying lease arrangement.

3. Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("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.

4. Short-Term Investments

Short-term investments consisted of the following:

		March 31, 2024			
Description	Maturity	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. Treasury securities	1 year or less	$ 66,767	$ 3	$ (38)	$ 66,732
U.S. government agency debt securities	1 year or less	78,857	—	(54)	78,803
		$ 145,624	$ 3	$ (92)	$ 145,535

		December 31, 2023			
Description	Maturity	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. Treasury securities	1 year or less	$ 80,160	$ 59	$ (1)	$ 80,218
U.S. government agency debt securities	1 year or less	73,774	17	(8)	73,783
		$ 153,934	$ 76	$ (9)	$ 154,001

The Company did not have any investments in a continuous unrealized loss position for more than 12 months as of March 31, 2024. As of March 31, 2024, the Company believes that the cost basis of its available-for-sale securities is recoverable, and the Company has the intent and ability to hold its available-for-sale securities until recovery. Therefore, no allowance for credit losses was recorded.

5. Fair Value Measurement

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).

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:

		Fair Value Measurements at Reporting Date Using		
Description	March 31, 2024	Level 1	Level 2	Level 3
Assets:				
Money market funds (included in cash and cash equivalents)	$ 19,660	$ 19,660	$ —	$ —
U.S. government agency debt securities	78,803	—	78,803	—
U.S. Treasury securities	66,732	66,732	—	—
Total assets	$ 165,195	$ 86,392	$ 78,803	$ —

Description	December 31, 2023	Fair Value Measurements at Reporting Date Using		
		Level 1	Level 2	Level 3
Assets:				
Money market funds (included in cash and cash equivalents)	$ 33,830	$ 33,830	$ —	$ —
U.S. government agency debt securities	73,783	—	73,783	—
U.S. Treasury securities	80,218	80,218	—	—
Total assets	$ 187,831	$ 114,048	$ 73,783	$ —

There have been no transfers between fair value levels during the three months ended March 31, 2024.

6. License Agreement

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 March 31, 2024, the Company had incurred a life-to-date total of $0.4 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 the 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 the three months ended March 31, 2024, the Company incurred a $0.5 million milestone payment following completion of dosing of the first patient in the Company's pivotal clinical trial of INZ-701 in pediatric patients with ENPP1 Deficiency. 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, which may be subject to reductions. Yale is guaranteed a minimum royalty payment amount (ranging in dollar amounts from the mid six figures to low seven figures) for each year after the first sale of a therapeutic or prophylactic-licensed product that results in net sales. Yale is guaranteed a minimum royalty payment amount (ranging from the low tens of thousands of dollars to the mid tens of thousands of dollars) for each year after the first sale of a diagnostic licensed product that results in net sales. Such minimum royalty payment amounts are summed for each year after the first sale of both a therapeutic or prophylactic-licensed product and a diagnostic licensed product has occurred. The Company must also pay Yale a percentage in the twenties of certain types of income it receives from sublicensees. The Company is also responsible for costs relating to the prosecution and maintenance of the licensed patents. Finally, subject to certain conditions, all payments due by the Company to Yale will be tripled following any patent challenge or challenge to a claim by Yale that a product is a licensed product under the agreement, made by the Company against Yale if Yale prevails in such challenge.

The Company has also agreed to pay for research support from Yale pursuant to a sponsored research agreement that the Company entered into with Yale in January 2017 and amended in February 2019, February 2022, May 2022, May 2023, and January 2024. Under the sponsored research agreement, as amended, the Company agreed to pay Yale an aggregate of $3.0 million over eight years, ending in December 2024. As of March 31, 2024, the Company incurred a total of $2.8 million for research support under this agreement since inception.

7. Commitments and Contingencies

Operating Leases

The Company held the following significant operating leases as of March 31, 2024:

- 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
- 6,244 square feet of laboratory space in Boston, Massachusetts that expires in 2025 with an option to extend the term for five years.

The exercise of each option was determined not to be reasonably certain and thus neither option was included in the operating lease liability on the condensed consolidated balance sheets as of March 31, 2024 or December 31, 2023.

During the three months ended March 31, 2024, cash paid for amounts included in the measurement of lease liabilities was $0.3 million, and the Company recorded operating lease expense of $0.2 million.

Future lease payments under non-cancelable leases as of March 31, 2024 are as follows:

Year Ending December 31,		
2024 (remaining 9 months)	$	762
2025		944
	$	1,706

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters arising out of the relationship between such parties and the Company. In addition, the Company has entered into indemnification agreements with members of its board of directors and senior management that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and it has not accrued any liabilities related to such obligations as of March 31, 2024 or December 31, 2023.

Legal Proceedings

The Company is not currently a party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses the costs related to its legal proceedings as they are incurred. No such costs have been incurred during the three months ended March 31, 2024 and 2023.

8. Convertible Debt

Loan Agreement with K2 HealthVentures LLC

On July 25, 2022, the Company, as borrower, entered into the Loan Agreement with K2 HealthVentures LLC (together with any other lender from time to time, the “Lenders”), 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 contained an additional $20.0 million available to be drawn at the Company’s option through March 31, 2023. The Company elected to borrow the remaining $20.0 million in February 2023. Two subsequent tranche commitments totaling $20.0 million in the aggregate were 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. The Company borrowed $7.5 million under the second tranche commitment in June 2023 and borrowed $12.5 million under the third tranche commitment in December 2023. 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 at its discretion. The fourth tranche commitment is subject to an additional 0.75% facility fee. As of March 31, 2024, a total of $25.0 million of borrowing capacity remained available under the Loan Agreement, subject to the terms and conditions set forth therein. 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 March 31, 2024 was 9.60%. 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 to 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 March 31, 2024, 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. At March 31, 2024, the carrying value of the Loan Agreement approximated 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 March 31, 2024:

	March 31, 2024
Gross proceeds	$ 45,000
Unamortized debt issuance costs and accretion of final payments, net	32
Carrying value	$ 45,032

Future principal payments, which include the Final Fee, in connection with the Loan Agreement as of March 31, 2024 are as follows:

Fiscal Year		
2024	$	—
2025	$	14,508
2026		33,305
Total	$	47,813

9. Stockholders' Equity

July 2023 Underwritten Offering

On July 27, 2023, the Company entered into an underwriting agreement with BofA Securities, Inc., Cowen and Company, LLC and Piper Sandler & Co., as representatives of the several underwriters named therein (collectively, the "Underwriters"), relating to an underwritten public offering of 14,375,000 shares of the Company's common stock, which included 1,875,000 shares issued upon the exercise in full by the underwriters of their option to purchase additional shares (the "July 2023 Shares"). The closing of the offering took place on August 1, 2023. All of the July 2023 Shares were sold by the Company. The offering price of the July 2023 Shares was $4.80 per share. Net proceeds from the sale and issuance of the July 2023 Shares were approximately $64.4 million, after deducting underwriting discounts and commissions and offering expenses.

Open Market Sale Agreement

On August 11, 2021, the Company filed a universal shelf registration statement on Form S-3, which was declared effective on August 23, 2021 (the "Registration Statement"). Under the Registration Statement, the Company 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, the Company entered into an Open Market Sale Agreement with Jefferies LLC, as sales agent, pursuant to which the Company may offer and sell shares of its common stock with an aggregate offering price of up to $50.0 million under an "at-the-market" offering program. As of December 31, 2023, the Company had sold 3,553,995 shares of its common stock pursuant to the Open Market Sale Agreement for aggregate net proceeds of $21.2 million. No shares of the Company's common stock were sold pursuant to the Open Market Sale Agreement during the three months ended March 31, 2024.

Equity Incentive Plans

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.

On February 27, 2023, the Company's board of directors adopted the 2023 Inducement Stock Incentive Plan (the "Inducement Plan"). The Inducement Plan provides for the grant of non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards to persons who (a) were not previously an employee or director or (b) are commencing employment with the Company following a bona fide period of non-employment, in either case, as an inducement material to such person's entry into employment with the Company and in accordance with the requirements of the Nasdaq Stock Market Rule 5635(c)(4).

Stock Options

The Company estimates the fair value of stock options using the Black-Scholes option-pricing model. The underlying assumptions used to value stock options granted to participants using the Black-Scholes option-pricing model were as follows:

	For the Three Months Ended March 31,	
	2024	2023
Risk-free interest rate range	3.78% to 4.22%	3.36% to 4.15%
Dividend yield	—	—
Expected term of options (years)	6.02 to 6.08	5.73 to 6.48
Volatility rate range	88.35% to 88.55%	87.68% to 88.77%

The weighted-average grant date fair value of options granted in the three months ended March 31, 2024 was $4.35 per share. The total unrecognized compensation cost related to outstanding option awards as of March 31, 2024 was $21.6 million and is expected to be recognized over a weighted-average period of 3.09 years.

Restricted Stock Units

The total unrecognized compensation cost related to outstanding RSUs as of March 31, 2024 was $0.4 million and is expected to be recognized over a weighted-average period of 3.0 years.

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

	Three Months Ended March 31,	
	2024	2023
Research and development	$ 849	$ 818
General and administrative	842	1,274
Total	$ 1,691	$ 2,092

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:

	Three Months Ended March 31,	
	2024	2023
Net loss attributable to common stockholders—basic and diluted	$ (23,347)	$ (17,404)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.38)	$ (0.40)
Weighted-average common shares and pre-funded warrants outstanding—basic and diluted	61,772,279	43,720,578

The Company 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 were issuable for little or no consideration, they were considered outstanding for both basic and diluted loss per share from the date of issuance. The Company excluded the following potential shares of common stock, 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 March 31,	
	2024	2023
Options to purchase common stock	9,223,135	5,505,608
Unvested RSUs	100,000	—
Total	9,323,135	5,505,608

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 condensed consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the Securities and Exchange Commission ("SEC") on March 12, 2024. 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 that address pathologic mineralization and intimal proliferation, or smooth muscle cell overgrowth that leads to narrowing and the obstruction of blood vessels, to improve the underlying causes of these debilitating diseases. It is well established that low levels of plasma pyrophosphate ("PPi") drive pathologic mineralization and low levels of adenosine drive intimal proliferation in a number of rare diseases. We are initially focused on developing a novel therapy for diseases characterized by pathologic calcification and intimal proliferation, including ENPP1 Deficiency and ABCC6 Deficiency as well as calciphylaxis.

ENPP1 and ABCC6 Deficiencies are rare chronic, systemic, and progressive genetic diseases occurring over the course of a patient's lifetime, starting as early as fetal development and spanning into adulthood. These diseases represent a significant unmet medical need, with high mortality rates for infants with ENPP1 Deficiency and high levels of morbidity occurring for patients with these diseases throughout their lives. Calciphylaxis is a rare disorder with a high mortality rate that mostly affects patients with end-stage kidney disease ("ESKD"). There are currently no approved therapies for ENPP1 Deficiency, ABCC6 Deficiency, or calciphylaxis. Currently available treatments seek to minimize the manifestations of these diseases and do not address the underlying causes of these diseases.

Our lead product candidate, INZ-701, is a soluble, recombinant, or genetically engineered, fusion protein that is designed to cleave extracellular adenosine triphosphate ("ATP") to generate plasma PPi and adenosine monophosphate ("AMP"), which can be processed to phosphate and adenosine. This process is central to the regulation of calcium deposition throughout the body and is further associated with the inhibition of intimal proliferation. We have generated robust proof of concept data in preclinical models of ENPP1 Deficiency, ABCC6 Deficiency, and in support of our calciphylaxis program, chronic kidney disease ("CKD") demonstrating that INZ-701 prevented pathologic mineralization and skeletal abnormalities, led to improvements in overall health and survival, and prevented intimal proliferation.

We are currently conducting clinical trials of INZ-701 for the treatment of ENPP1 Deficiency, ABCC6 Deficiency, and calciphylaxis. The U.S. Food and Drug Administration, ("FDA"), has granted Orphan Drug Designation and the European Medicines Agency ("EMA"), has granted Orphan 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. Refer to the "Clinical Overview—ENPP1 Deficiency" and "Clinical Overview— ABCC6 Deficiency" sections below for further details on our clinical programs.

Executive Summary

During the three months ended March 31, 2024, we continued to advance our ongoing clinical trials of INZ-701 in patients with ENPP1 Deficiency, ABCC6 Deficiency, and calciphylaxis. Key highlights and accomplishments since the year ended December 31, 2023, as well as upcoming anticipated milestones include:

Key Highlights

- In April 2024, we reported positive topline safety, pharmacokinetic, pharmacodynamic and exploratory efficacy data from the ongoing Phase 1/2 clinical trials of INZ-701 in adults with ENPP1 Deficiency and ABCC6 Deficiency.
- In March 2024, we announced PROPEL, a global patient registry launched in partnership with GACI Global to advance understanding of ENPP1 Deficiency and infantile-onset ABCC6 Deficiency.
- In February 2024, we initiated SEAPORT-1, a Phase 1 clinical trial designed to assess safety, tolerability, pharmacokinetics, and pharmacodynamics of INZ-701 in patients with ESKD receiving hemodialysis.

Select Anticipated Milestones for INZ-701

ENPP1 Deficiency

- We anticipate initiating ENERGY-2, a pivotal trial of INZ-701 in infants with ENPP1 Deficiency outside of the United States, in the second half of 2024.
- We expect to report interim data from the ENERGY-1 trial in the second half of 2024.
- We anticipate reporting topline data from the ENERGY-3 pivotal trial in pediatric patients in mid-2025.

ABCC6 Deficiency

- Subject to regulatory review and sufficient funding, we plan to initiate a pivotal clinical trial of INZ-701 in pediatric patients with ABCC6 Deficiency in the first quarter of 2025.

Calciphylaxis

- We plan to report interim data from SEAPORT-1 in the fourth quarter of 2024.

Clinical Overview

ENPP1 Deficiency

Phase 1/2 Clinical Trial in Adults with ENPP1 Deficiency

In November 2021, we initiated our Phase 1/2 clinical trial of INZ-701 in adult patients with ENPP1 Deficiency. The Phase 1/2 clinical trial of INZ-701 is an open-label, first-in-human, multiple ascending dose trial. The trial is primarily assessing the safety and tolerability of INZ-701 in adult patients with ENPP1 Deficiency, as well as characterizing the pharmacokinetic and pharmacodynamic profile of INZ-701, including evaluation of levels of plasma PPi and other biomarker levels. In the Phase 1 dose-escalation portion of the trial, we assessed 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, with three patients planned per dose cohort. Patients received a single dose and then began twice-weekly dosing one week later. The trial initially enrolled nine patients with ENPP1 Deficiency at sites in North America and Europe. The Phase 1 dose-escalation portion of the trial sought to identify a safe and tolerable dose that increases plasma PPi levels, and that can be used for further clinical development. The Phase 1 dose-escalation portion of the trial is complete. The ongoing open-label Phase 2 portion of the trial is assessing long-term safety, pharmacokinetics, and pharmacodynamics of continued treatment with INZ-701 for up to 48 weeks, where patients may receive doses of INZ-701 at home depending on site-specific protocols. Exploratory endpoints include evaluations of ectopic calcification, skeletal, vascular, and physical function, patient-reported outcomes and exploratory biomarkers.

In April 2022, we announced preliminary biomarker, safety, and pharmacokinetic data from the 0.2 mg/kg cohort of the Phase 1 dose escalation portion 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 PPi levels. Preclinical findings demonstrated plasma PPi being a key predictive biomarker of therapeutic benefit in ENPP1 Deficiency. The range of plasma 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 plasma 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 plasma 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) (1002 nM to 2169 nM). Increased plasma PPi levels observed after dosing of INZ-701 were associated with systemic exposure and activity of INZ-701. Pharmacokinetic analysis showed INZ-701 nearing steady-state by Day 29 with an approximately 4-fold accumulation from Day 1, based on Area under the curve from 0-72 hours ("AUC0-72HRS"). 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 portion of the trial. At week 12, low titers of anti-drug antibodies were observed in two out of three patients in the first cohort. The significantly increased plasma PPi levels observed during the 32-day dose evaluation period were sustained in all three patients through week 12 of the Phase 2 portion of the trial.

In November 2022, we announced the first self-administration of INZ-701 in the open-label Phase 2 portion of the trial.

In February 2023, we reported interim pharmacokinetic, pharmacodynamic, and safety data from this trial. A rapid, significant, and sustained increase in plasma PPi was observed in all dose cohorts and in all patients, with a target plasma PPi threshold observed from the lowest dose of 0.2 mg/kg. Plasma PPi increased in all patients to levels comparable to those observed in a

study of healthy subjects (n=10) (1002 nM and 2169 nM). The mean baseline plasma PPi across all three cohorts in the trial was 426±407 nM.

In February 2023, we also reported patient reported outcome data as measured by global impression of change ("GIC"). The measurement is performed by the clinician ("C-GIC") and the patient ("P-GIC") and assesses overall change in health from baseline on a 7-point scale as measured from "very much worse" (-3) to "very much improved" (+3). GIC is an exploratory endpoint in the trial and an early indicator of potential clinical outcomes. Six of eight patients showed concordant improvements on overall health on C-GIC and P-GIC. Five of eight patients showed "much improved" (+2) or "very much improved" (+3) on P-GIC. No patients showed a deterioration in overall health from baseline on C-GIC or P-GIC.

In the second quarter of 2023, we dosed two patients in a fourth cohort at 1.2 mg/kg to investigate the potential for once-weekly dosing of INZ-701 in the ongoing trial. We completed enrollment of this fourth cohort in the fourth quarter of 2023.

In September 2023, we reported positive interim safety, pharmacokinetic, pharmacodynamic, and exploratory efficacy data from this trial. A rapid, significant, and sustained increase in plasma PPi was observed in all dose cohorts and in all patients, and a significant elevation in plasma PPi was maintained for up to 18 months. INZ-701 activity increased in proportion to dose level and a long half-life of approximately 126 hours, and drug accumulation as shown by a greater-than-dose proportional exposure suggests the potential for once-weekly dosing. Exploratory biomarker data were collected to provide evidence of the potential for disease modification with ongoing treatment with INZ-701. Notable changes in key biomarkers support our clinical hypothesis. Clinical outcome measures were also collected to assess potential clinical benefit with ongoing treatment with INZ-701 and to inform the design and patient selection of future trials. Notable changes in patient reported outcomes and functional outcomes were observed in all cohorts, including concordant improvement in GIC scores reported by patients and clinicians, and no patient showed a deterioration from baseline. INZ-701 was generally well-tolerated and exhibited a favorable safety profile, with no serious or severe adverse events attributed to INZ-701 and no adverse events leading to study withdrawal. Three of the nine patients experienced mild adverse events related to INZ-701 including injection site reactions (bruising or pain) occurring in two of nine patients, and other mild adverse events including decreased appetite and fatigue. There were two serious adverse events not related to INZ-701. INZ-701 exhibited a favorable immunogenicity profile with low titers of non-neutralizing anti-drug antibodies observed in seven of the nine patients. All nine patients enrolled in the Phase 2 portion of the trial, and two of them subsequently withdrew for personal reasons not related to adverse events. The anti-drug antibody levels were transient in three of seven patients.

In April 2024, we reported positive topline safety, pharmacokinetic, pharmacodynamic, and exploratory efficacy data from this trial. Notable changes from baseline in key biomarkers were observed and support our clinical hypothesis. Significant reductions of fibroblast growth factor-23, increases in bone specific alkaline phosphatase levels, and decreases in c-telopeptide were observed in the 1.8 mg/kg dose cohort (Cohort 3) through week 48, which indicates the restoration of proper bone mineralization. Favorable responses on the Patient-Reported Outcome Measurement Information Scales of Pain Intensity, Fatigue and Pain Interference, and P-GIC were maintained. Data from the once-weekly dose cohort showed a sustained increase in plasma PPi levels comparable to those observed in our study of healthy subjects (n=10). INZ-701 was generally well-tolerated and exhibited a favorable safety profile, with no serious or severe adverse events ("AEs") attributed to INZ-701 and no AEs leading to study withdrawal. 11 patients remain in the trial, and 10 self-administer INZ-701 treatment. Time on study ranged from 22 to over 742 days. Total time on treatment across all dose cohorts corresponds to approximately 12+ patient-years. INZ-701 exhibited a favorable immunogenicity profile with low titers of non-neutralizing anti-drug antibodies ("ADA") observed in 11 of 14 patients. The ADA levels were transient in three of 11 patients. Plasma PPi levels observed after INZ-701 administration are shown in the table below:

			Mean Plasma PPi (nM) ± SEM		
			Cohort 1 (0.2 mg/kg)	Cohort 2 (0.6 mg/kg)	Cohort 3 (1.8 mg/kg)
Phase 1	**Single Dose**	**Day 1-8**	1229±87	1438±146	1220±87
	2x/Week Dose	**Day 11-32**	1494±111	1745±170	1352±71
Phase 2	**2x/Week Dose**	**Day 32-672**	1118±93	1316±116	1598±322

Cohort 1 – n=2 post day 84; Cohort 2 n=2 post day 336; Cohort 3 n=2 post day 252

ENERGY-1 Clinical Trial in Infants with ENPP1 Deficiency

In June 2023, we dosed the first infant patient in our Phase 1b, single arm, open-label clinical trial of INZ-701 (the "ENERGY-1 trial"), designed primarily to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics of INZ-701 in infants with ENPP1 Deficiency. The ENERGY-1 trial is expected to enroll up to eight infants between the ages of 1 and 12 months across multiple sites in the United States and Europe. Patients will receive subcutaneous doses of INZ-701 during the treatment period of 52 weeks and may continue to receive INZ-701 in an extension period beyond 52 weeks. Doses range from 0.2 mg/kg once weekly through 0.6 mg/kg twice weekly, with the ability to increase the dose further depending on the results of pharmacokinetics, pharmacodynamics, and safety data. Other outcome measures include evaluation of plasma PPi levels, survival, growth, development, functional performance, cardiac function, and exploratory biomarkers. We expect to report interim data from the ENERGY-1 trial in the second half of 2024.

Global Development Strategy of INZ-701 for the Treatment of ENPP1 Deficiency

We initiated pivotal trial meetings with the FDA in the first quarter of 2023. In July 2023, we announced a regulatory update for our global development strategy of INZ-701 for the treatment of ENPP1 Deficiency following meetings with the FDA and the Paediatric Committee of the EMA ("PDCO"). Also in July 2023, we completed a scientific advice procedure and reached alignment with the Committee for Medicinal Products for Human Use ("CHMP") regarding our global development strategy.

We plan to conduct pivotal clinical trials of INZ-701 designed to support registration in infant, pediatric, and adult patient populations with ENPP1 Deficiency. Many companies pursuing marketing approval for enzyme replacement therapies in rare diseases have followed a similar clinical development strategy.

We anticipate initiating the ENERGY-2 trial, an open label, single arm, pivotal trial of INZ-701 in infants with ENPP1 Deficiency, outside of the United States in the second half of 2024. The trial's co-primary endpoints will be change in plasma PPi from baseline and survival. The trial is expected to enroll up to 12 infants between birth and up to 12 months of age. Primary endpoint data from this trial will be compared to a natural history control group with patients matched on covariates associated with mortality.

We have reached agreement with the EMA on a Paediatric Investigational Plan for a pivotal trial of INZ-701 in pediatric patients with ENPP1 Deficiency. We have shared the design for a global pivotal clinical trial of INZ-701 in pediatric patients with ENPP1 Deficiency (the "ENERGY-3 trial"). In September 2023, we opened the first site for our pivotal trial of INZ-701 in pediatric patients with ENPP1 Deficiency (the "ENERGY-3 trial"). The ENERGY-3 trial is a multicenter, randomized, open label trial expected to enroll up to 33 patients between the ages of one and less than 13 years across multiple sites globally. The trial is designed primarily to assess the efficacy and safety of INZ-701 in pediatric patients with ENPP1 Deficiency. Enrollment criteria for the trial include a confirmed genetic diagnosis of ENPP1 Deficiency, radiographic evidence of skeletal abnormalities and low plasma PPi. Patients will be randomized in a 2:1 ratio to an INZ-701 arm or a control arm (conventional therapy, which is oral phosphate and active vitamin D) for 52 weeks, followed by an open label extension period during which all patients may receive INZ-701. INZ-701 will be administered at a 2.4 mg/kg once weekly dose via subcutaneous injection.

ENERGY-3 is a single, multicenter, clinical trial with differences in the statistical treatment of endpoints, based on guidance from the FDA and PDCO. In the United States, the primary endpoint is change in plasma PPi from baseline, and the secondary endpoints are Radiographic Global Impression of Change ("RGI-C") score, Rickets Severity Score ("RSS"), Growth Z-score and pharmacokinetics. Based on recommendations from the FDA, the primary endpoint of plasma PPi should be supported by consistent trends in appropriate secondary endpoints. In the European Union, the primary endpoint is change in plasma PPi from baseline and RGI-C score ($p<0.2$), and the secondary endpoints are RSS, Growth-Z score and pharmacokinetics. Based on the agreed Paediatric Investigational Plan with PDCO, plasma PPi and RGI-C are co-primary endpoints, with a relaxed p-value of <0.2 for RGI-C. Patient recruitment is underway in the ENERGY-3 trial, with the Company incurring a $0.5 million milestone payment following completion of dosing of the first patient in the Company's pivotal clinical trial of INZ-701 in pediatric patients with ENPP1 Deficiency. We anticipate reporting topline data from the ENERGY-3 trial in mid-2025. Subject to regulatory review and sufficient funding, we also intend to treat ENPP1-deficient patients ineligible for ENERGY-3 or other ongoing studies to further our understanding of INZ-701's safety and efficacy.

Pending appropriate financial resources, we also plan to conduct a pivotal trial in adolescents and adults with ENPP1 Deficiency.

Basis for Planned Marketing Applications

Based on regulatory feedback from the FDA and EMA, positive data from the ongoing and planned clinical trials of INZ-701 in patients with ENPP1 Deficiency, including comprehensive data demonstrating clinical impact of plasma PPi, could provide the basis for our submission of marketing applications in both the United States and the European Union. These data will include final

results from our ongoing Phase 1/2 trial in adult patients with ENPP1 Deficiency, available results from our ongoing ENERGY-1 trial, available results from the planned pivotal ENERGY-2 trial in infants to be initiated outside of the United States, and final results from the ongoing pivotal ENERGY-3 trial in pediatric patients.

If these marketing applications are approved, we expect to commercially launch INZ-701 for infant and pediatric patients as early as the second half of 2026. Data from the planned ENERGY-4 trial in adolescent and adult patients with ENPP1 Deficiency may provide a basis for a supplemental marketing application.

ABCC6 Deficiency

In April 2022, we initiated our Phase 1/2 clinical trial of INZ-701 in adult patients with ABCC6 Deficiency. The Phase 1/2 clinical trial of INZ-701 is an open-label multiple ascending dose trial, which initially enrolled nine adult patients at sites in the United States and Europe. The trial is primarily assessing the safety and tolerability of INZ-701 in adult patients with ABCC6 Deficiency, as well as characterizing the pharmacokinetic and pharmacodynamic profile of INZ-701, including the evaluation of levels of plasma PPi and other biomarker levels. In the Phase 1 dose-escalation portion of the clinical trial, we assessed 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, with three patients per dose cohort, which doses were selected based on preclinical studies and pharmacokinetic/pharmacodynamic modeling. Patients received a single dose and then began twice-weekly dosing one week later. The Phase 1 dose-escalation portion of the trial sought to identify a safe and tolerable dose that increases plasma PPi levels for further clinical development. The open-label Phase 2 portion of the trial will assess long-term safety, pharmacokinetics, and pharmacodynamics of continued treatment with INZ-701 for up to 48 weeks, where patients may receive doses of INZ-701 at home depending on site-specific protocols. Exploratory endpoints will include evaluations of ectopic calcification, vascular and retinal function, patient reported outcomes, and exploratory biomarkers.

Beginning in January 2023, self-administration of INZ-701 in the open-label Phase 2 portion of the trial was available.

In February 2023, we reported interim pharmacokinetic, pharmacodynamic, and safety data from this trial. A rapid, significant, and sustained increase in plasma PPi was observed in all cohorts with a dose response observed. Plasma PPi showed sustained increase in the highest dose cohort to levels comparable to those observed in our study of healthy subjects (n=10) (1002 nM to 2169 nM). Mean baseline plasma PPi across all three cohorts in the trial was 947±193 nM.

In September 2023, we reported positive interim safety, pharmacokinetic, pharmacodynamic, and exploratory efficacy data from this trial. A dose-dependent response in plasma PPi levels was observed, with a sustained increase in the highest dose cohort to levels comparable to those observed in our study of healthy subjects. INZ-701 activity in a greater-than-dose proportional manner was observed, and drug accumulation as shown by a greater-than-dose proportional exposure suggests the potential for once weekly dosing. Clinical outcome measures were collected to provide evidence of clinical benefit and to inform the design of future trials in adults. All patients showed improvements on clinician-reported GIC scores and seven of the nine patients showed improvement from baseline on patient-reported GIC scores at the last follow-up. INZ-701 was generally well-tolerated and exhibited a favorable safety profile, with no serious or severe adverse events attributed to INZ-701. Seven of the 10 patients experienced adverse events related to INZ-701 (including mild injection site reactions (discoloration, erythema, induration, pain, or pruritus) occurring in seven of the 10 patients and other adverse events included erythema, fatigue, night sweats, and urticaria). All adverse events were mild to moderate in severity. One patient withdrew from the trial during the Phase 2 portion for personal reasons not related to an adverse event. INZ-701 exhibited a favorable immunogenicity profile with low titers of non-neutralizing anti-drug antibodies observed in eight of the 10 patients. The anti-drug antibody levels were transient in three out of eight patients.

In April 2024, we reported positive topline safety, pharmacokinetic, pharmacodynamic, and exploratory efficacy data from this trial. Exploratory markers of clinical benefit were collected throughout the trial to provide evidence of the potential for disease modification with ongoing INZ-701 treatment. Reduction or stabilization of carotid intima-media thickness was observed across all dose cohorts (seven of eight evaluable patients), indicating a potential beneficial effect of INZ-701 on vascular pathology. Increased choroidal thickness was observed across all dose cohorts (seven of eight evaluable patients), which indicated a potential beneficial effect of INZ-701 on retinal disease. Four of six evaluable patients with Global Visual Function Questionnaire ("VFQ-25") scores below normal at baseline improved over 48 weeks. Improvement in visual function was greater in older patients. A correlation between improvements in VFQ-25 and increases in choroidal thickness was preserved after 48 weeks. All evaluable patients (nine of nine) showed improvement from baseline on C-GIC, and seven of nine evaluable patients showed improvement from baseline on P-GIC. The rapid increase in plasma PPi levels observed at the 1.8 mg/kg dose level (Cohort 3) was sustained to levels comparable to those observed in our study of healthy subjects (n=10). INZ-701 was generally well tolerated and exhibited a favorable safety profile, with no serious or severe AEs. All AEs were mild to moderate in severity. Eight patients remain in the trial, and seven self-administer INZ-701 treatment. Time on study ranged from 45 to over 631 days, and total time on treatment across all cohorts corresponds to approximately 12+ patient-years. INZ-701 exhibited a favorable immunogenicity profile with low titers of non-neutralizing ADAs observed in eight of 10 patients. The ADA levels were transient in three of eight patients. Plasma PPi levels observed after INZ-701 administration are shown in the table below:

			Mean Plasma PPi (nM) ± SEM		
			Cohort 1 (0.2 mg/kg)	Cohort 2 (0.6 mg/kg)	Cohort 3 (1.8 mg/kg)
Phase 1	**Single Dose**	**Day 1-8**	1087±162	1326±67	1540±169
	2x/Week Dose	**Day 11-32**	1023±99	1119±48	1312±122
Phase 2	**2x/Week Dose**	**Day 32-588**	1018±73	931±87	1613±188

Cohort 1 n=2 post day 504; Cohort 2 n=3; Cohort 3 n=2 post day 84

Subject to regulatory review and sufficient funding, we plan to initiate a pivotal clinical trial of INZ-701 in pediatric patients with ABCC6 Deficiency in the first quarter of 2025 for registrational purposes. Prior to initiating this pivotal clinical trial, we plan to engage with the regulatory authorities in the United States, Europe, and other jurisdictions to determine appropriate primary efficacy endpoints and other requirements for potential marketing approval. In particular, if we propose new or novel endpoints or methodologies for our clinical trials, regulatory authorities will ultimately need to conclude that the endpoints of our clinical trials have provided clinically meaningful results before we are able to obtain potential marketing approval. Given the high risk of cerebrovascular disease in the pediatric population, we believe that endpoints predictive of ischemic stroke (for example, progression of cerebral vasculopathy) may provide a suitable basis for accelerated approval in the United States and conditional marketing authorization in the European Union of INZ-701 in children with ABCC6 Deficiency. Results from the Phase 1/2 clinical trial have provided evidence of the restoration of plasma PPi levels and informed the design of our planned pivotal clinical trial. Our clinical strategy, subject to ongoing discussions with the regulatory authorities in the United States, Europe, and other jurisdictions, is to pursue registration of INZ-701 for ABCC6 Deficiency by linking the restoration of plasma PPi levels to measures of physiological and clinical efficacy in this patient population.

Clinical Development Plan for Calciphylaxis

In February 2024, we initiated SEAPORT-1, a Phase 1 clinical trial designed to assess safety, tolerability, pharmacokinetics, and pharmacodynamics of INZ-701 in up to 10 patients with ESKD receiving hemodialysis. Patients will receive 1.8 mg/kg of INZ-701 once weekly coinciding with their hemodialysis treatment for a total of 30 days. The trial's primary endpoint will assess safety and change from baseline plasma PPi concentration, with secondary endpoints including pharmacokinetic and pharmacodynamic parameters. We plan to report interim data from SEAPORT-1 in the fourth quarter of 2024 and expect data from this trial to inform our study design for patients with calciphylaxis in the future.

Expanded Access Program

In February 2023, we dosed our first pediatric patient with ENPP1 Deficiency with INZ-701 under our expanded access program. Under our expanded access program, we can use INZ-701 outside of our clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options and when other criteria are met. Other criteria include, but are not limited to, lack of success from standard treatments, ineligibility for participation in any ongoing clinical trial of INZ-701 (including lack of access due to geographic limitations), and having a disease for which there is sufficient evidence of a projected benefit from the use of INZ-701. We expect that data collected from patients treated under our expanded access program will provide further support for the potential safety and clinical benefits of INZ-701.

Future Development Plans; Other Potential Indications for INZ-701

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.

Based on its mechanism of action, we believe that INZ-701 has the potential to increase plasma PPi levels and provide therapeutic benefit to patients beyond those with monogenic defects in the ENPP1 or ABCC6 gene. We intend to explore the potential of INZ-701 as a therapy in other, non-genetic diseases of pathologic mineralization associated with low levels of plasma PPi.

Diseases of intimal proliferation include diseases without a clear genetic basis. In preclinical studies, INZ-701 prevented intimal proliferation in both wild-type and Enpp1-deficient mice, which we believe is attributable to increased levels of adenosine. We plan to continue to explore the potential of INZ-701 in non-genetic diseases in which arteries have been damaged or disrupted by insertion of a stent, bypass graft occlusion, transplant vasculopathy, or inflammation known as arteritis.

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, conducting preclinical studies and early-stage clinical trials, establishing arrangements for the manufacture of INZ-701, and longer-term planning for potential commercialization.

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.

We expect to continue to incur significant operating expenses for the foreseeable future. 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 and security agreement with K2 HealthVentures LLC (the "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.

Based on our current operating plan, we believe that our existing cash, cash equivalents, and short-term investments as of March 31, 2024 will enable us to fund our cash flow requirements into the fourth quarter of 2025. We 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 adults with ENPP1 and ABCC6 Deficiencies, our ongoing Phase 1b clinical trial of INZ-701 for infants with ENPP1 Deficiency, our ongoing pivotal trial of INZ-701 in pediatrics with ENPP1 Deficiency, and our ongoing Phase 1 clinical trial of INZ-701 in patients with ESKD receiving hemodialysis;
- prepare for, initiate, and conduct our planned clinical trials of INZ-701 for patients with ENPP1 and ABCC6 Deficiencies, including our planned pivotal clinical trials of INZ-701 for infants, and in adolescents and adults with ENPP1 Deficiency, and our planned pivotal clinical trial of INZ-701 for pediatric patients with ABCC6 Deficiency;
- conduct research, preclinical testing, and clinical trials of INZ-701 for additional indications;
- conduct research, preclinical testing, and clinical trials of other product candidates;
- engage in regulatory interactions with the FDA, the EMA, and other regulatory authorities;
- submit regulatory filings and 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 ("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, scientific, and commercial personnel;
- 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; and
- make any principal and interest payments when due under the terms of the Loan Agreement.

Financial Operations Overview

Research and Development Expenses

Research and development activities are central to our business model. Research and development costs consist of direct and indirect costs related to specific projects as well as fees paid to other entities that conduct certain research and development activities on our behalf and primarily relate to 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 ("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 clinical trials;
- manufacturing scale-up expenses and the costs of acquiring and manufacturing preclinical trial materials, including manufacturing validation batches;
- personnel-related expenses, consisting primarily of salaries, related benefits, and stock-based compensation expense for employees engaged in research and development functions;
- the costs and acquisition of laboratory supplies, and developing preclinical studies and clinical trial materials;
- costs related to compliance with regulatory requirements; and
- an allocation of facilities costs, which include depreciation of equipment, and expenses for rent, information technology, 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. We do not currently track research and development expenses by specific indication.

We are currently conducting our Phase 1/2 clinical trials of INZ-701 for adults with ENPP1 Deficiency and ABCC6 Deficiency, our Phase 1b ENERGY-1 trial for infants with ENPP1 Deficiency, our pivotal ENERGY-3 trial of INZ-701 for pediatric patients with ENPP1 Deficiency, and our Phase 1 SEAPORT-1 clinical trial of INZ-701 for up to 10 patients with ESKD receiving hemodialysis. 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. We expect that our research and development expenses will continue to increase substantially for the foreseeable future as we execute on our global development strategy, prepare for and conduct the ongoing and planned clinical trials of INZ-701, further scale our manufacturing processes, advance development of INZ-701 for additional indications, and potentially develop additional product candidates.

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 an allocation of facilities and information technology infrastructure costs. 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. Additionally, we may experience an increase in payroll and expense as a result of our preparation for potential commercial operations, especially related to sales and marketing costs. We expect that our general and administrative expenses will increase in future periods as we expand our operations and execute on our global development strategy.

Interest Income

Interest income consists of income from bank deposits and investments.

Interest Expense

Interest expense consists of interest expense related to our Loan Agreement, as well as amortization of debt discount and debt issuance costs.

Other Expense, net

Other expense, net primarily consists of realized gains and losses on marketable securities and foreign exchange gains or losses.

Results of Operations

Comparison of the Three Months Ended March 31, 2024 and 2023

The following table summarizes our results of operations for the three months ended March 31, 2024 and 2023 (in thousands):

	Three Months Ended March 31,		
	2024	2023	Change
Operating expenses:			
Research and development	$ 19,111	$ 11,857	$ 7,254
General and administrative	5,234	6,512	(1,278)
Total operating expenses	24,345	18,369	5,976
Loss from operations	(24,345)	(18,369)	5,976
Other income (expense):			
Interest income	2,374	1,327	1,047
Interest expense	(1,325)	(328)	(997)
Other expense, net	(51)	(34)	(17)
Other income (expense), net	998	965	33
Net loss	$ (23,347)	$ (17,404)	$ 5,943

Research and Development Expense

The following table summarizes our research and development expense for the three months ended March 31, 2024 and 2023 (in thousands):

	Three Months Ended March 31,		
	2024	2023	Change
INZ-701-related research and development expense	$ 13,105	$ 6,919	$ 6,186
Unallocated expenses:			
Personnel-related expense (including stock-based compensation)	5,210	4,135	1,075
Facilities and administrative expense	796	803	(7)
Total	19,111	11,857	7,254

Research and development expense increased $7.3 million for the three months ended March 31, 2024 compared to the three months ended March 31, 2023 primarily due to a $6.2 million increase in INZ-701-related research and development expense.

INZ-701-related research and development expense increased $6.2 million primarily due to a $2.7 million increase in chemistry, manufacturing, and controls expense to support our ongoing clinical trials and prepare for potential commercialization and a $2.6 million increase in clinical development and related consulting costs to support our ongoing clinical trials.

General and Administrative Expense

General and administrative expense decreased $1.3 million for the three months ended March 31, 2024 primarily due to $1.4 million recorded in the three months ended March 31, 2023 for the transition and separation agreement entered into with our former chief executive officer.

Interest Income

Interest income for the three months ended March 31, 2024 increased approximately $1.0 million compared to the three months ended March 31, 2023 due to higher interest rates and a larger cash balance on which we are earning interest in 2024.

Interest Expense

Interest expense increased $1.0 million for the three months ended March 31, 2024 compared to the three months ended March 31, 2023 primarily due to additional borrowings in February, June, and December of 2023 under our Loan Agreement.

Other Expense, net

Other expense, net remained relatively flat for the three months ended March 31, 2024 compared to the three months ended March 31, 2023.

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. 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.

On August 11, 2021, we filed a universal shelf registration statement on Form S-3 (the "2021 Registration Statement"), which was declared effective on August 23, 2021. Under the 2021 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 2021 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. As of December 31, 2023, we had sold 3,553,995 shares of our common stock pursuant to the Open Market Sale Agreement for aggregate net proceeds of $21.2 million. No sales of shares of our common stock were made pursuant to the Open Market Sale Agreement during the three months ended March 31, 2024.

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 2021 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 the Loan Agreement with K2 HealthVentures LLC (together with any other lender from time to time, "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 of which the remaining $20.0 million was funded at our election in February 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, financial, clinical, and regulatory milestones relating to INZ-701 of which $7.5 million was funded at our election in June 2023 and the remaining $12.5 million was funded at our election in December 2023, and (iii) a fourth tranche commitment of $25.0 million is available to be drawn at our option through August 31, 2025, subject to use of proceeds limitations and Lenders' consent in its discretion. We have an aggregate of $45.0 million principal in term loans outstanding. The Lenders may elect to purchase up to $5.0 million of shares of our common stock pursuant to the Loan Agreement. Additional information on the Loan Agreement is described in Note 8 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

In August 2023, we closed an underwritten offering in which we sold 14,375,000 shares of common stock under the 2021 Registration Statement. Net proceeds from the offering were approximately $64.4 million, after deducting underwriting discounts and commissions and estimated offering expenses.

On November 7, 2023, we filed a universal shelf registration statement on Form S-3 (the "2023 Registration Statement"), which was declared effective on November 15, 2023. Under the 2023 Registration Statement, we may offer and sell up to $300.0 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.

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 March 31, 2024 and December 31, 2023 (in thousands):

	March 31, 2024	December 31, 2023
Cash and cash equivalents	$ 20,618	$ 34,588
Short-term investments	145,535	$ 154,001
Total cash, cash equivalents, and short-term investments	$ 166,153	$ 188,589

Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2024 and 2023 (in thousands):

	Three Months Ended March 31,	
	2024	2023
Net cash used in operating activities	$ (24,533)	$ (17,772)
Net cash provided by investing activities	10,394	13,766
Net cash provided by financing activities	159	20,096
Net (decrease) increase in cash, cash equivalents, and restricted cash	$ (13,980)	$ 16,090

Net Cash Used in Operating Activities

Net cash used in operating activities increased approximately $6.8 million in the three months ended March 31, 2024 compared to the three months ended March 31, 2023 primarily due to a $7.5 million increase in our net loss adjusted for non-cash items, which was partially offset by approximately $0.8 million of changes in operating assets and liabilities.

Net Cash Provided by Investing Activities

Net cash provided by investing activities decreased approximately $3.4 million for the three months ended March 31, 2024 compared to the three months ended March 31, 2023, primarily due to a $3.3 million increase in purchases of marketable securities in the three months ended March 31, 2024.

Net Cash Provided by Financing Activities

Net cash provided by financing activities decreased $19.9 million for the three months ended March 31, 2024, as the three months ended March 31, 2023 included $20.0 million in net proceeds received from the issuance of long-term debt.

Funding Requirements

We expect to devote substantial financial resources toward our ongoing and planned activities, particularly as we execute on our global development strategy, conduct our ongoing clinical trials of INZ-701 for ENPP1 Deficiency, ABCC6 Deficiency, and calciphylaxis, and continue research and development and initiate additional planned clinical trials of, and seek marketing approval for, INZ-701 and any other product candidates we develop. We expect our expenses to increase substantially in connection with our ongoing and planned activities. 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.

Debt financing and 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 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.

Based on our current operating plan, we believe that our existing cash, cash equivalents, and short-term investments as of March 31, 2024 will enable us to fund our cash flow requirements into the fourth quarter of 2025. 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 or 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.

Contractual Obligations, Commitments and Contingencies

During the three months ended March 31, 2024, there were no material changes to our contractual obligations and commitments from those described in Part II, 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, 2023.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these condensed 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 condensed consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. During the three months ended March 31, 2024, there were no material changes to our critical accounting estimates from those described in Part II, 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, 2023.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012 permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to use the extended transition period for complying with new or revised accounting standards and will do so until such time that we either (1) irrevocably elect to "opt out" of such extended transition period or (2) no longer qualify as an emerging growth company.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of March 31, 2024, our cash equivalents consisted of short-term money market funds and U.S. government agency debt securities. As of March 31, 2024, our short-term investments consisted of U.S. Treasury securities and U.S. government agency debt 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 short-term nature of the investments in our portfolio and the low risk profile of our investments, an immediate change of 100 basis points in interest rates would not have a material effect on the fair market value of our investment portfolio or on our financial position or results of operations.

As of March 31, 2024, the aggregate principal amount outstanding under the Loan Agreement was $45.0 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%. Of the $45.0 million aggregate principal amount outstanding, $5.0 million was funded at closing, and we borrowed an additional $20.0 million in February 2023, $7.5 million in June 2023, and $12.5 million in December 2023 under the Loan Agreement. The interest rate as of March 31, 2024 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 the three months ended March 31, 2024 and 2023.

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 March 31, 2024. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2024, 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.

In addition to all of the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors discussed in Part I, Item 1A, “Risk Factors” in our Annual Report on Form 10–K for the year ended December 31, 2023, 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, 2023 is qualified by the information that is described in this Quarterly Report on Form 10-Q. The risks described in our Annual Report on Form 10–K for the year ended December 31, 2023 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.

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 (the "Securities Act"), during the three months ended March 31, 2024.

Item 5. Other Information.

(c) Director and Officer Trading Arrangements

None of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) during the three months ended March 31, 2024.

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 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-39397) filed with the Securities and Exchange Commission on June 14, 2023).
10.1†	Corporate Sponsored Research Agreement, dated January 6, 2017, by and between Yale University and the Registrant, as amended by Amendment No. 1 to Corporate Sponsored Research Agreement, dated February 19, 2019, by and between Yale University and the Registrant, as amended by Amendment No. 2 to Corporate Sponsored Research Agreement, effective December 31, 2021, by and between Yale University and the Registrant and as amended by Amendment No. 3 to Corporate Sponsored Research Agreement, dated May 31, 2022, by and between Yale University and the Registrant and as amended by Amendment No. 4 to Corporate Sponsored Research Agreement, dated March 24, 2023, by and between Yale University and the Registrant, and as amended by Amendment No. 5 to Corporate Sponsored Research Agreement, dated January 24, 2024, by and between Yale University and the Registrant (incorporated by reference to Exhibit 10.11 to the Registrant's Annual Report on Form 10-K (File No. 001-39397) filed with the Securities and Exchange Commission on March 12, 2024).
10.2*	Summary of Non-Employee Director Compensation Policy.
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: May 7, 2024

By: /s/ Douglas A. Treco

Douglas A. Treco
Chief Executive Officer
(Principal Executive Officer)

Date: May 7, 2024

By: /s/ Sanjay S. Subramanian

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

Exhibit 10.2

INOZYME PHARMA, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

The Company's non-employee directors shall receive the following compensation for their service as members of the Board of Directors (the "Board") of Inozyme Pharma, Inc. (the "Company").

Director Compensation

Our goal is to provide compensation for our non-employee directors in a manner that enables us to attract and retain outstanding director candidates and reflects the substantial time commitment necessary to oversee the Company's affairs. We also seek to align the interests of our directors and our stockholders and we have chosen to do so by compensating our non-employee directors with a mix of cash and equity-based compensation.

Cash Compensation

The fees that will be paid to our non-employee directors for service on the Board, and for service on each committee of the Board on which the director is then a member, and the fees that will be paid to the chairman of the Board and the lead independent director, if one is then appointed, and the chairman of each committee of the Board will be as follows:

	Member Annual Fee	Chair Incremental Annual Fee	Lead Independent Director Incremental Annual Fee
Board of Directors	$ 40,000	$ 30,000	$ 20,000
Audit Committee	$ 7,500	$ 7,500	—
Compensation Committee	$ 5,000	$ 5,000	—
Nominating and Corporate Governance Committee	$ 4,000	$ 4,000	—
Research and Development Committee	$ 4,000	$ 4,000	—

The foregoing fees will be payable in arrears in four equal quarterly installments on the last day of each quarter, provided that the amount of such payment will be prorated for any portion of such quarter that the director is not serving on the Board, on such committee or in such position.

Equity Compensation

Initial Grants. Upon initial election to the Board, each non-employee director will be granted, automatically and without the need for any further action by the Board, an initial equity award of an option to purchase 56,000 shares of our common stock. The initial award shall have a term of ten years from the grant date of the award, and shall vest and become exercisable as to 2.7778% of the shares underlying such award at the end of each successive one-month period following the grant date until the third anniversary of the grant date, subject to the director's continued service to the Company as a director through each applicable vesting date. The vesting shall accelerate as to 100% of the shares upon a change in control of the Company. The exercise price shall be the closing price of our common stock on the date of grant.

Annual Grants. Each non-employee director who has served as a member of the Board for at least six months prior to the date of our annual meeting of stockholders for a particular year will be granted, automatically and without the need for any further action by the Board, an equity award on the date of the first Board meeting held after our annual meeting of stockholders for such year of an option to purchase 28,000 shares of our common stock. The annual award shall have a term of ten years from the grant date of the award, and shall vest and become exercisable in full on the one-year anniversary of the grant date (or, if earlier, immediately prior to the first annual meeting of stockholders occurring after the grant date), subject to the director's continued service to the Company as a director through each

applicable vesting date. The vesting shall accelerate as to 100% of the shares upon a change in control of the Company. The exercise price shall be the closing price of our common stock on the date of grant.

The foregoing share amounts shall be automatically adjusted in the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event effecting our common stock, or any distribution to holders of our common stock other than an ordinary cash dividend.

The initial awards and the annual awards shall be subject to the terms and conditions of our 2020 Stock Incentive Plan, or any successor plan, and the terms of the option agreements entered into with each director in connection with such awards.

Expenses

Upon presentation of documentation of such expenses reasonably satisfactory to the Company, each non-employee director shall be reimbursed for his or her reasonable out-of-pocket business expenses incurred in connection with attending meetings of the Board and committees thereof or in connection with other business related to the Board, and each non-employee director shall also be reimbursed for his or her reasonable out-of-pocket business expenses authorized by the Board or a committee of the Board that are incurred in connection with attendance at various conferences or meetings with management of the Company, in accordance with the Company's travel policy, as it may be in effect from time to time.

***

Last Amended: March 21, 2024

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, Douglas A. Treco, 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: May 7, 2024

By: /s/ Douglas A. Treco

Douglas A. Treco
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 S. 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: May 7, 2024

By: /s/ Sanjay S. Subramanian

Sanjay S. 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 March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Date: May 7, 2024

By: /s/ Douglas A. Treco

Douglas A. Treco
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 March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Date: May 7, 2024

By: /s/ Sanjay S. Subramanian

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