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 June 30, 2023

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 August 3, 2023, the registrant had 61,729,666 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 and our ongoing Phase 1b clinical trial of INZ-701 for infants with ENPP1 Deficiency (the ENERGY-1 trial), 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 trial), pediatrics (ENERGY-3 trial), and adolescents and adults (ENERGY-4 trial) with ENPP1 Deficiency;
- our plans to conduct research, preclinical testing and clinical testing of INZ-701 for additional indications;
- our plans to conduct research, preclinical testing and clinical testing 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)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 40,845	$ 32,915
Short-term investments	99,402	94,951
Prepaid expenses and other current assets	3,341	3,527
Total current assets	143,588	131,393
Property and equipment, net	1,788	2,018
Restricted cash	311	354
Right-of-use assets	1,381	1,620
Prepaid expenses, net of current portion	3,861	3,810
Total assets	$ 150,929	$ 139,195
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,014	$ 2,544
Accrued expenses	9,205	11,355
Operating lease liabilities	862	816
Total current liabilities	12,081	14,715
Operating lease liabilities, net of current portion	1,378	1,823
Long-term debt, net	31,877	4,139
Other long-term liabilities	—	124
Total liabilities	45,336	20,801
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred Stock, $0.0001 par value – 5,000,000 shares authorized at June 30, 2023 and December 31, 2022; no shares issued and outstanding at June 30, 2023 or December 31, 2022	—	—
Common Stock, $0.0001 par value – 200,000,000 shares authorized at June 30, 2023 and December 31, 2022; 46,379,088 shares issued and outstanding at June 30, 2023 and 40,394,363 shares issued and outstanding at December 31, 2022	5	4
Additional paid in-capital	353,285	333,356
Accumulated other comprehensive income (loss)	51	(205)
Accumulated deficit	(247,748)	(214,761)
Total stockholders' equity	105,593	118,394
Total liabilities and stockholders' equity	$ 150,929	$ 139,195

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 11,666	$ 10,007	$ 23,523	$ 21,821
General and administrative	4,728	5,384	11,240	10,409
Total operating expenses	16,394	15,391	34,763	32,230
Loss from operations	(16,394)	(15,391)	(34,763)	(32,230)
Other income (expense):				
Interest income, net	839	321	1,838	381
Other expense, net	(28)	(191)	(62)	(296)
Other income, net	811	130	1,776	85
Net loss	$ (15,583)	$ (15,261)	$ (32,987)	$ (32,145)
Other comprehensive income (loss):				
Unrealized gains (losses) on available-for-sale securities	76	(225)	226	(357)
Foreign currency translation adjustment	11	(43)	30	(58)
Total other comprehensive income (loss)	87	(268)	256	(415)
Comprehensive loss	$ (15,496)	$ (15,529)	$ (32,731)	$ (32,560)
Net loss attributable to common stockholders—basic and diluted	$ (15,583)	$ (15,261)	$ (32,987)	$ (32,145)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.35)	$ (0.38)	$ (0.74)	$ (1.01)
Weighted-average common shares and pre-funded warrants outstanding—basic and diluted	44,860,279	39,703,550	44,293,577	31,739,197

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
	Shares	Amount				
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
Other comprehensive income (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
Stock-based compensation	—	—	1,600	—	—	1,600
Shares issued in at-the-market offering	2,591,995	1	16,086	—	—	16,087
Exercise of stock options	21,608	—	55	—	—	55
Other comprehensive income (loss):						
Unrealized gain on investments	—	—	—	76	—	76
Foreign currency translation adjustment	—	—	—	11	—	11
Net loss	—	—	—	—	(15,583)	(15,583)
Balance at June 30, 2023	46,379,088	$ 5	$ 353,285	$ 51	$ (247,748)	$ 105,593
Balance at December 31, 2021	23,668,747	$ 2	$ 256,948	$ 18	$ (147,700)	$ 109,268
Stock-based compensation	—	—	1,752	—	—	1,752
Exercise of stock options	149,664	—	240	—	—	240
Other comprehensive loss:						
Unrealized loss on investments	—	—	—	(132)	—	(132)
Foreign currency translation adjustment	—	—	—	(15)	—	(15)
Net loss	—	—	—	—	(16,884)	(16,884)
Balance at March 31, 2022	23,818,411	$ 2	$ 258,940	$ (129)	$ (164,584)	$ 94,229
Stock-based compensation	—	—	2,185	—	—	2,185
Exercise of stock options	1,678	—	4	—	—	4
Issuance of common stock, net of issuance costs	16,276,987	2	56,135	—	—	56,137
Issuance of pre-funded warrants, net of issuance costs	—	—	12,150	—	—	12,150
Other comprehensive loss:						
Unrealized loss on investments	—	—	—	(225)	—	(225)
Foreign currency translation adjustment	—	—	—	(43)	—	(43)
Net loss	—	—	—	—	(15,261)	(15,261)
Balance at June 30, 2022	40,097,076	$ 4	$ 329,414	$ (397)	$ (179,845)	$ 149,176

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)

	Six Months Ended June 30,	
	2023	**2022**
Operating activities		
Net loss	$ (32,987)	$ (32,145)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	416	357
Stock-based compensation expense	3,692	3,937
Amortization of premiums and discounts on marketable securities	(1,850)	(583)
Reduction in the carrying value of right-of-use assets	239	209
Non-cash interest expense and amortization of debt issuance costs	238	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	186	1,273
Accounts payable	(530)	(1,090)
Accrued expenses	(2,150)	(21)
Operating lease liabilities	(399)	(358)
Other assets	—	(25)
Prepaid expenses, net of current portion	(51)	(401)
Other long-term liabilities	(124)	—
Net cash used in operating activities	(33,320)	(28,847)
Investing activities		
Purchases of marketable securities	(106,875)	(81,647)
Maturities of marketable securities	104,500	81,500
Purchases of property and equipment	(186)	(217)
Net cash used in investing activities	(2,561)	(364)
Financing activities		
Net proceeds from issuance of long-term debt	27,500	—
Proceeds from issuance of common stock	16,087	56,179
Net proceeds from issuance of pre-funded warrants	—	12,150
Proceeds from exercise of stock options	55	244
Proceeds from issuance of common stock for cash under Employee Stock Purchase Plan	96	—
Net cash provided by financing activities	43,738	68,573
Net increase in cash, cash equivalents, and restricted cash	7,857	39,362
Effect of foreign currency exchange rate on cash	30	(58)
Cash, cash equivalents, and restricted cash at beginning of period	33,269	23,670
Cash, cash equivalents, and restricted cash at end of period	$ 41,156	$ 62,974
Supplemental cash flow information:		
Cash and cash equivalents	$ 40,845	$ 62,620
Restricted cash	311	354
Cash, cash equivalents, and restricted cash at end of period	$ 41,156	$ 62,974
Property and equipment unpaid at end of period	$ —	$ 35
Public offering costs included in accounts payable and accrued expenses	$ —	$ 44

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 to address the underlying causes of these debilitating diseases. It is well established that two genes, ENPP1 and ABCC6, play key roles in this critical pathway and that defects in these genes lead to low levels of plasma pyrophosphate, which drives pathologic mineralization, and low levels of adenosine, which drives intimal proliferation. The Company is initially focused on developing a novel therapy to treat rare genetic diseases of ENPP1 and ABCC6 Deficiencies.

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

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") for interim financial information. Accordingly, these unaudited condensed consolidated financial statements do not include all of the information and note disclosures required by U.S. GAAP for audited year-end financial statements. The accompanying unaudited condensed consolidated financial statements reflect all normal recurring adjustments that are, in the opinion of management, necessary for a fair presentation of the interim period results. The results for the three and six month periods ended June 30, 2023 are not necessarily indicative of results to be expected for the year ending December 31, 2023, 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, 2022.

Liquidity, Capital Resources, and Going Concern

Since the Company’s incorporation in 2017 and through June 30, 2023, 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 $33.0 million in the six months ended June 30, 2023 and had an accumulated deficit of $247.7 million as of June 30, 2023. The Company had cash, cash equivalents, and short-term investments of $140.2 million as of June 30, 2023.

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 June 30, 2023 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.

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, 2022 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022. There have been no material changes in the Company's significant accounting policies during the six months ended June 30, 2023.

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

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

3. Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the 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.

Recently Adopted Accounting Standards

In June 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. ASU 2016-13 and its subsequent related updates establish a new forward-looking "expected loss model" that requires entities to estimate current expected credit losses on accounts receivable and financial instruments by using all practical and relevant information. The Company adopted this standard effective January 1, 2023. There was no impact to the Company's financial statements upon adoption.

4. Balance Sheet Details

Short-term investments consisted of the following:

		June 30, 2023			
Description	Maturity	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper	1 year or less	$ 38,193	$ 7	$ (1)	$ 38,199
U.S. Treasury securities	1 year or less	5,878	1	—	5,879
U.S. government agency debt securities	1 year or less	55,306	21	(3)	55,324
		$ 99,377	$ 29	$ (4)	$ 99,402

		December 31, 2022			
Description	Maturity	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper	1 year or less	$ 78,451	$ 4	$ (119)	$ 78,336
U.S. Treasury securities	1 year or less	16,698	—	(83)	16,615
		$ 95,149	$ 4	$ (202)	$ 94,951

The Company did not have any investments in a continuous unrealized loss position for more than 12 months as of June 30, 2023. As of June 30, 2023, 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.

Accrued expenses consisted of the following:

	At June 30, 2023	At December 31, 2022
Payroll and related liabilities	$ 2,682	$ 2,799
Other professional fees	1,464	746
Research and development costs	4,569	7,066
Other	490	744
Total	$ 9,205	$ 11,355

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:

Description	June 30, 2023	Fair Value Measurements at Reporting Date Using Level 1	Level 2	Level 3
Assets:				
Money market funds (included in cash and cash equivalents)	$ 30,563	$ 30,563	$ —	$ —
Commercial paper	38,199	—	38,199	—
U.S. government agency debt securities (amounts included in either cash and cash equivalents or short-term investments)	64,306	—	64,306	—
U.S. Treasury securities	5,879	5,879	—	—
Total assets	$ 138,947	$ 36,442	$ 102,505	$ —

Description	December 31, 2022	Fair Value Measurements at Reporting Date Using Level 1	Level 2	Level 3
Assets:				
Money market funds (included in cash and cash equivalents)	$ 26,587	$ 26,587	$ —	$ —
Commercial paper	78,336	—	78,336	—
U.S. Treasury securities	16,615	16,615	—	—
Total assets	$ 121,538	$ 43,202	$ 78,336	$ —

There have been no transfers between fair value levels during the three or six months ended June 30, 2023.

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 June 30, 2023, the Company incurred a life-to-date total of $0.7 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 addition, the Company is required to pay Yale an amount in the several hundreds of thousands of dollars, based on the achievement of a specified net product sales milestone or specified development and commercialization milestones, for each diagnostic licensed product developed. While the agreement remains in effect, the Company is required to pay Yale low single-digit percentage royalties on aggregate worldwide net sales of certain licensed products. Yale is guaranteed a minimum royalty payment amount (ranging in dollar amounts from the mid six figures to low seven figures) for each year after the first sale of a therapeutic or prophylactic-licensed product that results in net sales. Yale is guaranteed a minimum royalty payment amount (ranging from the low tens of thousands of dollars to the mid tens of thousands of dollars) for each year after the first sale of a diagnostic licensed product that results in net sales. The Company must also pay Yale a percentage in the twenties of certain types of income it receives from sublicensees. The Company is also responsible for costs relating to the prosecution and maintenance of the licensed patents. Finally, subject to certain conditions, all payments due by the Company to Yale will be tripled following any patent challenge or challenge to a claim by Yale that a product is a licensed product under the agreement, made by the Company against Yale if Yale prevails in such challenge.

7. Commitments and Contingencies

Operating Leases

The Company held the following significant operating leases as of June 30, 2023:

- 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.

During the six months ended June 30, 2023, cash paid for amounts included in the measurement of lease liabilities was $0.5 million, and the Company recorded operating lease expense of $0.3 million.

Future lease payments under non-cancelable leases as of June 30, 2023 are as follows:

Year Ending December 31,		
2023 (remaining 6 months)	$	497
2024		1,016
2025		944
	$	2,457

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 June 30, 2023 or December 31, 2022.

Legal Proceedings

The Company is not currently a party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses the costs related to its legal proceedings as they are incurred. No such costs have been incurred during the three and six months ended June 30, 2023 and 2022.

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 (“K2HV”, 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 are available to be drawn at the Company’s option during certain availability periods, subject to the achievement of certain clinical and regulatory milestones relating to INZ-701. The Company elected to borrow $7.5 million under the second tranche commitment in June 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 in its discretion. The fourth tranche commitment is subject to an additional 0.75% facility fee. As of June 30, 2023, a total of $37.5 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 June 30, 2023 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 June 30, 2023, the Company was in compliance with all covenants under the Loan Agreement.

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

The Company incurred debt issuance costs of $0.5 million in connection with the term loan. In addition, at the time of closing, the Company paid to the Lenders a facility fee of $0.4 million, as well as $0.1 million of other expenses incurred by the Lenders and reimbursed by the Company ("Lender Expenses"). The debt issuance costs, Lender Expenses and the Final Fee are being amortized as additional interest expense over the term of the loan using the effective interest method. The Company recorded interest expense of $0.8 million and $1.1 million during the three and six months ended June 30, 2023, respectively. At June 30, 2023, 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 June 30, 2023:

		June 30, 2023
Gross proceeds	$	32,500
Unamortized debt issuance costs		(623)
Carrying value	$	31,877

Future principal payments, which include the Final Fee, in connection with the Loan Agreement as of June 30, 2023 are as follows:

Fiscal Year		
2023	$	—
2024		—
2025		10,479
2026		24,052
Total	$	34,531

9. Stockholders' Equity

April 2022 Underwritten Offering

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

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

The pre-funded warrants were classified as a component of permanent equity and were recorded at the issuance date using a relative fair value allocation method. The pre-funded warrants were equity classified because they were freestanding financial instruments that were legally detachable and separately exercisable from the equity instruments, were immediately exercisable, did not embody an obligation for the Company to repurchase its shares, and permitted the holders to receive a fixed number of shares of common stock upon exercise. In addition, such pre-funded warrants did not provide any guarantee of value or return. As of March 31, 2023, all 3,523,013 pre-funded warrants have been exercised by means of cashless exercise in exchange for the issuance of 3,522,884 shares of the Company's common stock.

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, or 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 (the "Sales Agreement") with Jefferies LLC ("Jefferies"), 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 June 30, 2023, the Company sold 2,591,995 shares of its common stock pursuant to the Sale Agreement for aggregate net proceeds of $16.1 million. From July 1, 2023 through the date of this Quarterly Report on Form 10-Q, the Company sold 962,000 additional shares of its common stock pursuant to the Sale Agreement for aggregate net proceeds of $5.1 million.

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:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Risk-free interest rate range	3.47% to 3.95 %	2.52% to 3.22%	3.36% to 4.15%	1.58% to 3.22%
Dividend yield	—	—	—	—
Expected term of options (years)	5.50 to 6.48	5.38 to 6.08	5.50 to 6.48	5.08 to 6.48
Volatility rate range	87.97% to 89.67%	85.04% to 87.15%	87.68% to 89.67%	85.04% to 87.15%

The weighted-average grant date fair value of options granted in the three and six months ended June 30, 2023 was $4.47 per share and $3.62 per share, respectively. The total unrecognized compensation cost related to outstanding option awards as of June 30, 2023 was $13.0 million and is expected to be recognized over a weighted-average period of 2.7 years.

Restricted Stock Units

Activity related to restricted stock units ("RSUs") for the six months ended June 30, 2023 is summarized in the table below:

	Number of Shares
Outstanding as of January 1, 2023	—
Granted	100,000
Cancelled / Forfeited	—
Vested / Settled	—
Outstanding as of June 30, 2023	100,000

The weighted-average grant date fair value of RSUs granted in both the three and six months ended June 30, 2023 was $5.73 per share. The total unrecognized compensation cost related to outstanding RSUs as of June 30, 2023 was $0.5 million and is expected to be recognized over a weighted-average period of 3.8 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Research and development	$ 889	$ 1,096	$ 1,707	$ 1,992
General and administrative	711	1,089	1,985	1,945
Total	$ 1,600	$ 2,185	$ 3,692	$ 3,937

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net loss attributable to common stockholders—basic and diluted	$ (15,583)	$ (15,261)	$ (32,987)	$ (32,145)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.35)	$ (0.38)	$ (0.74)	$ (1.01)
Weighted-average common shares and pre-funded warrants outstanding—basic and diluted	44,860,279	39,703,550	44,293,577	31,739,197

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Stock options	6,876,049	4,740,444	6,876,049	4,740,444
Unvested RSUs	100,000	—	100,000	—
Employee stock purchase plan shares	22,423	24,260	22,423	24,260
Total	6,998,472	4,764,704	6,998,472	4,764,704

11. Subsequent Events

From July 1, 2023 through the date of this report, the Company issued and sold an aggregate of 962,000 additional shares of common stock pursuant to its Company's Sales Agreement with Jefferies for aggregate net proceeds of $5.1 million.

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, relating to an underwritten public offering under the Company's registration statement on Form S-3 of 14,375,000 shares of the Company's common stock, inclusive of the exercise by the underwriters of their option to purchase 1,875,000 shares of common stock. The closing of the offering took place on August 1, 2023. The offering price of the shares of common stock to the public was $4.80 per share. Net proceeds from the offering were approximately $64.5 million, after deducting underwriting discounts and commissions and estimated offering expenses.

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, 2022 filed with the Securities and Exchange Commission, or SEC, on March 22, 2023. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of our most recent Annual Report on Form 10-K and in this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in or implied by these forward-looking statements. For convenience of presentation some of the numbers have been rounded in the text below.

Overview

We are a clinical-stage rare disease biopharmaceutical company developing novel therapeutics for the treatment of diseases impacting the vasculature, soft tissue, and skeleton. Through our in-depth understanding of a key biological pathway, we are pursuing the development of therapeutics to address the underlying causes of these debilitating diseases. It is well established that two genes, ENPP1 and ABCC6, play key roles in this critical pathway and that defects in these genes lead to low levels of plasma pyrophosphate ("PPi"), which drives pathologic mineralization, and low levels of adenosine, which drives intimal proliferation. We are initially focused on developing a novel therapy to treat the rare genetic diseases of ENPP1 and ABCC6 Deficiencies.

Our lead product candidate, INZ-701, is a soluble, recombinant, or genetically engineered, fusion protein that is designed to correct a defect in a pathway involving ENPP1 and ABCC6 Deficiencies. This pathway is central to the regulation of calcium deposition throughout the body and is further associated with the inhibition of intimal proliferation, or narrowing and obstruction of blood vessels. We have generated robust proof of concept data in preclinical models demonstrating that INZ-701 prevented pathological calcification and skeletal abnormalities, led to improvements in overall health and survival, and prevented intimal proliferation. 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 the treatment of ENPP1 Deficiency.

Executive Summary

During the three months ended June 30, 2023, we continued to advance our ongoing clinical trials of INZ-701 in patients with ENPP1 and ABCC6 Deficiencies. Key highlights and accomplishments during the three months ended June 30, 2023, as well as upcoming anticipated milestones include:

Key Highlights

- In June 2023, we dosed the first patient in a Phase 1b clinical trial of INZ-701 in infants with ENPP1 Deficiency, or the ENERGY-1 trial.
- We initiated home self-administration of INZ-701 in the open label Phase 2 portion of our Phase 1/2 clinical trial of INZ-701 in adult patients with ABCC6 Deficiency. We previously initiated home self-administration in the open label Phase 2 portion of our Phase 1/2 clinical trial of INZ-701 in adult patients with ENPP1 Deficiency.
- We initiated a scientific advice process regarding our comprehensive development plan covering all age groups with the EMA.

Select Anticipated Milestones for INZ-701

ENPP1 Deficiency

- We plan to report interim data from the first three cohorts of the ongoing Phase 2 portion of our clinical trial of INZ-701 in adults with ENPP1 Deficiency in September 2023.
- We anticipate initiating the ENERGY-3 trial, a pivotal trial of INZ-701 in pediatric patients with ENPP1 Deficiency, in October 2023 and anticipate reporting topline data from this trial in mid-2025.
- We expect to report topline data from the first three cohorts of the ongoing Phase 1/2 clinical trial of INZ-701 in adults with ENPP1 Deficiency in the first quarter of 2024.

ABCC6 Deficiency

- We plan to report interim data from the ongoing Phase 2 portion of our Phase 1/2 clinical trial of INZ-701 in adults with ABCC6 Deficiency in September 2023.
- We expect to report topline data from the ongoing Phase 2 portion of our Phase 1/2 clinical trial of INZ-701 in adults with ABCC6 Deficiency in the first quarter of 2024.
- Subject to regulatory review and sufficient funding, we plan to initiate a Phase 2 clinical trial of INZ-701 in adult patients with ABCC6 Deficiency 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 trial will primarily assess the safety and tolerability of INZ-701 in adult patients with ENPP1 Deficiency, as well as characterize 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 PPi levels, and that can be used for further clinical development. 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 this 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 positive topline pharmacokinetic, pharmacodynamic, and safety data from this trial. A rapid, significant, and sustained increase in PPi was observed in all dose cohorts and in all patients, with a target PPi threshold achieved from the lowest dose of 0.2 mg/kg. PPi increased in all patients to levels comparable to those observed in a study of healthy subjects (n=10), which study showed PPi levels between 1002 nM and 2169 nM. 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. 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. 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.

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.

As of June 30, 2023, a total of nine patients are currently enrolled in the trial in North America and Europe.

We plan to report interim data from the first three cohorts of the ongoing Phase 2 portion of the clinical trial of INZ-701 in adults with ENPP1 Deficiency in September 2023. We expect to report topline data from the first three cohorts of the ongoing Phase 2 portion of the ongoing Phase 1/2 clinical trial of INZ-701 in adults with ENPP1 Deficiency in the first quarter of 2024.

In February 2023, we dosed our first pediatric patient with ENPP1 Deficiency with INZ-701 under our expanded access program. Under an 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.

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, or 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.

Additional Anticipated Clinical Trials of INZ-701 for the Treatment of ENPP1 Deficiency

We anticipate initiating the ENERGY-2 trial, a pivotal trial of INZ-701 in infants with ENPP1 Deficiency, outside of the United States in the second quarter of 2024.

We initiated pivotal trial meetings with the FDA in the first quarter of 2023. We have reached agreement with the EMA on a PIP for a pivotal trial of INZ-701 in pediatric patients with ENPP1 Deficiency. We have finalized the design for a global pivotal clinical trial of INZ-701 in pediatric patients with ENPP1 Deficiency, the ENERGY-3 trial, and plan to initiate it in October 2023.We anticipate reporting topline data from the ENERGY-3 trial in mid-2025.

Pending regulatory discussions and appropriate financial resources, we also plan to conduct a pivotal trial in adolescents and adults with ENPP1 Deficiency, or the ENERGY-4 trial.

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

On July 26, 2023, we announced a regulatory update for our global development strategy of INZ-701 for the treatment of ENPP1 Deficiency following recent meetings with the FDA and the Paediatric Committee of the EMA.

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 planned 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 trial initially enrolled nine patients with ABCC6 Deficiency at sites in the United States and Europe. The trial will primarily assess the safety and tolerability of INZ-701 in adult patients with ABCC6 Deficiency, as well as characterize the pharmacokinetic and pharmacodynamic profile of INZ-701, including the evaluation of levels of plasma PPi and other biomarkers. 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. Patients received a single dose and then began twice-weekly dosing one week later. In July 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. Beginning in 2023, self-administration of INZ-701 in the open label Phase 2 portion of the trial was available. The Phase 1 dose-escalation portion of the trial sought to identify a safe and tolerable dose that increases 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.

In February 2023, we reported positive topline safety, pharmacodynamic, and pharmacokinetic 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. 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 nine patients experienced adverse events related to INZ-701. All adverse events were mild to moderate in severity. One patient from the highest dose cohort (1.8 mg/kg) was withdrawn from the Phase 1 portion of the trial at day 18 due to a moderate adverse event (erythema/urticaria) related to INZ-701. A replacement patient was enrolled in the Phase 1 portion of the trial and, as of June 30, 2023, all nine patients continue in the Phase 2 portion of the trial in the United States and Europe.

We plan to report interim data from the ongoing Phase 2 portion of the trial on INZ-701 in adults with ABCC6 Deficiency in September 2023. We expect to report topline data from the ongoing Phase 1/2 clinical trial of INZ-701 in adults with ABCC6 Deficiency in the first quarter of 2024. Subject to regulatory review and sufficient funding, we plan to initiate a Phase 2 clinical trial of INZ-701 in adult patients with ABCC6 Deficiency in the fourth quarter of 2024.

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, including those without a clear genetic basis, such as calciphylaxis or calcifications as a result of end-stage kidney disease.

In December 2022, the FDA allowed our Investigational New Drug to enable us to evaluate INZ-701 in a clinical trial in patients with end-stage kidney disease and calciphylaxis. We intend to initiate a Phase 1 clinical trial in end-stage kidney disease patients, and we expect data from this trial to inform our development plans in calciphylaxis. We are also exploring the potential for development of a gene therapy for ENPP1 Deficiency.

Our Operations

We have not yet commercialized any products or generated any revenue from product sales. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, securing intellectual property rights, conducting research and development activities, 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 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 June 30, 2023, together with the net proceeds from our underwritten offering that closed in August 2023, 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 clinical trials of INZ-701 for ENPP1 Deficiency and ABCC6 Deficiency;
- prepare for, initiate, and conduct planned clinical trials of INZ-701 for patients with ENPP1 and ABCC6 Deficiencies;
- conduct research, preclinical, and clinical testing of INZ-701 for additional indications;
- conduct research, preclinical, and clinical testing of other product candidates;
- 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 and our ENERGY-1 trial for infants with ENPP1 Deficiency. Product candidates in later stages of clinical development generally have higher development costs than those in preclinical development or in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. 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 anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We incur, and anticipate that we will continue to incur, costs associated with being a public company, including costs of accounting, audit, legal, regulatory, compliance and tax-related services related to maintaining compliance with requirements of Nasdaq and the SEC; director and officer insurance costs; and investor and public relations costs. 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, execute on our global development strategy, and incur costs associated with being a public company.

Interest Income, net

Interest income, net consists of income from bank deposits and investments and interest expense related to our Loan Agreement.

Other Expense, net

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

Results of Operations

Comparison of the Three Months Ended June 30, 2023 and 2022

The following table summarizes our results of operations for the three months ended June 30, 2023 and 2022 (in thousands):

	Three Months Ended June 30,		
	2023	2022	Change
Operating expenses:			
Research and development	$ 11,666	$ 10,007	$ 1,659
General and administrative	4,728	5,384	(656)
Total operating expenses	16,394	15,391	1,003
Loss from operations	(16,394)	(15,391)	1,003
Other income (expense):			
Interest income, net	839	321	518
Other expense, net	(28)	(191)	(163)
Other income, net	811	130	681
Net loss	$ (15,583)	$ (15,261)	$ 322

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended June 30, 2023 and 2022 (in thousands):

	Three Months Ended June 30,		
	2023	2022	Change
INZ-701-related research and development expense	$ 6,709	$ 5,567	$ 1,142
Unallocated expenses:			
Personnel-related expenses (including stock-based compensation)	4,346	3,881	465
Facilities and administrative expenses	611	559	52
Total	$ 11,666	$ 10,007	$ 1,659

Research and development expense increased approximately $1.7 million for the three months ended June 30, 2023 compared to the three months ended June 30, 2022 primarily due to increases of $1.1 million in INZ-701-related research and development expense and $0.5 million in personnel-related expenses.

INZ-701-related research and development expense increased $1.1 million, primarily due to a $0.7 million increase in chemistry, manufacturing, and controls expenses incurred to develop our manufacturing capabilities and support our ongoing clinical trials and a $0.5 million increase in clinical development costs, which was primarily driven by consulting costs needed to support our clinical trials. The increase in total research and development expense was also impacted by a $0.5 million increase in personnel-related expense primarily due to increased headcount needed to support our ongoing clinical trials.

General and Administrative Expense

General and administrative expense decreased $0.7 million for the three months ended June 30, 2023 compared to the three months ended June 30, 2022 primarily due to a $0.4 million decrease in stock-based compensation expense primarily due to the separation of executives in prior periods and a $0.4 million decrease associated with various cost-savings initiatives.

Interest Income, net

Interest income, net for the three months ended June 30, 2023 increased approximately $0.5 million compared to the three months ended June 30, 2022 due to a $1.3 million increase in interest income as a result of higher interest rates and a larger cash balance on which we are earning interest, partially offset by a $0.8 million increase in interest expense associated with the Loan Agreement.

Other Expense, net

Other expense, net decreased approximately $0.2 million for the three months ended June 30, 2023 compared to the three months ended June 30, 2022. The three months ended June 30, 2022 reflected approximately $0.2 million of unrealized losses associated with cash balances we held which were denominated in Euros.

Comparison of the Six Months Ended June 30, 2023 and 2022

The following table summarizes our results of operations for the six months ended June 30, 2023 and 2022 (in thousands):

	Six Months Ended June 30,		
	2023	2022	Change
Operating expenses:			
Research and development	$ 23,523	$ 21,821	$ 1,702
General and administrative	11,240	10,409	831
Total operating expenses	34,763	32,230	2,533
Loss from operations	(34,763)	(32,230)	2,533
Other income (expense):			
Interest income, net	1,838	381	1,457
Other expense, net	(62)	(296)	(234)
Other income, net	1,776	85	1,691
Net loss	$ (32,987)	$ (32,145)	$ 842

Research and Development Expenses

The following table summarizes our research and development expenses for the six months ended June 30, 2023 and 2022 (in thousands):

	Six Months Ended June 30,		
	2023	2022	Change
INZ-701-related research and development expense	$ 13,828	$ 13,253	$ 575
Unallocated expenses:			
Personnel-related expense (including stock-based compensation)	8,482	7,499	983
Facilities and administrative expense	1,213	1,069	144
Total	$ 23,523	$ 21,821	$ 1,702

Research and development expense increased approximately $1.7 million for the six months ended June 30, 2023 compared to the six months ended June 30, 2022 primarily due to increases of $1.0 million in personnel-related expense and $0.6 million in INZ-701-related research and development expense.

Personnel-related expense increased $1.0 million primarily due to increased headcount needed to support ongoing clinical trials. INZ-701-related research and development expense increased $0.6 million, primarily due to a $0.5 million increase in chemistry, manufacturing, and controls expenses incurred to develop our manufacturing capabilities and support our ongoing clinical trials.

General and Administrative Expense

General and administrative expense increased $0.8 million for the six months ended June 30, 2023 compared to the six months ended June 30, 2022 primarily due to a $1.0 million increase in personnel-related expense driven by expenses recorded for the transition and separation agreement entered into with our former chief executive officer in the three months ended March 31, 2023.

Interest Income, net

Interest income, net for the six months ended June 30, 2023 increased approximately $1.5 million compared to the six months ended June 30, 2022 due to a $2.6 million increase in interest income as a result of higher interest rates and a larger cash balance on which we are earning interest, partially offset by a $1.1 million increase in interest expense associated with the Loan Agreement.

Other Expense, net

Other expense, net decreased approximately $0.2 million for the six months ended June 30, 2023 compared to the six months ended June 30, 2022. The six months ended June 30, 2022 reflected approximately $0.2 million of unrealized losses associated with cash balances we held which were denominated in Euros.

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, which was declared effective on August 23, 2021, or the Registration Statement. Under the Registration Statement, we may offer and sell up to $200.0 million of a variety of securities, including common stock, preferred stock, depositary shares, debt securities, warrants, subscription rights or units from time to time pursuant to one or more offerings at prices and terms to be determined at the time of the sale. In connection with the filing of the Registration Statement, we entered into an Open Market Sale Agreement with Jefferies LLC, as sales agent, pursuant to which we may offer and sell shares of our common stock with an aggregate offering price of up to $50.0 million under an “at-the-market” offering program. As of June 30, 2023, we sold 2,591,995 shares of our common stock pursuant to the Open Market Sale Agreement for aggregate net proceeds of $16.1 million. From July 1, 2023 through the date of this Quarterly Report on Form 10-Q, we sold 962,000 additional shares of our common stock pursuant to the Open Market Sale Agreement for aggregate net proceeds of $5.1 million.

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

In July 2022, we entered into a Loan Agreement with K2 HealthVentures LLC (“K2HV”, 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 (iii) a fourth tranche commitment of $25.0 million available to be drawn at our option through August 31, 2025, subject to use of proceeds limitations and Lenders’ consent in its discretion. We have an aggregate of $32.5 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 Registration Statement. Net proceeds from the offering were approximately $64.5 million, after deducting underwriting discounts and commissions and estimated offering expenses.

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 June 30, 2023 and December 31, 2022 (in thousands):

	June 30, 2023	December 31, 2022
Cash and cash equivalents	$ 40,845	$ 32,915
Short-term investments	99,402	94,951
Total cash, cash equivalents, and short-term investments	$ 140,247	$ 127,866

Cash Flows

The following table provides information regarding our cash flows for the six months ended June 30, 2023 and 2022 (in thousands):

	Six Months Ended June 30,	
	2023	2022
Net cash used in operating activities	$ (33,320)	$ (28,847)
Net cash used in investing activities	(2,561)	(364)
Net cash provided by financing activities	43,738	68,573
Net increase in cash, cash equivalents, and restricted cash	$ 7,857	$ 39,362

Net Cash Used in Operating Activities

The increase in net cash used in operating activities of $4.5 million was primarily due to a $2.4 million increase in operating assets and liabilities and a $1.3 million increase in amortization on marketable securities in the six months ended June 30, 2023 compared to the six months ended June 30, 2022.

Net Cash Used in Investing Activities

Net cash used in investing activities increased approximately $2.2 million for the six months ended June 30, 2023 compared to the six months ended June 30, 2022, as a $25.2 million increase in purchases of marketable securities exceeded a $23.0 million increase in maturities of marketable securities in the six months ended June 30, 2023.

Net Cash Provided by Financing Activities

Net cash provided by financing activities decreased $24.8 million for the six months ended June 30, 2023, as $68.3 million of net cash proceeds from the underwritten offering in April 2022 greatly exceeded proceeds of $27.5 million from the issuance of long-term debt and $16.1 million from sales of common stock under our at-the-market facility in the six months ended June 30, 2023.

Funding Requirements

We expect to devote substantial financial resources to our ongoing and planned activities, particularly as we execute on our global development strategy, conduct our ongoing clinical trials of INZ-701 for ENPP1 and ABCC6 Deficiencies, and continue research and development and initiate additional planned clinical trials of, and seek marketing approval for, INZ-701 and any other product candidate we develop. 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. 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 June 30, 2023, together with the net proceeds from the underwritten offering that closed in August 2023, 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.

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 and six months ended June 30, 2023, 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, 2022.

Contractual Obligations, Commitments and Contingencies

Except for the additional borrowings under the Loan Agreement in February 2023 and June 2023 and described in Note 8 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, during the three and six months ended June 30, 2023, 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, 2022.

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 June 30, 2023, our cash equivalents consisted of short-term money market funds and U.S. government agency debt securities. As of June 30, 2023, our short-term investments consisted of commercial paper, 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 June 30, 2023, the aggregate principal amount outstanding under the Loan Agreement was $32.5 million, which bears interest at a variable rate equal to the greater of (i) 7.85% and (ii) the sum of (A) the prime rate last quoted in The Wall Street Journal (or a comparable replacement rate if The Wall Street Journal ceases to quote such rate) and (B) 3.85%; provided that the interest rate cannot exceed 9.60%. The interest rate as of June 30, 2023 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 six months ended June 30, 2023 and 2022.

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 June 30, 2023. 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 June 30, 2023, 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, 2022, 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, 2022 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, 2022 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, or the Securities Act, during the three months ended June 30, 2023.

Use of Proceeds from Initial Public Offering

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

We received aggregate gross proceeds from our IPO, inclusive of the exercise by the underwriters of their option to purchase additional shares, of approximately $128.8 million, or aggregate net proceeds of approximately $115.9 million after deducting underwriting discounts and commissions and offering expenses.

We have used approximately $93.1 million of the net proceeds from the IPO as of June 30, 2023 to fund clinical development of INZ-701 and our preclinical research and development activities, and for working capital and other general corporate purposes. There has been no material change in our planned use of the net proceeds from our IPO as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on July 24, 2020.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-39397) filed with the Securities and Exchange Commission on July 28, 2020).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.1 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	Consulting Agreement, dated April 30, 2023, by and between the Registrant and Axel Bolte (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39397) filed with the Securities and Exchange Commission on May 9, 2023).
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.

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: August 8, 2023

By: /s/ Douglas A. Treco

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

Date: August 8, 2023

By: /s/ Sanjay S. Subramanian

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

Exhibit 31.1

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

I, 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: August 8, 2023

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: August 8, 2023

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 June 30, 2023 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: August 8, 2023

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 June 30, 2023 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: August 8, 2023

By: /s/ Sanjay S. Subramanian

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