UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2023

OR

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

Commission File Number: 001-38793

INMUNE BIO INC.
(Exact name of registrant as specified in its charter)

Nevada	**47-5205835**
(State of incorporation)	*(I.R.S. Employer Identification No.)*

David Moss
225 NE Mizner Blvd., Suite 640
Boca Raton, FL 33432
(Address of principal executive office) (Zip code)

(858) 964-3720
(Registrant's telephone number, including area code)

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 $0.001 per share	INMB	The NASDAQ Stock Market LLC

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 than the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

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

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

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

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

As of November 1, 2023, there were 18,021,692 shares of our common stock, par value $0.001 per share, outstanding.

INMUNE BIO INC.
FORM 10-Q
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2023

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

INMUNE BIO INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)
(Unaudited)

	September 30, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 41,813	$ 52,153
Research and development tax credit receivable	2,087	8,099
Other tax receivable	176	362
Prepaid expenses and other current assets	1,535	4,027
Prepaid expenses – related party	-	34
TOTAL CURRENT ASSETS	45,611	64,675
Operating lease – right of use asset	444	507
Other assets	129	99
Acquired in-process research and development intangible assets	16,514	16,514
TOTAL ASSETS	$ 62,698	$ 81,795
LIABILITIES, REDEEMABLE COMMON STOCK AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 3,675	$ 5,206
Accounts payable and accrued liabilities – related parties	79	9
Deferred liabilities	496	616
Current portion of long-term debt	10,000	5,000
Operating lease, current liabilities	106	87
TOTAL CURRENT LIABILITIES	14,356	10,918
Long-term debt, net	2,376	9,697
Long-term operating lease liabilities	430	526
Accrued liability – long-term	804	550
TOTAL LIABILITIES	17,966	21,691
COMMITMENTS AND CONTINGENCIES		
Redeemable common stock, $0.001 par value; 75,697 and 0 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively (Note 9)	799	-
STOCKHOLDERS' EQUITY		
Preferred stock, $0.001 par value, 10,000,000 shares authorized, 0 shares issued and outstanding	-	-
Common stock, $0.001 par value, 200,000,000 shares authorized, 17,945,995 shares issued and outstanding	18	18
Additional paid-in capital	157,264	151,799
Accumulated other comprehensive loss	(735)	(699)
Accumulated deficit	(112,614)	(91,014)
TOTAL STOCKHOLDERS' EQUITY	43,933	60,104
TOTAL LIABILITIES, REDEEMABLE COMMON STOCK AND STOCKHOLDERS' EQUITY	$ 62,698	$ 81,795

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

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
REVENUE	$ 43	$ 98	$ 127	$ 277
OPERATING EXPENSES				
General and administrative	2,586	2,382	7,223	6,929
Research and development	5,985	5,159	14,266	13,657
Total operating expenses	8,571	7,541	21,489	20,586
LOSS FROM OPERATIONS	(8,528)	(7,443)	(21,362)	(20,309)
OTHER EXPENSE, NET	(35)	(282)	(238)	(1,157)
NET LOSS	$ (8,563)	$ (7,725)	$ (21,600)	$ (21,466)
Net loss per common share – basic and diluted	$ (0.48)	$ (0.43)	$ (1.20)	$ (1.20)
Weighted average common shares outstanding – basic and diluted	18,008,295	17,945,995	17,966,990	17,921,036
COMPREHENSIVE LOSS				
Net loss	$ (8,563)	$ (7,725)	$ (21,600)	$ (21,466)
Other comprehensive loss – foreign currency translation	(23)	(441)	(36)	(1,143)
Total comprehensive loss	$ (8,586)	$ (8,166)	$ (21,636)	$ (22,609)

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

INMUNE BIO INC.

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2023
(In thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2022	17,945,995	$ 18	$ 151,799	$ (699)	$ (91,014)	$ 60,104
Stock-based compensation	-	-	1,737	-	-	1,737
Loss on foreign currency translation	-	-	-	(9)	-	(9)
Net loss	-	-	-	-	(6,536)	(6,536)
Balance as of March 31, 2023	17,945,995	18	153,536	(708)	(97,550)	55,296
Stock-based compensation	-	-	1,863	-	-	1,863
Loss on foreign currency translation	-	-	-	(4)	-	(4)
Net loss	-	-	-	-	(6,501)	(6,501)
Balance as of June 30, 2023	17,945,995	18	155,399	(712)	(104,051)	50,654
Issuance of common stock for cash, net	75,697	-	775	-	-	775
Reclassification to redeemable common stock	(75,697)		(799)			(799)
Stock-based compensation	-	-	1,889	-	-	1,889
Loss on foreign currency translation	-	-	-	(23)	-	(23)
Net loss	-	-	-	-	(8,563)	(8,563)
Balance as of September 30, 2023	17,945,995	$ 18	$ 157,264	$ (735)	$ (112,614)	$ 43,933

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

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2022
(In thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2021	17,843,303	$ 18	$ 143,921	$ 1	$ (63,715)	$ 80,225
Issuance of common stock for cash	82,900	-	699	-	-	699

Exercise of warrants for cash	19,792	-	30	-	-	30
Stock-based compensation	-	-	1,536	-	-	1,536
Gain on foreign currency translation	-	-	-	55	-	55
Net loss	-	-	-	-	(6,903)	(6,903)
Balance as of March 31, 2022	17,945,995	18	146,186	56	(70,618)	75,642
Stock-based compensation	-	-	1,886	-	-	1,886
Loss on foreign currency translation	-	-	-	(757)	-	(757)
Net loss	-	-	-	-	(6,838)	(6,838)
Balance as of June 30, 2022	17,945,995	18	148,072	(701)	(77,456)	69,933
Stock-based compensation	-	-	1,939	-	-	1,939
Loss on foreign currency translation	-	-	-	(441)	-	(441)
Net loss	-	-	-	-	(7,725)	(7,725)
Balance as of September 30, 2022	17,945,995	$ 18	$ 150,011	$ (1,142)	$ (85,181)	$ 63,706

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

INMUNE BIO INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	For the Nine Months Ended September 30,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (21,600)	$ (21,466)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	5,489	5,361
Accretion of debt discount	179	171
Impairment of operating lease – right of use asset	-	89
Changes in operating assets and liabilities:		
Research and development tax credit receivable	6,012	496
Other tax receivable	186	477
Prepaid expenses	2,492	(2,321)
Prepaid expenses – related party	34	(109)
Other assets	(30)	-
Accounts payable and accrued liabilities	(1,531)	(268)
Accounts payable and accrued liabilities – related parties	70	(72)
Deferred liabilities	(120)	304
Accrued liability – long-term	254	264
Operating lease liabilities	(14)	83
Net cash used in operating activities	(8,579)	(16,991)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from sale of common stock	775	699
Repayments of debt	(2,500)	-
Net proceeds from the exercise of warrants	-	30
Net cash (used in) provided by financing activities	(1,725)	729
Impact on cash from foreign currency translation	(36)	(1,143)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(10,340)	(17,405)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	52,153	74,810
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 41,813	$ 57,405
SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:		
Cash paid for income taxes	$ -	$ -
Cash paid for interest expense	$ 1,394	$ 962

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

INMUNE BIO INC.

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – ORGANIZATION AND DESCRIPTION OF BUSINESS

INmune Bio Inc. (the "Company" or "INmune Bio") was organized in the State of Nevada on September 25, 2015 and is a clinical stage biotechnology pharmaceutical company focused on developing and commercializing its product candidates to treat diseases where the innate immune system is not functioning normally and contributing to the patient's disease. INmune Bio has two product platforms. The DN-TNF product platform utilizes dominant-negative technology to selectively neutralize soluble TNF, a key driver of innate immune dysfunction and mechanistic target of many diseases. DN-TNF is currently being developed for Alzheimer's and treatment resistant depression ("XPro") and cancer ("INB03") and an out-licensing strategy for Duchenne's Muscular Dystrophy ("DMD"). The Natural Killer Cell Priming Platform includes INKmune aimed at priming the patient's NK cells to eliminate minimal

residual disease in patients with cancer. INmune Bio's product platforms utilize a precision medicine approach for the treatment of a wide variety of hematologic malignancies, solid tumors and chronic inflammation.

NOTE 2 – LIQUIDITY

As of September 30, 2023, the Company had an accumulated deficit of $ 112,614,000 and experienced losses since its inception. The Company had cash and cash equivalents of $41,813,000 as of September 30, 2023, and has not generated positive cash flows from operations. To date, the Company has funded its operations primarily through the sale of its common stock. Although it is difficult to predict the Company's liquidity requirements, as of September 30, 2023, and based upon the Company's current operating plan, the Company believes that it will have sufficient cash to meet its projected operating requirements for at least the next 12 months following the filing date of this Quarterly Report on Form 10-Q based on the balance of cash available as of September 30, 2023.

Management expects operating losses to continue for the foreseeable future. There can be no assurance that the Company will ever earn revenues or achieve profitability, or if achieved, that they will be sustained on a continuing basis. In addition, the manufacturing, clinical and preclinical development activities as well as the commercialization of the Company's products, if approved, will require significant additional financing. The Company may be unable to secure such financing when needed, or if available, such financings may be under terms that are unfavorable to the Company or the current stockholders. If the Company is unable to raise additional funds when needed, it may be required to delay, reduce the scope of, or eliminate development programs, which may adversely affect its business and operations.

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying financial statements are presented in U.S. dollars and have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP"), and pursuant to the accounting and disclosure rules and regulations of the U.S. Securities and Exchange Commission ("SEC"). The consolidated financial statements include the accounts of INmune Bio Inc. and its subsidiaries. Intercompany transactions and balances have been eliminated.

In the opinion of management, the interim financial information includes all normal recurring adjustments necessary for a fair statement of the results for the interim periods. These unaudited consolidated interim financial statements should be read in conjunction with the audited financial statements and notes thereto 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, filed with the SEC on March 2, 2023.

Impact of Geopolitical and Macroeconomic Factors

There may be significant uncertainty resulting from the impact of other geopolitical and macroeconomic factors, including the ongoing COVID-19 (coronavirus) pandemic, inflation, supply chain issues, rising interest rates, future bank failures, a potential US government shutdown, the impact of the conflicts in Russia/Ukraine and Israel, in addition to geopolitical, trade and investment tensions between the United States and China.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical studies, clinical trials and regulatory approval prior to commercialization. These efforts require significant amounts of additional resources, adequate personnel, infrastructure and extensive compliance and reporting.

The Company's product candidates are still in development and, to date, none of the Company's product candidates have been approved for sale.

There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained or maintained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate any revenue from any of its products. The Company operates in an environment of rapid change in technology and substantial competition from other pharmaceutical and biotechnology companies.

The Company relies and expects to continue to rely on a small number of vendors to manufacture supplies and materials for its use in the clinical trial programs. These programs could be adversely affected by a significant interruption in these manufacturing services.

Use of Estimates

Preparing financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, and expenses. Actual results and outcomes may differ from management's estimates and assumptions.

Fair Value of Financial Instruments

The Company measures certain assets and liabilities in accordance with authoritative guidance which requires fair value measurements to be classified and disclosed in one of the following three categories:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities.

Level 2: Observable prices that are based on inputs not quoted on active markets but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available.

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. The Company reviews the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain assets or liabilities within the fair value hierarchy. The Company did not have any transfers of assets and liabilities between the levels of the fair value measurement hierarchy during the years presented.

The carrying amounts of financial instruments such as cash and cash equivalents, research and development tax credit receivable, other receivable, prepaid expenses, and accounts payable and accrued liabilities approximate the related fair values due to the short-term maturities of these instruments.

Cash and Cash Equivalents

The Company considers all short-term, highly liquid investments with an original maturity at the date of purchase of three months or less to be cash equivalents. The Company maintains cash balances that may be uninsured or in deposit accounts that exceed Federal Deposit Insurance Corporation limits. The Company maintains its cash deposits with major financial institutions.

Research and Development Tax Incentive Receivable

The Company, through its wholly owned subsidiary in Australia ("AUS"), participates in the Australian research and development tax incentive program, such that a percentage of our qualifying research and development expenditures are reimbursed by the Australian government, and such incentives are reflected as a reduction of research and development expense. The Australian research and development tax incentive is recognized when there is reasonable assurance that the incentive will be received, the relevant expenditure has been incurred and the amount of the consideration can be reliably measured. At each period end, management estimates the reimbursement available to the Company based on available information at the time.

The Company, through its wholly owned subsidiary in the United Kingdom ("UK"), participates in the research and development program provided by the United Kingdom tax relief program, such that a percentage of our qualifying research and development expenditures are reimbursed by the United Kingdom government, and such incentives are reflected as a reduction of research and development expense. The United Kingdom research and development tax incentive is recognized when there is reasonable assurance that the incentive will be received, the relevant expenditure has been incurred and the amount of the consideration can be reliably measured. At each period end, management estimates the reimbursement available to the Company based on available information at the time.

Intangible Assets

The Company capitalizes costs incurred in connection with in-process research and development purchased from others if the asset has alternative uses and such uses are not restricted under applicable license agreements; patent applications (principally legal fees), patent purchases, and trademarks related to its cell line as intangible assets. Acquired in-process research and development costs that do not have alternative uses are expensed as incurred. When the assets are determined to have a finite life (upon completion of the development of the in-process research and development for its DN-TNF platform), the useful life will be determined and the in-process research and development intangible assets will be amortized.

During the fourth quarter and if business factors indicate more frequently, the Company performs an assessment of the qualitative factors affecting the fair value of our in-process research and development. If the qualitative assessment suggests that impairment is more likely than not, a quantitative analysis is performed. The quantitative analysis involves a comparison of the fair value of the in-process research and development with the carrying amount. If the carrying amount of the in-process research and development exceeds its fair value, an impairment loss is recognized in an amount equal to that excess.

Basic and Diluted Loss per Share

Basic loss per share is computed by dividing net loss available to common shareholders by the weighted average number of outstanding common shares during the period. Diluted loss per share gives effect to all dilutive potential common shares outstanding during the period. Dilutive loss per share excludes all potential common shares if their effect is anti-dilutive. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

At September 30, 2023 and 2022, the Company had potentially issuable shares as follows:

	September 30,	
	2023	**2022**
Stock options	5,501,000	4,851,000
Warrants	74,074	74,074
Total	5,575,074	4,925,074

Revenue Recognition

The Company recognizes revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration the Company expects to receive in exchange for those goods or services. The Company recognizes revenue following the five-step model prescribed under ASC Topic 606: (1) identify contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenues when (or as) the Company satisfies the performance obligations. The Company records the expenses related to revenue in research and development expense, in the periods such expenses were incurred.

The Company records deferred revenues when cash payments are received or due in advance of performance, including amounts which are refundable.

Stock-Based Compensation

The Company utilizes the Black-Scholes option pricing model to estimate the fair value of stock option awards at the date of grant, which requires the input of highly subjective assumptions, including expected volatility and expected life. Changes in these inputs and assumptions can materially affect the measure of estimated fair value of our share-based compensation. These assumptions are subjective and generally require significant analysis and judgment to develop. When estimating fair value, some of the assumptions will be based on, or determined from, external data and other assumptions may be derived from our historical experience with stock-based payment arrangements. The appropriate weight to place on historical experience is a matter of judgment, based on relevant facts and circumstances. The Company accounts for forfeitures of stock options as they occur.

Research and Development

Research and development ("R&D") costs are expensed as incurred. Research and development credits are recorded by the Company as a reduction of research and development costs. Major components of research and development costs include cash compensation, stock-based compensation, costs of preclinical studies, clinical trials and related clinical manufacturing, costs of drug development, costs of materials and supplies, facilities cost, overhead

costs, regulatory and compliance costs, and fees paid to consultants and other entities that conduct certain research and development activities on the Company's behalf.

The Company recognizes grants as contra research and development expense in the consolidated statement of operations on a systematic basis over the periods in which the entity recognizes as expenses the related costs for which the grants are intended to compensate.

Income Taxes

The Company follows the liability method of accounting for income taxes. Under this method, deferred income tax assets and liabilities are recognized for the estimated tax consequences attributable to differences between the financial statement carrying values and their respective income tax basis (temporary differences). The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

Foreign Currency Translation

The Company's financial statements are presented in the U.S. dollar ("$"), which is the Company's reporting currency, while its functional currencies are the U.S. Dollar for its U.S. based operations, British Pound ("GBP") for its United Kingdom-based operations and Australian Dollars ("AUD") for its Australian-based operations. All assets and liabilities are translated at the exchange rate on the balance sheet date, stockholders' equity is translated at historical rates and statement of operations items are translated at the weighted average exchange rate for the period. The resulting translation adjustments are reported under other comprehensive income. Gains and losses resulting from the translations of foreign currency transactions and balances are reflected in the statement of operations and comprehensive income (loss).

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments, as clarified in subsequent amendments. ASU 2016-13 changes the impairment model for certain financial instruments. The new model is a forward-looking expected loss model and will apply to financial assets subject to credit losses and measured at amortized cost and certain off-balance sheet credit exposures. This includes loans, held-to-maturity debt securities, loan commitments, financial guarantees and net investments in leases, as well as trade receivables. For available-for-sale debt securities with unrealized losses, credit losses will be measured in a manner similar to today, except that the losses will be recognized as allowances rather than reductions in the amortized cost of the securities. In October 2019, the FASB voted to delay the effective date of this standard. Topic 326 became effective for the Company on January 1, 2023. Adoption of the ASU is on a modified retrospective basis. The Company adopted ASU 2013-13 on January 1, 2023, and the adoption of the ASU did not impact the Company's financial position, results of operations, cash flows or net loss per share.

Subsequent Events

The Company evaluates events that have occurred after the balance sheet date of September 30, 2023, through the date which the financial statements are issued.

NOTE 4 – RESEARCH AND DEVELOPMENT ACTIVITY

According to UK tax law, the Company is allowed an R&D tax credit that reduces a company's tax bill in the UK for expenses incurred in R&D subject to certain requirements. The Company's UK subsidiary submits R&D tax credit requests annually for research and development expenses incurred. At September 30, 2023 and December 31, 2022, the Company recorded a research and development tax credit receivable in the amount of $0 and $2,690,000, respectively. During the nine months ended September 30, 2023 and 2022, the Company received $ 2,710,000 and $0, respectively, of R&D tax credit reimbursements from the UK.

According to AUS tax law, the Company is allowed an R&D tax credit that reduces a company's tax bill in AUS for expenses incurred in R&D subject to certain requirements. The Company's Australian subsidiary submits R&D tax credit requests annually for research and development expenses incurred. At September 30, 2023 and December 31, 2022, the Company recorded a research and development tax credit receivable of $2,087,000 and $5,409,000, respectively, for R&D expenses incurred in Australia. During the nine months ended September 30, 2023 and 2022, the Company received $3,763,000 and $0, respectively, of R&D tax credit reimbursements from Australia.

Xencor, Inc. License Agreement

On October 3, 2017, the Company entered into a license agreement ("Xencor License Agreement") with Xencor, Inc. ("Xencor"), which discovered and developed a proprietary biological molecule that inhibits soluble tumor necrosis factor. On June 10, 2021, the Company and Xencor entered into a First Amendment to License Agreement pursuant to which, among other things, Section 3.2 of the Xencor License Agreement was amended to change the due diligence milestones. Pursuant to the Xencor License Agreement, Xencor granted the Company an exclusive worldwide, royalty-bearing license in licensed patent rights, licensed know-how and licensed materials (as defined in the license agreement) to make, develop, use, sell and import any pharmaceutical product that comprises, contains, or incorporates Xencor's proprietary protein known as "XPro" that inhibits soluble tumor necrosis factor (or all modifications, formulations and variants of the licensed protein that specifically bind soluble tumor necrosis factor) alone or in combination with one or more active ingredients, in any dosage or formulation ("Licensed Products"). The Company believes the protein has numerous medical applications. Such additional alternative applications of the technology are available under the Xencor License Agreement.

The Company also agreed to pay Xencor a 5% royalty on Net Sales of all Licensed Products in a given calendar year, which are payable on a country-by- country and licensed product by licensed product basis until the date that is the later of (a) the expiration of the last to expire valid claim covering such Licensed Product in such country or (b) ten years following the first sale to a third party of the licensed product in such country.

INKmune License Agreement

On October 29, 2015, the Company entered into an exclusive license agreement (the "INKmune License Agreement") with Immune Ventures, LLC ("Immune Ventures"). Pursuant to the INKmune License Agreement, the Company was granted exclusive worldwide rights to the patents, including rights to incorporate any improvements or additions to the patents that may be developed in the future. In consideration for the patent rights, the Company agreed to the following milestone payments:

(in thousands)	
Each Phase I initiation	$ 25
Each Phase II initiation	$ 250
Each Phase III initiation	$ 350
Each NDA/EMA filing	$ 1,000
Each NDA/EMA awarded	$ 9,000

In addition, the Company agreed to pay the licensor a royalty of 1% of net sales during the life of each patent granted to the Company. The License is owned by Immune Ventures. RJ Tesi, the Company's President and a member of our Board of Directors, David Moss, its Chief Financial Officer and Treasurer and Mark Lowdell, its Chief Scientific Officer, are the owners of Immune Ventures. No sales have occurred under this license.

The term of the agreement began on October 29, 2015 and ends on a country-by-country basis on the date of the expiration of the last to expire patent rights where patent rights exists, unless terminated earlier in accordance with the agreement. Upon the termination of the agreement, we shall have a fully paid up, perpetual, royalty-free license without further obligation to Immune Ventures. The agreement can be terminated by Immune Ventures if, after 60 days from the Company's receipt of notice that the Company has not made a payment under the agreement, and the Company still does not make this payment. On July 20, 2018 and October 30, 2020, the parties amended the agreement under which the Company was required achieve milestones pursuant to the agreement.

On April 17, 2023, the parties executed an additional amendment to the agreement under which the Company removed the due diligence requirements to achieve reasonable commercial efforts to bring INKmune to market. This removed all requirements of clinical trial timelines and the filing timelines of an NDA or equivalent. All other provisions in the INKmune License Agreement shall continue in full force and effect.

University of Pittsburg License Agreement

On October 3, 2017, the Company entered into an Assignment and Assumption Agreement with Immune Ventures related to intellectual property licensed from the University of Pittsburgh. Pursuant to the Assignment and Assumption Agreement ("Assignment Agreement"), Immune Ventures assigned all of its rights, obligations and liabilities under an Exclusive License Agreement between the University of Pittsburgh – Of the Commonwealth System of Higher Education ("Licensor") and Immune Ventures to INmune Bio ("Licensee"), (the "PITT Agreement").

Consideration under the PITT Agreement includes: (i) annual maintenance fees, (ii) royalty payments based on the sale of products making use of the licensed technology, and (iii) milestone payments.

Annual maintenance fees under the PITT Agreement include the following:

(in thousands)	
June 26 of each year 2021-2022	$ 5
June 26 of each year 2023-2024	$ 10
June 26 of each year 2025 until first commercial sale	$ 25

Upon first commercial sale of a product making use of the licensed technology under the PITT Agreement, the Licensee is required to pay royalties equal to 2.5% of Net Sales each calendar quarter.

Moreover, under the PITT Agreement the Licensee is required to make milestone payments as follows:

(in thousands)	
Each Phase I initiation	$ 50
Each Phase III initiation	$ 500
First commercial sale of product making use of licensed technology	$ 1,250

The Company had no amounts owed pursuant to the PITT Agreement as of September 30, 2023.

The PITT Agreement expires upon the earlier of: (i) expiration of the last claim of the Patent Rights (as defined in the PITT Agreement) forming the subject matter of the PITT Agreement; or (ii) the date that is 20 years from the effective date of the agreement (June 26, 2037).

The Licensee may terminate the PITT Agreement upon 3 months prior written notice provided all payments under the license are current. The Licensor may terminate the PITT Agreement upon written notice if: (i) Licensee defaults as to performance of material obligations which have not been cured within 60 days after receiving written notice; or (ii) Licensee ceases to carry out its business, becomes bankrupt or insolvent, applies for or consents to the appointment of a trustee, receiver or liquidator of its assets or seeks relief under any law for the aid of debtors.

NOTE 5 – FAIR VALUE MEASUREMENTS

The following table presents the hierarchy for assets and liabilities measured at fair value on a recurring basis:

(in thousands)	Total	Quoted Price in Active Market (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
September 30, 2023:				
Cash equivalents				
Money market funds	$ 41,567	$ 41,567	$ -	$ -
Total cash equivalents	$ 41,567	$ 41,567	$ -	$ -

(in thousands)	Total	Quoted Price in Active Market (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
December 31, 2022:				
Cash equivalents				
Money market fund	$ 51,058	$ 51,058	$ -	$ -
Total cash equivalents	$ 51,058	$ 51,058	$ -	$ -

NOTE 6 – LEASE

The Company leases office space in Florida from a third party. The lease agreement has a 64-month term and commenced during the fourth quarter of 2021.

Below is a summary of the Company's right-of-use assets and liabilities:

(in thousands, except years and rate)	September 30, 2023	December 31, 2022
Right-of-use asset	$ 444	$ 507
Operating lease, current liability	$ 106	$ 87
Long-term operating lease liability	$ 430	$ 526
Total lease liability	$ 536	$ 613
Weighted-average remaining lease term	3.5 years	4.3 years
Weighted-average discount rate	12.0%	12.0%

NOTE 7 – RELATED PARTY TRANSACTIONS

UCL

At September 30, 2023 and December 31, 2022, the Company owed UCL Consultants Limited ("UCL") $ 9,000 in connection with medical research performed on behalf of the Company. During the nine months ended September 30, 2023 and 2022, the Company paid UCL $334,000 and $486,000, respectively, for medical research performed on behalf of the Company. At September 30, 2023 and December 31, 2022, the Company recorded $0 and $34,000, respectively, of prepaid expenses – related party for payments made to UCL in advance of services to be provided. UCL is a wholly owned subsidiary of the University of London. The Company's Chief Scientific and Manufacturing Officer is a professor at the University of London.

AmplifyBio

At September 30, 2023 and December 31, 2022, the Company owed AmplifyBio $ 70,000 and $0, respectively, in connection with medical research performed on behalf of the Company. The CEO of AmplifyBio is on the Board of Directors of the Company. During the nine months ended September 30, 2023 and 2022, the Company paid AmplifyBio $7,000 and $145,000, respectively, for pre-clinical research performed on behalf of the Company.

NOTE 8 – DEBT

On June 10, 2021, the Company entered into a Loan and Security Agreement (the "Term Loan") with Silicon Valley Bank and SVB Innovation Credit Fund VIII, L.P. The Term Loan provided for a $ 15.0 million term loan, of which the Company borrowed the entire amount on June 10, 2021, and is secured by the Company's assets. On June 7, 2023, the Company entered into an amendment to the Term Loan pursuant to which, among other things, certain covenants to the Term Loan were amended.

The term loan and debt discount are as follows as of September 30, 2023:

(in thousands)	
Term Loan	$ 12,500
Less: debt discount and financing costs, net	(124)
Less: current portion	(10,000)
Long-term debt	$ 2,376

For the three and nine months ended September 30, 2023, the Company recognized interest expense of $ 568,000 and $1,811,000, respectively, related to the Term Loan. For the three and nine months ended September 30, 2022, the Company recognized interest expense of $525,000 and $1,424,000, respectively, related to the Term Loan.

The Company is required to make interest and principal payments monthly through the maturity date of January 1, 2025. All outstanding principal and accrued and unpaid interest will be due and payable on the maturity date. The Term Loan provides for an annual interest rate equal to the greater of (i) the prime rate then in effect as reported in The Wall Street Journal plus 4.50% and (ii) 7.75%. At September 30, 2023, the interest rate was 13.0%.

The Term Loan includes a final payment fee equal to 6.5% of the original principal amount borrowed payable on the earlier of the repayment of the loan in full and the maturity date. The Company has the option to prepay the outstanding balance of the term loan in full, subject to a prepayment premium of 1% of the original principal amount borrowed for any prepayment before the maturity date.

The expected repayment of the Term loan principal is as follows as of September 30, 2023:

(in thousands, except years)	
2023	$ 2,500
2024	10,000

Total debt	$ 12,500

Upon the occurrence of certain events, including but not limited to the Company's failure to satisfy its payment obligations under the Term Loan, the breach of certain of its other covenants under the Term Loan, or the occurrence of a material adverse change, the Lenders will have the right, among other remedies, to declare all principal and interest immediately due and payable, and will have the right to receive the final payment fee and, if the payment of principal and interest is due prior to maturity, the applicable prepayment fee. The Company violated certain non-financial debt covenants as of December 31, 2022 and received a waiver from the Lenders waiving these debt covenant violations during the nine months ended September 30, 2023. The Company was in compliance with its debt covenants at September 30, 2023 and the filing date of these financial statements.

NOTE 9 – STOCKHOLDERS' EQUITY

Common Stock – At the Market Offering

During March 2021, the Company entered into a sales agreement ("Sales Agreement") with BTIG, LLC ("BTIG"), as sales agent, to establish an At-The-Market ("ATM") offering program of up to $45 million of common stock, subject to certain limitations on the amount of common stock that may be offered and sold by the Company set forth in the sales agreement. During August 2023, the Company and BTIG entered into Amendment No. 1 to the Sales Agreement. The Company is required to pay BTIG a commission of 3% of the gross proceeds from the sale of shares.

During July 2023, the Company sold 75,697 shares of its common stock at an average price of $ 10.56 per share under the ATM program. The aggregate net proceeds were approximately $775,000 after offering expenses. These shares were inadvertently sold under a registration statement filed with the SEC that had in fact expired prior to the time the shares were sold. Consequently, the Company may be subject to claims for rescission by purchasers who purchased shares of common stock under the ATM program. Under Section 12(a)(1) of the Securities Act, a purchaser of security in a transaction made in violation of Section 5 of the Securities Act may obtain recovery of the consideration paid in connection with its purchase, plus statutory interest, or, if it had already sold the shares, recover damages resulting from its purchase. While the Company believes, it is unlikely that a successful claim will be asserted against the Company by any purchasers who purchased shares of common stock under the ATM Agreement in July 2023, the Company cannot guarantee that no such legal claims will be asserted against the Company by any purchasers. In addition, the Company could become subject to enforcement actions and/or penalties and fines by federal authorities, and the Company is unable to predict the likelihood of any such enforcement actions being brought, or the amount of any such potential penalties or fines. As of September 30, 2023, there have been no claims or demands to exercise such rights. As a result of these potential rescission rights, the Company reclassified 75,697 shares, with an aggregate purchase price of $799,000 of its common stock as temporary equity presented outside stockholders' equity. The reclassification of these shares shall remain for a period of one year from transaction date. These shares have been treated as issued and outstanding for financial reporting purposes.

At September 30, 2023, the Company has $28.7 million of common stock available under the ATM program. During September 2023, the Company and BTIG suspended the Sales Agreement.

Common Stock – Issuance to Directors and Officers

During the nine months ended September 30, 2022, directors and officers of the Company purchased 82,900 shares of the Company's common stock from the Company at $8.43 per share (which was the closing price of the Company's common stock on March 22, 2022) for gross proceeds of $699,000.

Stock options

On June 1, 2023, the Company's shareholders approved an amendment to the 2021 Incentive Stock Plan ("2021 Amended and Restated Incentive Stock Plan") to increase the shares of the Company's common stock available for issuance thereunder to 4,000,000 shares.

During the nine months ended September 30, 2023, the Company granted certain employees and directors options to purchase 665,000 shares of its common stock pursuant to the 2017 and 2019 Incentive Stock Plans and 2021 Amended and Restated Incentive Stock Plan. The stock options had a fair value of approximately $4.9 million that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 3.84% – 3.99% based on the applicable US Treasury bill rate (2) expected life of 6.0 – 6.25 years, (3) expected volatility of approximately 91% based on the trading history of similar companies, and (4) zero expected dividends.

The following table summarizes stock option activity during the nine months ended September 30, 2023:

(in thousands, except share and per share amounts)	Number of Shares	Weighted-average Exercise Price	Weighted-average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at January 1, 2023	4,841,417	$ 8.60	6.28	$ 4,155
Options granted	665,000	$ 9.69	-	-
Options exercised	-	$ -	-	-
Options cancelled	(5,417)	$ 15.48	-	-
Outstanding at September 30, 2023	5,501,000	$ 8.73	6.53	$ 4,891
Exercisable at September 30, 2023	4,190,104	$ 7.99	5.86	$ 4,880

During the three and nine months ended September 30, 2023, the Company recognized stock-based compensation expense of approximately $ 1.9 million and $5.5 million, respectively, related to the vesting of stock options. During the three and nine months ended September 30, 2022, the Company recognized stock-based compensation expense of approximately $1.9 million and $5.4 million, respectively, related to the vesting of stock options. As of September 30, 2023, there was approximately $10.5 million of total unrecognized compensation cost related to non-vested stock options which is expected to be recognized over a weighted-average period of 1.98 years.

Warrants

The Company issued warrants to the Company's lenders upon obtaining its loan in June 2021. The warrants have a 10-year term and an exercise price of $14.05. At September 30, 2023, 45,386 of these warrants are outstanding and the intrinsic value of these warrants is $ 0.

The Company issued warrants to its placement agents in connection with its February 2019 initial public offering. The warrants are exercisable until December 19, 2023, and have an exercise price of $9.60. At September 30, 2023, 28,688 of these warrants are outstanding and the intrinsic value is $ 0.

During the nine months ended September 30, 2022, a third party exercised 19,792 warrants for cash proceeds of approximately $ 30,000.

Stock-based Compensation by Class of Expense

The following summarizes the components of stock-based compensation expense in the consolidated statements of operations for the nine months ended September 30, 2023 and 2022 respectively:

(in thousands)	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Research and development	$ 705	$ 725	$ 2,043	$ 1,971
General and administrative	1,184	1,214	3,446	3,390
Total	$ 1,889	$ 1,939	$ 5,489	$ 5,361

Shareholder Rights Agreement

On December 30, 2020, the Board of Directors (the "Board") of the Company approved and adopted a Rights Agreement, dated as of December 30, 2020, by and between the Company and VStock Transfer, LLC, as rights agent, pursuant to which the Board declared a dividend of one preferred share purchase right (each, a "Right") for each outstanding share of the Company's common stock held by stockholders as of the close of business on January 11, 2021. When exercisable, each right initially would represent the right to purchase from the Company one one-thousandth of a share of a newly designated series of preferred stock, Series A Junior Participating Preferred Stock, par value $ 0.001 per share, of the Company, at an exercise price of $300.00 per one one-thousandth of a Series A Junior Participating Preferred Share, subject to adjustment. Subject to various exceptions, the Rights become exercisable in the event any person (excluding certain exempted or grandfathered persons) becomes the beneficial owner of twenty percent or more of the Company's common stock without the approval of the Board. On December 20, 2021, the Company entered into Amendment No. 1 to the Rights Agreement ("Amendment No. 1") to extend the expiration of the Rights Agreement to December 30, 2022. On December 9, 2022, the Company and VStock Transfer, LLC entered into Amendment No. 2 to Rights Agreement ("Amendment No. 2"). Pursuant to Amendment No. 2, the Rights Agreement extended the expiration of the Rights Agreement to December 30, 2023. The Rights are in all respects subject to and governed by the provisions of the Rights Agreement, as amended by the Amendment No.1 and Amendment No. 2.

NOTE 10 – COLLABORATIVE AGREEMENTS

During September 2020, the Company was awarded a grant of up to $ 2.9 million from the National Institutes of Health ("NIH"). The grant will support a Phase 2 study of XPro1595 in patients with treatment resistant depression. As of September 30, 2023, the Company has not received any proceeds pursuant to this grant.

NOTE 11 – COMMITMENTS

Lease

During September 2021, the Company signed a lease agreement with a third party for office space in Boca Raton, Florida. The lease agreement has a 64-month term and commenced during the fourth quarter of 2021.

Future minimum payments pursuant to the leases are as follows:

(in thousands, except years)	
2023	$ 31
2024	187
2025	192
2026	198
2027	51
Total lease payments	659
Less: imputed interest	(123)
Present value of future lease payments	536
Less: operating lease, current liabilities	(106)
Long-term operating lease liabilities	$ 430

During the three and nine months ended September 30, 2023, the Company recognized $ 41,000 and $123,000, respectively, in operating lease expense, which is included in general and administrative expenses in the Company's consolidated statement of operations.

During the three and nine months ended September 30, 2022, the Company recognized $ 45,000 and $162,000, respectively, in operating lease expense, which is included in general and administrative expenses in the Company's consolidated statement of operations

Litigation

The Company is subject to claims and suits that arise from time to time in the ordinary course of our business. Although management currently believes that resolving claims against the Company, individually or in aggregate, will not have a material adverse impact in the Company's consolidated financial statements, these matters are subject to inherent uncertainties and management's view of these matters may change in the future.

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

Forward-Looking Statements

This Form 10-Q contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. For this purpose, any statements contained in this Form 10-Q that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, words such as “may,” “will,” “expect,” “believe,” “anticipate,” “estimate” or “continue” or comparable terminology are intended to identify forward-looking statements. These statements by their nature involve substantial risks and uncertainties, and actual results may differ materially depending on a variety of factors, many of which are not within our control. These factors include but are not limited to economic conditions generally and in the industries in which we may participate; competition within our chosen industry, including competition from much larger competitors; technological advances and failure to successfully develop business relationships.

Description of Business

Overview

We are a clinical-stage immunology company focused on developing drugs that may reprogram the patient’s innate immune system to treat disease. We believe this may be done by targeting cells of the innate immune system that cause acute and chronic inflammation and are involved in immune dysfunction associated with chronic diseases such as cancer and neurodegenerative diseases. The Company’s drugs are still in the clinical trial stage and have not been approved by a regulatory authority. The Company has two therapeutic platforms – a dominant-negative TNF platform (“DN-TNF”, “XPro™”, “XPro1595™” or “*pegipanermin and pSar DN-TNF”*) and a Natural Killer (“NK”, or “INKmune™”) platform. The DN-TNF platform neutralizes soluble tumor necrosis factor (“sTNF”) without affecting trans-membrane TNF (“tmTNF”) or TNF receptors -TNFR1 and TNFR2. This unique biologic mechanism differentiates the DN-TNF drugs from currently approved non-selective TNF inhibitors that inhibit both sTNF and tmTNF. Protecting the function of tmTNF and TNF receptors while neutralizing the function of sTNF is a potentially potent anti-inflammatory strategy that does not cause immunosuppression or demyelination which occur in the currently approved non-selective TNF inhibitors. Currently approved non-selective TNF inhibitors treat autoimmune disease, but are contraindicated in patients with infection, cancer and neurologic diseases because they increase the risk of infection, cancer and demyelinating neurologic diseases, respectively; these safety problems are due to off-target effects on inhibiting tmTNF. The NK platform targets the dysfunctional natural killer cells in patients with cancer. NK cells are part of the normal immunologic response to cancer with important roles in immunosurveillance to prevent cancer and in preventing relapse by eliminating residual disease. Residual disease is the cancer left behind after therapy is finished. Residual disease can grow to cause relapse. The mechanism by which INKmune may improve the ability of the patient’s NK cells to kill their cancer is complex. The NK cells of cancer patients lose the ability to bind and kill cancer cells. A measure of NK cell binding to cancer cells is avidity. The higher the avidity, the greater the bond between the NK cell to cancer cell and thus the greater NK killing of cancer cells. INKmune increases NK avidity and further improves mitochondrial function and upregulates nutrient receptors. These metabolic changes may help the INKmune primed NK cell to function in the hostile tumor microenvironment and persist much longer in the patient. These mechanisms thus may improve the ability of INKmune primed NK cells to overcome the immune evasion of the patient’s cancer cells. We believe INKmune would best be used to eliminate residual disease after the patient has completed other cancer therapies. Both the DN-TNF platform and the INKmune platform have the potential to be used to treat multiple diseases. The DN-TNF platform is being developed to be used as an immunotherapy for the treatment of cancer and neurodegenerative disease. INKmune is being developed to treat NK sensitive hematologic malignancies and solid tumors.

We believe our DN-TNF platform can be used as a cancer therapy to reduce resistance in immunotherapy and as a CNS (“central nervous system”) therapy to target glial activation to prevent progression of Alzheimer’s disease (“AD”), to target neuroinflammation in treatment resistant depression (“TRD”), and as a drug to prevent muscle degeneration, prevent fibrosis and promote muscle regeneration in Duchene muscular dystrophy (“DMD”). The drug is named differently for the oncology and CNS indications; INB03™ or XPro™, respectively, but it is the same drug product. For DMD, the company is exploring pSar DN-TNF compounds optimized for the treatment of DMD. The pSar DN-TNF compound has the same mechanism of action, a different half-life extender and novel IP protection. In each case, we believe neutralizing sTNF is a cornerstone to the treatment of these diseases. As an immunotherapy for cancer, we are developing INB03 to neutralize sTNF produced by HER2+ trastuzumab resistant breast cancers to reverse resistance to targeted therapy. sTNF produced by the tumor causes an up-regulation of MUC4 expression causing steric hindrance of trastuzumab binding to the HER receptor on HER2+ breast cancer cells. Without binding, trastuzumab based therapies are not effective. Neutralizing sTNF reverses MUC4 expression converting a trastuzumab resistant breast cancer cell into a trastuzumab sensitive breast cancer cell. In addition, INB03 may change the immunobiology of the tumor microenvironment by decreasing the number of immunosuppressive myeloid cells, both myeloid derived suppressor cells and tumor active macrophages, and increasing the number of cytotoxic lymphocytes and phagocytic macrophages in the TME. Recently, the Company has shown the combination of INB03 with trastuzumab-deruxtecan (Enhertu), decreases tumor growth in the multi-resistant JIMT-1 tumor model. The Company has completed an open label dose escalation trial in cancer patients with metastatic solid tumors that have failed multiple lines of therapy. The trial informs the design of the planned Phase II trial by demonstrating that INB03 was safe and well tolerated, defining the dose of INB03 to carry into Phase II trials, and demonstrating a pharmacodynamic endpoint – a decrease in inflammatory cytokines in the blood. A Phase II trial is planned in patients with advanced MUC4+ expressing cancer.

Likewise, we believe the DN-TNF platform can be used to treat selected neurodegenerative diseases by modifying the brain microenvironment (“BME”). The Company believes the core pathology of cognitive decline is a combination of neurodegeneration and synaptic dysfunction. Neurodegeneration is nerve cell death that may include demyelination. Synaptic dysfunction means the connections between nerve cells stop working efficiently and may decrease in number or become disconnected. The combination of neurodegeneration and synaptic dysfunction causes cognitive decline and behavioral changes associated with Alzheimer’s disease (“AD”). XPro completed a Phase I trial treating patients with Alzheimer’s disease that was partially funded by a Part-the-Clouds Award from the Alzheimer’s Association. We believe XPro targets activated microglia and astrocytes of the brain that produce sTNF that promotes nerve cell loss and synaptic dysfunction, key elements in the development of dementia. In animal models, elimination of sTNF prevents nerve cell dysfunction and reverses synaptic pruning. The Phase I trial in patients with biomarkers of inflammation with AD has been completed. The open label, dose escalation trial was designed to demonstrate that XPro can safely decrease neuroinflammation in patients with ADi. ADi is the term used to delineate patients with AD with biomarkers of inflammation. This appears to be more than 40% of patients with AD. The endpoints of the trial are measures of neuroinflammation and neurodegeneration in blood and cerebral spinal fluid by measuring changes in inflammatory cytokine levels in the CNS and using MRI-DTI to measure white matter free water. White matter free water is a validated measure of neuroinflammation in the brain. XPro, at the 1mg/kg/week dose decreased inflammatory cytokines in the CSF and decreased white matter free water in the brain demonstrating that XPro can decrease neuroinflammation in patients with ADi. We also studied downstream benefits of decreasing neuroinflammation by measuring changes in the CSF proteome and quantifying changes in novel white matter MRI biomarkers. XPro significantly decreased biomarkers of neurodegeneration as measured by changes in the CSF proteome including neurofilament light chain, phospho Tau 217 and VILIP-1; decreases of 84%, 46% and 91% respectively were observed after 3 months of therapy. Three months of XPro therapy improved measures of synaptic function, as measured in the CSF proteome including a 222% increase in contactin 2 and a 56% decrease of neurogranin, changes that contribute to improved synaptic function.

The successful completion of the Phase I trial in AD has informed the design of a blinded randomized, placebo-controlled Phase II trial in patients with early ADi. Early ADi includes patients with AD and MCI who have at least one biomarker of inflammation (ADi and MCI ^{2} respectively). The early ADi trial is a blinded randomized trial to test if treatment of early AD patients with neuroinflammation with XPro will affect cognitive decline. The Phase II trial in early ADi has six important elements. Two hundred and ten patients will be enrolled in a 2:1 ratio (XPro vs placebo). The patients will receive 1mg/kg/week as a subcutaneous injection for six months. An enrichment strategy identical to the successful strategy used in the Phase I trial will be used to ensure patients have neuroinflammation. Patients will need to have one or more enrichment criteria: elevated blood level of at least one of C-reactive protein, hemoglobin A1c, erythrocyte sedimentation and/or at least one allele of ApoE4. The primary endpoint will be Early/ild Alzheimer’s Cognitive

Composite (“EMACC”), a validated cognitive measure that is more sensitive than traditional end-points used in many studies of patients with early AD. The trial is open in Australia, Canada and the United Kingdom and will open in the US pending the lift of a clinical hold by the FDA. All patients will be offered to stay on therapy for at least 12 months in an extension trial. Clinical and biomarker data will be collected during the extension trial.

Effective therapy for TRD is a large unmet need. Twenty percent of patients with a Major Depressive Disorder have TRD. Once third of TRD patients have peripheral biomarkers to inflammation (elevated CRP). This is a large patient population. The role of TNF and anti-TNF therapeutics was explored in a small open label clinical trial by Prof. Andrew Miller, MD of Emory University. This study involved patients with elevated TNF levels who were treated with infliximab for their depression (Miller, 2011). The Company received a $2.9M USD award from the National Institute of Mental Health (“NIMH”) to treat TRD with XPro. The blinded, randomized Phase II trial will use biomarkers of peripheral inflammation to select patients with TRD for enrollment. Patients will be treated for 6 weeks. Primary endpoints include both clinical and neuroimaging measures. The final trial design is ongoing and discussions with the FDA are not complete. The Company anticipates receiving authorization to initiate the clinical trial once the pending clinical hold is lifted.

The Company completed an extensive series of studies in murine models of DMD. The data shows DN-TNF decreased muscle fiber inflammation and degeneration, and increased muscle fiber regeneration in an acute model of DMD. Cardiac function was studied using echocardiography after 30 weeks of treatment. Cardiac function did not change compared to placebo treated or prednisone treated animals. These data strongly suggest DN-TNF may be a therapy for treatment of patients with DMD that may have unique biologic attributes, muscle fiber regeneration, without corticosteroid associated metabolic toxicity such as insulin resistance, diabetes, obesity, hirsutism, short stature and muscle weakness.

We believe that INKmune improves the ability of the patient’s own NK cells to attack their tumor. INKmune interacts with the patient’s NK cells to convert them from inert resting NK cells into memory-like NK cells that attack the patient’s cancer cells. INKmune is a replication incompetent proprietary cell line that is given to the patient after determining that i) the patient has adequate NK cells in their circulation and ii) those NK cells are functional when exposed to INKmune in vitro. INKmune is designed to be given to patients after their immune system has recovered after cytotoxic chemotherapy to target the residual disease the remains after treatment with cytotoxic therapy. We believe INKmune can be used to treat numerous hematologic malignancies and solid tumors including leukemia, multiple myeloma, lymphoma, lung, ovary, breast, renal, nasopharyngeal and prostate cancer. The Company has initiated a Phase I trial using INKmune to treat patients with high risk MDS/AML, a form of leukemia. Two patients have been treated in the Phase I trial for MDS and three patients have been treated compassionately in AML. In the five patients, INKmune therapy showed a favorable safety profile, produced memory-like NK cells that killed cancer in vitro, and promoted development of cancer killing memory-like NK cells that were found in the patient’s circulation after 4 months. The Company will continue to enroll patients in the Phase I trial. The Company intends to initiate a separate Phase I/II trial of INKmune in a metastatic castration resistant prostate cancer (“mCRPC”) tumor during 2024. An IND for a Phase I/II trial in men with mCRPC was filed in May 2023. The trial will treat up to 30 patients with mCRPC in an open label trial. The trial has four goals: i) demonstrate safety of INKmune in men with mCRPC; ii) determine what dose of INKmune should be used in a blinded randomized Phase II trial on men with mCRPC; iii) determine tumor response using traditional biomarkers of mCRPC including blood PSA level and iv) use exploratory biomarkers of tumor response including circulating tumor DNA and PET PMSA imaging studies. The first patients should be treated 9 months after the IND is open.

Since our inception in 2015, we have devoted substantially all our resources to the discovery and development of our product candidates, including clinical trials and preclinical studies as well as general and administrative support for these operations. To date, we have generated no significant revenue. We have incurred net losses in each year since our inception and, as of September 30, 2023, we had an accumulated deficit of approximately $112.6 million. Our net losses were $21,600,000 and $21,466,000 for the nine months ended September 30, 2023 and 2022, respectively. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations, including stock-based compensation. We anticipate that we will continue to generate substantial losses for the foreseeable future.

There may be significant uncertainty resulting from the impact of other geopolitical and macroeconomic factors, including the ongoing COVID-19 (coronavirus) pandemic, inflation, supply chain issues, rising interest rates, future bank failures, a potential US government shutdown, and the impact of the conflicts in Russia/Ukraine and Israel, in addition to geopolitical, trade and investment tensions between the United States and China.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical studies, clinical trials and regulatory approval prior to commercialization. These efforts require significant amounts of additional resources, adequate personnel, infrastructure and extensive compliance and reporting.

The Company’s product candidates are still in development and, to date, none of the Company’s product candidates have been approved for sale.

There can be no assurance that the Company’s research and development will be successfully completed, that adequate protection for the Company’s intellectual property will be obtained or maintained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will generate any revenue from any of its products. The Company operates in an environment of rapid change in technology and substantial competition from other pharmaceutical and biotechnology companies.

The Company relies and expects to continue to rely on a small number of vendors to manufacture supplies and materials for its use in the clinical trial programs. These programs could be adversely affected by a significant interruption in these manufacturing services.

We classify our operating expenses into two categories: research and development; and general and administrative expenses. Personnel costs including salaries, benefits and stock-based compensation expense comprise a significant component of our research and development and general and administrative expense categories.

We qualify as an “emerging growth company” under the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- reduced disclosure about our executive compensation arrangements;
- no non-binding advisory votes on executive compensation or golden parachute arrangements;
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting; and

- delaying the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies.

We have elected to take advantage of the above-referenced exemptions and we may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1.235 billion in annual revenues, we have more than $700 million in market value of our stock held by non-affiliates, or we issue more than $1 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced burdens.

Research and Development

Research and development expense consists of expenses incurred while performing research and development activities to discover and develop our product candidates. This includes conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for product candidates. We recognize research and development expenses as they are incurred. Our research and development expense primarily consist of:

- clinical trial and regulatory-related costs;
- expenses incurred under agreements with investigative sites and consultants that conduct our clinical trials;
- manufacturing and testing costs and related supplies and materials; and
- employee-related expenses, including salaries, benefits, travel and stock-based compensation.

The following table summarizes our research and development expenses by product candidate for the periods indicated (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
External Costs				
DN-TNF - Alzheimer's disease	$ 3,823	$ 3,319	$ 8,498	$ 8,328
INKmune - High Risk MDS/AML & Prostate cancer	840	413	1,697	790
Preclinical and other programs	214	94	632	1,379
Accrued research and development rebate	(224)	132	(493)	(316)
Total external costs	4,653	3,958	10,334	10,181
Internal costs	1,332	1,201	3,932	3,476
Total	$ 5,985	$ 5,159	$ 14,266	$ 13,657

We typically use our employee resources across our development programs. We track outsourced development costs by product candidate or development program, but we do not allocate internal costs personnel costs including salaries and stock-based compensation to specific product candidates or development programs.

We participate, through our wholly owned subsidiary in Australia, in the Australian research and development tax incentive program, such that a percentage of our qualifying research and development expenditures are reimbursed by the Australian government, and such incentives are reflected as a reduction of research and development expense. The Australian research and development tax incentive is recognized when there is reasonable assurance that the incentive will be received, the relevant expenditure has been incurred and the amount of the consideration can be reliably measured.

We participate, through our wholly owned subsidiary in the United Kingdom, in the research and development program provided by the United Kingdom tax relief program, such that a percentage of our qualifying research and development expenditures are reimbursed by the United Kingdom government, and such incentives are reflected as a reduction of research and development expense. The United Kingdom research and development tax incentive is recognized when there is reasonable assurance that the incentive will be received, the relevant expenditure has been incurred and the amount of the consideration can be reliably measured.

Substantially all our research and development expenses to date have been incurred in connection with our current and future product candidates. We expect our research and development expenses to increase significantly for the foreseeable future as we advance an increased number of our product candidates through clinical development, including the conduct of our planned clinical trials and manufacturing drug to be used in those clinical trials. The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. The successful development of product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs required to complete the remaining development of any product candidates. This is due to the numerous risks and uncertainties associated with the development of product candidates.

The costs of clinical trials may vary significantly over the life of a project owing to, but not limited to, the following:

- per patient trial costs;
- the number of sites included in the clinical trials;
- the countries in which the clinical trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the clinical trials;
- the number of doses that patients receive;
- the cost of comparative agents used in clinical trials;
- the drop-out or discontinuation rates of patients;

- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up;
- the efficacy and safety profile of the product candidate; and
- the cost of manufacturing, finishing, labelling and storage drug used in the clinical trial.

We do not expect any of our product candidates to be commercially available for at least the next several years, if ever. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, which may fluctuate significantly from quarter-to-quarter and year-to-year. We anticipate that our expenses will increase substantially as we:

- continue research and development, including preclinical and clinical development of our existing product candidates;
- potentially seek regulatory approval for our product candidates;
- seek to discover and develop additional product candidates;
- establish a commercialization infrastructure and scale up our manufacturing and distribution capabilities to commercialize any of our product candidates for which we may obtain regulatory approval;
- seek to comply with regulatory standards and laws;
- maintain, leverage and expand our intellectual property portfolio;
- hire clinical, manufacturing, scientific and other personnel to support our product candidates development and future commercialization efforts;
- add operational, financial and management information systems and personnel; and
- incur additional legal, accounting and other expenses in operating as a public company.

General and Administrative Expenses

General and administrative expenses consist principally of payroll and personnel expenses, including stock-based compensation; professional fees for legal, consulting, accounting and tax services; overhead, including rent and utilities; and other general operating expenses not otherwise classified as research and development expenses.

Other income (expense)

Other income (expense consists) primarily of interest expense incurred on debt and interest income on investments in money market accounts.

Results of Operations

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

The following table summarizes our results of operations for the periods indicated:

	Three Months Ended September 30,		
(in thousands)	**2023**	**2022**	**Change**
Revenues	$ 43	$ 98	$ (55)
Operating expenses:			
Research and development	5,985	5,159	826
General and administrative	2,586	2,382	204
Total operating expenses	8,571	7,541	1,030
Loss from operations	(8,528)	(7,443)	(1,085)
Other expense, net	(35)	(282)	247
Net loss	$ (8,563)	$ (7,725)	$ (838)

Revenues

During the three months ended September 30, 2023 and 2022, the Company sold MSC's to one third-party and recognized $43,000 and $98,000, respectively, of revenues.

General and Administrative

General and administrative expenses were approximately $2.6 and $2.4 million during the three months ended September 30, 2023 and 2022, respectively. The $0.2 million increase in general and administrative expenses was due to higher consulting expense in 2023.

Research and Development

Research and development expenses were approximately $6.0 million during the three months ended September 30, 2023, compared to approximately $5.2 million during the three months ended September 30, 2022. The change in research and development expenses during the three months ending September 30, 2023 compared to the three months ending September 30, 2022 is largely due to incurring $0.5 million of additional expenses related to our Alzheimer's clinical program, $0.4 million of additional expenses on our INKmune clinical program, $0.1 million of additional other clinical program expenses and $0.1 million of higher employee compensation costs, partially offset by an increase of $0.4 million of accrued rebate.

Other Expense, net

The Company's other expense, net is lower during the three months ended September 30, 2023, due to the Company earning higher interest income on its money market accounts, which partially offsets the interest expense incurred on our debt.

Comparison of the Nine Months Ended September 30, 2023 and 2022

The following table summarizes our results of operations for the periods indicated:

	Nine Months Ended September 30,		
(in thousands)	**2023**	**2022**	**Change**
Revenues	$ 127	$ 277	$ (150)
Operating expenses:			
Research and development	14,266	13,657	609
General and administrative	7,223	6,929	294
Total operating expenses	21,489	20,586	903
Loss from operations	(21,362)	(20,309)	(1,053)
Other expense, net	(238)	(1,157)	919
Net loss	$ (21,600)	$ (21,466)	$ (134)

Revenues

During the nine months ended September 30, 2023, and 2022, the Company sold MSC's to one third-party and recognized $127,000 and $277,000, respectively, of revenues.

General and Administrative

General and administrative expenses were approximately $7.2 million and $6.9 million during the nine months ended September 30, 2023 and 2022, respectively. The $0.3 million increase in general and administrative expenses was due to higher stock-based compensation expense and higher consulting fees in 2023.

Research and Development

Research and development expenses were approximately $14.3 million and $13.7 million during the nine months ended September 30, 2023 and 2022, respectively. The increase in research and development expenses during the nine months ending September 30, 2023 compared to the nine months ending September 30, 2022 is largely due to incurring $0.9 million of additional expenses related to our INKmune clinical program, incurring $0.2 million of additional expenses with our Alzheimer's clinical program and $0.5 million of additional employee compensation, partially offset by incurring $0.7 million less expenses associated with other clinical programs and $0.2 million of additional accrued rebate.

Other Expense, net

The Company's other expense, net is lower during the nine months ended September 30, 2023, due to the Company earning higher interest income on its money market accounts, which partially offsets the interest expense incurred on our debt.

Liquidity and Capital Resources

Liquidity is the ability of a company to generate funds to support its current and future operations, satisfy its obligations and otherwise operate on an ongoing basis.

We incurred a net loss of $21.6 million and $21.5 million for the nine months ended September 30, 2023 and 2022, respectively. Net cash used in operating activities was $8.6 million and $17.0 million for the nine months ended September 30, 2023 and 2022, respectively. Since inception, we have funded our operations primarily with proceeds from the sales of our common stock. As of September 30, 2023, we had cash and cash equivalents of approximately $41.8 million. We anticipate that operating losses and net cash used in operating activities will increase over the next few years as we advance our products under development.

Our primary uses of capital are, and we expect will continue to be, third-party clinical and preclinical research and development services, compensation and related expenses, professional fees, patent and other regulatory expenses and general overhead costs. We believe our use of CROs provides us with flexibility in managing our spending.

The Company incurs various expenses in Australia and the United Kingdom. Fluctuations in the rate of exchange between the United States dollar and the pound sterling as well as the Australian dollar could adversely affect our financial results, including our expenses as well as assets and liabilities. We currently do not hedge foreign currencies but will continue to assess whether that strategy is appropriate. As of September 30, 2023, the cash balance held by our foreign subsidiaries with currencies other than the United States dollar was less than $0.1 million. We do not have any material financial exposure to one customer or one country that would significantly hinder our liquidity.

As a publicly traded company, we incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act of 2002, as well as rules adopted by the SEC and The Nasdaq Stock Market, require public companies to implement specified corporate governance practices that were inapplicable to us as a private company. We expect these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

As of September 30, 2023, the Company had an accumulated deficit of $112.6 million and working capital of $31.3 million. Losses have principally occurred as a result of stock-based compensation expense as well as the substantial resources required for research and development of the Company's products which included the general and administrative expenses associated with its organization and product development, as well as the lack of sources of revenues until such time as the Company's products are commercialized. As of September 30, 2023, we had cash and cash equivalents of approximately $41.8 million. We believe our cash and cash equivalents will be sufficient to fund our operations for at least the next 12 months following the filing date of this Quarterly Report on Form 10-Q based on the balance of cash available as of September 30, 2023. We anticipate,

however, that we will continue to generate losses for the foreseeable future, and we expect the losses to increase materially as we continue the development of, and seek regulatory approvals for, our drug candidates, and seek to commercialize any drugs for which we receive regulatory approval. We will need to raise additional capital to fund our operations and complete our ongoing and planned clinical trials. Although we expect to finance future cash needs through public equity or debt offerings, no assurance can be given that any future funding will be available to us, or if available that such proposed funding will be on terms that are acceptable to us. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Nine Months Ended September 30,	
(in thousands)	**2023**	**2022**
Net cash and cash equivalents (used in) provided by:		
Operating activities	$ (8,579)	$ (16,991)
Financing activities	(1,725)	729
Change in cash and cash equivalents	(10,304)	(16,262)
Impact on cash from foreign currency translation	(36)	(1,143)
Cash and cash equivalents, beginning of period	52,153	74,810
Cash and cash equivalents, end of period	$ 41,813	$ 57,405

Operating Activities

Our cash used in operating activities was primarily driven by our net loss.

Operating activities used approximately $8.6 million of cash during the nine months ended September 30, 2023, resulting from our loss of $21.6 million, partially offset by changes in our net operating assets and liabilities of $7.4 million and non-cash stock-based compensation of $5.5 million. The change in our net operating assets and liabilities was mainly due to a decrease in research and development tax credit receivable of $6.0 million and a decrease in prepaid expenses of $2.5 million, partially offset by a decrease in accounts payable and accrued liabilities of $1.5 million.

Operating activities used approximately $17.0 million of cash during the nine months ended September 30, 2022, resulting from our loss of $21.5 million and changes in our net operating assets and liabilities of $1.1 million, partially offset by non-cash stock-based compensation of $5.4 million. The change in our net operating assets and liabilities was mainly due to an increase in prepaid expenses of approximately $2.3 million, partially offset by a decrease in other tax receivable of $0.5 million and a decrease in research and development tax credit receivable of $0.5 million.

Financing Activities

During the nine months ended September 30, 2023, the Company sold 75,697 shares of its common stock for net proceeds of $775,000 under the Company's ATM program with BTIG. The Company suspended its Sales Agreement with BTIG during September 2023.

During the nine months ended September 30, 2023, the Company repaid $2,500,000 of its debt.

During the nine months ended September 30, 2022, the Company sold 82,900 shares of its common stock to certain officers and directors for approximately $0.7 million.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based upon our unaudited consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. Actual results may differ from these estimates. Our critical accounting policies and estimates are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, and there have been no material changes during the nine months ended September 30, 2023.

Item 3. *Quantitative and Qualitative Disclosures About Market Risk*

Pursuant to Item 305(e) of Regulation S-K (§ 229.305(e)), the Company is not required to provide the information required by this Item as it is a "smaller reporting company," as defined by Rule 229.10(f)(1).

Item 4. *Controls and Procedures*

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) at the end of the period covered by this quarterly report.

Based on this evaluation, we concluded that, as of such date, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

We recognize that any controls system, no matter how well designed and operated, can provide only reasonable assurance of achieving its objectives, and our management necessarily applies its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the period covered by this quarterly report that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act).

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any pending legal proceedings that we believe will have a material adverse effect on our business or financial conditions. We may, however, be subject to various claims and legal actions arising in the ordinary course of business from time to time.

Item 1A. Risk Factors

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. The following information updates, and should be read in conjunction with, the information disclosed in Part I, Item 1A, "Risk Factors," contained in the Annual Report. Except as described below, our risk factors as of the date of this Report have not changed materially from those described in "Part I, Item 1A. Risk Factors" of our Annual Report.

Certain shares previously sold under our ATM Sales Agreement may have been sold in violation of federal and state securities laws and may be subject to rescission rights and other penalties, requiring us to repurchase shares sold thereunder.

In connection with our At-the-Market-Sales Agreement, dated March 10, 2021 (the "Sales Agreement"), we recently became aware that our shelf registration statement on Form S-3 (file number 333-237368) (the "Registration Statement") expired on April 2, 2023. Prior to becoming aware of the expiration, we sold an aggregate of 75,697 shares of our common stock following the expiration of the Registration Statement and through July 17, 2023 at an average price of approximately $10.56 per share for an aggregate of approximately $799,212 under the Registration Statement pursuant to the Sales Agreement (the "Sales"). Because the Registration Statement had already expired, the Sales could be determined to be unregistered sales of securities and, in accordance with Section 5 of the Securities Act, direct purchasers in the Sales may have rescission rights pursuant to which they may be entitled to recover the amount paid for such shares, plus statutory interest, upon returning the shares to us within one year from the transaction date. In addition, we could be subject to enforcement actions or penalties and fines by federal and/or state regulatory authorities. We cannot predict the likelihood of any claims or actions being brought against us or the amount of any penalties or fines in connection with the Sales.

Item 2. Recent Sales of Unregistered Securities; Use of Proceeds from Registered Securities

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

No.	Description
31.1	Rule 13a-14(a)/ 15d-14(a) Certification of Chief Executive Officer*
31.2	Rule 13a-14(a)/ 15d-14(a) Certification of Chief Financial Officer*
32.1	Section 1350 Certification of Chief Executive Officer**
32.2	Section 1350 Certification of Chief Financial Officer**
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 and contained in Exhibit 101).

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.

INmune Bio Inc.

Date: November 1, 2023

By: /s/ Raymond J. Tesi
Raymond J. Tesi
Chief Executive Officer
(Principal Executive Officer)

Date: November 1, 2023

By: /s/ David J. Moss
David J. Moss
Chief Financial Officer, Treasurer, Secretary
(Principal Financial and Accounting Officer)

Exhibit 31.1

Certifications

I, Raymond J. Tesi, certify that:

1. I have reviewed this quarterly report on Form 10-Q of INmune Bio Inc.

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 1, 2023

/s/ Raymond J. Tesi
Raymond J. Tesi
Chief Executive Officer
(Principal executive officer)

Exhibit 31.2

Certifications

I, David J. Moss, certify that:

1. I have reviewed this quarterly report on Form 10-Q of INmune Bio Inc.;

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 1, 2023

/s/ David J. Moss
David J. Moss
Chief Financial Officer
(Principal Financial 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 INmune Bio Inc. (the "Company") on Form 10-Q for the period ended September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Raymond J. Tesi, Chief Executive Officer of the Company, certify to my knowledge and in my capacity, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(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.

Dated: November 1, 2023

/s/ Raymond J. Tesi
Raymond J. Tesi
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 INmune Bio Inc. (the "Company") on Form 10-Q for the period ended September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David J. Moss, Chief Financial Officer of the Company, certify to my knowledge and in my capacity, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(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.

Dated: November 1, 2023

/s/ David J. Moss
David J. Moss
Chief Financial Officer
(Principal Financial Officer)