

REFINITIV

# DELTA REPORT

## 10-Q

INMB - INMUNE BIO, INC.  
10-Q - SEPTEMBER 30, 2024 COMPARED TO 10-Q - JUNE 30, 2024

The following comparison report has been automatically generated

TOTAL DELTAS	433
CHANGES	161
DELETIONS	131
ADDITIONS	141

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 JUNE SEPTEMBER 30, 2024

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**

(State of incorporation)

**47-5205835**

(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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

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

As of August 1, 2024 October 31, 2024, there were 19,782,429 22,172,451 shares of our common stock, par value \$0.001 per share, outstanding.

INMUNE BIO INC.  
FORM 10-Q  
FOR THE ~~SIX~~ NINE MONTHS ENDED ~~JUNE~~ SEPTEMBER 30, 2024

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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)

	June 30, 2024	December 31, 2023	September 30, 2024	December 31, 2023
<b>ASSETS</b>				
<b>CURRENT ASSETS</b>				
Cash and cash equivalents	\$ 31,069	\$ 35,848	\$ 33,552	\$ 35,848
Research and development tax credit receivable	3,143	1,905	1,109	1,905
Other tax receivable	270	537	311	537
Prepaid expenses and other current assets	1,013	1,510	864	1,510
Prepaid expenses – related party	-	142	15	142
<b>TOTAL CURRENT ASSETS</b>	<b>35,495</b>	<b>39,942</b>	<b>35,851</b>	<b>39,942</b>
Operating lease – right of use asset	363	414	335	414
Other assets	81	131	82	131
Acquired in-process research and development intangible assets	16,514	16,514	16,514	16,514
<b>TOTAL ASSETS</b>	<b>\$ 52,453</b>	<b>\$ 57,001</b>	<b>\$ 52,782</b>	<b>\$ 57,001</b>
<b>LIABILITIES, REDEEMABLE COMMON STOCK AND STOCKHOLDERS' EQUITY</b>				
<b>CURRENT LIABILITIES</b>				
Accounts payable and accrued liabilities	\$ 9,282	\$ 7,901	\$ 10,590	\$ 7,901
Accounts payable and accrued liabilities – related parties	139	35	55	35
Deferred liabilities	521	489	549	489
Current portion of long-term debt	4,979	9,921	2,494	9,921
Operating lease, current liability	130	119	135	119
<b>TOTAL CURRENT LIABILITIES</b>	<b>15,051</b>	<b>18,465</b>	<b>13,823</b>	<b>18,465</b>
Long-term operating lease liability	322	397	284	397
<b>TOTAL LIABILITIES</b>	<b>15,373</b>	<b>18,862</b>	<b>14,107</b>	<b>18,862</b>
<b>COMMITMENTS AND CONTINGENCIES</b>				
Redeemable common stock, \$0.001 par value; 75,697 shares issued and outstanding (Note 9)	799	799		
Redeemable common stock, \$0.001 par value; no shares and 75,697 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively (Note 9)			-	799
<b>STOCKHOLDERS' EQUITY</b>				
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, and 19,706,732 and 17,950,776 shares issued and outstanding, respectively	20	18		
Common stock, \$0.001 par value, 200,000,000 shares authorized, and 22,172,451 and 17,950,776 shares issued and outstanding, respectively			22	18
Additional paid-in capital	178,767	159,143	193,575	159,143
Accumulated other comprehensive loss	(713)	(799)	(1,036)	(799)
Accumulated deficit	(141,793)	(121,022)	(153,886)	(121,022)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>36,281</b>	<b>37,340</b>	<b>38,675</b>	<b>37,340</b>
<b>TOTAL LIABILITIES, REDEEMABLE COMMON STOCK AND STOCKHOLDERS' EQUITY</b>	<b>\$ 52,453</b>	<b>\$ 57,001</b>	<b>\$ 52,782</b>	<b>\$ 57,001</b>

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



INMUNE BIO INC.

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,		For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023	2024	2023	2024	2023
<b>REVENUE</b>	\$ -	\$ 46	\$ 14	\$ 84	\$ -	\$ 43	\$ 14	\$ 127
<b>OPERATING EXPENSES</b>								
General and administrative	2,812	2,309	5,150	4,637	2,219	2,586	7,369	7,223
Research and development	7,053	4,148	15,746	8,281	10,067	5,985	25,813	14,266
Total operating expenses	9,865	6,457	20,896	12,918	12,286	8,571	33,182	21,489
<b>LOSS FROM OPERATIONS</b>	(9,865)	(6,411)	(20,882)	(12,834)	(12,286)	(8,528)	(33,168)	(21,362)
<b>OTHER INCOME (EXPENSE), NET</b>	119	(90)	111	(203)	193	(35)	304	(238)
<b>NET LOSS</b>	<u>\$ (9,746)</u>	<u>\$ (6,501)</u>	<u>\$ (20,771)</u>	<u>\$ (13,037)</u>	<u>\$ (12,093)</u>	<u>\$ (8,563)</u>	<u>\$ (32,864)</u>	<u>\$ (21,600)</u>
Net loss per common share – basic and diluted	\$ (0.50)	\$ (0.36)	\$ (1.11)	\$ (0.73)	\$ (0.60)	\$ (0.48)	\$ (1.71)	\$ (1.20)
Weighted average common shares outstanding – basic and diluted	19,307,323	17,945,995	18,666,898	17,945,995	20,185,676	18,008,295	19,176,853	17,966,990
<b>COMPREHENSIVE LOSS</b>								
Net loss	\$ (9,746)	\$ (6,501)	\$ (20,771)	\$ (13,037)	\$ (12,093)	\$ (8,563)	\$ (32,864)	\$ (21,600)
Other comprehensive income (loss) – foreign currency translation	(44)	(4)	86	(13)				
Other comprehensive loss – foreign currency translation					(323)	(23)	(237)	(36)
Total comprehensive loss	<u>\$ (9,790)</u>	<u>\$ (6,505)</u>	<u>\$ (20,685)</u>	<u>\$ (13,050)</u>	<u>\$ (12,416)</u>	<u>\$ (8,586)</u>	<u>\$ (33,101)</u>	<u>\$ (21,636)</u>

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

INMUNE BIO INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY  
FOR THE THREE AND ~~SIX~~ NINE MONTHS ENDED ~~JUNE~~ SEPTEMBER 30, 2024

(In thousands, except share amounts)  
(Unaudited)

	Accumulated						Accumulated					
	Common Stock		Additional	Other	Accumulated	Total	Common Stock		Additional	Other	Accumulated	Total
	Shares	Amount	Paid-In Capital	Comprehensive Income (Loss)	Deficit	Stockholders' Equity	Shares	Amount	Paid-In Capital	Comprehensive Income (Loss)	Deficit	Stockholders' Equity
Balance as of December 31, 2023	17,950,776	\$ 18	\$ 159,143	\$ (799)	\$ (121,022)	\$ 37,340	17,950,776	\$ 18	\$ 159,143	\$ (799)	\$ (121,022)	\$ 37,340
Stock-based compensation	-	-	1,779	-	-	1,779	-	-	1,779	-	-	1,779
Gain on foreign currency translation	-	-	-	130	-	130	-	-	-	130	-	130
Net loss	-	-	-	-	(11,025)	(11,025)	-	-	-	-	(11,025)	(11,025)
Balance as of March 31, 2024	17,950,776	18	160,922	(669)	(132,047)	28,224	17,950,776	18	160,922	(669)	(132,047)	28,224
Stock-based compensation	-	-	2,350	-	-	2,350	-	-	2,350	-	-	2,350
Common stock issued for cash	198,364	-	2,032	-	-	2,032	198,364	-	2,032	-	-	2,032
Common stock and warrants issued for cash	1,557,592	2	13,463	-	-	13,465	1,557,592	2	13,463	-	-	13,465
Loss on foreign currency translation	-	-	-	(44)	-	(44)	-	-	-	(44)	-	(44)
Net loss	-	-	-	-	(9,746)	(9,746)	-	-	-	-	(9,746)	(9,746)
Balance as of June 30, 2024	19,706,732	\$ 20	\$ 178,767	\$ (713)	\$ (141,793)	\$ 36,281	19,706,732	20	178,767	(713)	(141,793)	36,281
Stock-based compensation	-	-	-	-	-	-	-	-	1,719	-	-	1,719
Common stock and warrants issued for cash	-	-	-	-	-	-	2,390,022	2	12,290	-	-	12,292
Reclassification from redeemable common stock	-	-	-	-	-	-	75,697	-	799	-	-	799
Loss on foreign currency translation	-	-	-	-	-	-	-	-	-	(323)	-	(323)
Net loss	-	-	-	-	-	-	-	-	-	-	(12,093)	(12,093)
Balance as of September 30, 2024	-	-	-	-	-	-	22,172,451	\$ 22	\$ 193,575	\$ (1,036)	\$ (153,886)	\$ 38,721

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

INMUNE BIO INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY  
FOR THE THREE AND SIX NINE MONTHS ENDED JUNE SEPTEMBER 30, 2023

(In thousands, except share amounts)

(Unaudited)

	Accumulated						Accumulated					
	Common Stock		Additional	Other	Accumulated	Total	Common Stock		Additional	Other	Accumulated	Total
	Shares	Amount	Paid-In Capital	Comprehensive Loss	Deficit	Stockholders' Equity	Shares	Amount	Paid-In Capital	Comprehensive Loss	Deficit	Stockholders' Equity
Balance as of December 31, 2022	17,945,995	\$ 18	\$ 151,799	\$ (699)	\$ (91,014)	\$ 60,104	17,945,995	\$ 18	\$ 151,799	\$ (699)	\$ (91,014)	\$ 60,104
Stock-based compensation	-	-	1,737	-	-	1,737	-	-	1,737	-	-	1,737
Loss on foreign currency translation	-	-	-	(9)	-	(9)	-	-	-	(9)	-	(9)
Net loss	-	-	-	-	(6,536)	(6,536)	-	-	-	-	(6,536)	(6,536)
Balance as of March 31, 2023	17,945,995	18	153,536	(708)	(97,550)	55,296	17,945,995	18	153,536	(708)	(97,550)	55,296
Stock-based compensation	-	-	1,863	-	-	1,863	-	-	1,863	-	-	1,863
Loss on foreign currency translation	-	-	-	(4)	-	(4)	-	-	-	(4)	-	(4)
Net loss	-	-	-	-	(6,501)	(6,501)	-	-	-	-	(6,501)	(6,501)
Balance as of June 30, 2023	17,945,995	\$ 18	\$ 155,399	\$ (712)	\$ (104,051)	\$ 50,654	17,945,995	\$ 18	\$ 155,399	\$ (712)	\$ (104,051)	\$ 50,654
Issuance of common stock for cash, net							75,697	-	775	-	-	76,472
Reclassification to redeemable common stock							(75,697)	-	(799)	-	-	(875)
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)	\$ 44,913

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 Six Months Ended June 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>				
Net loss	\$ (20,771 )	\$ (13,037 )	\$ (32,864 )	\$ (21,600 )
Adjustments to reconcile net loss to net cash used in operating activities:				
Stock-based compensation	4,129	3,600	5,848	5,489
Accretion of debt discount	58	125	73	179
Changes in operating assets and liabilities:				
Research and development tax credit receivable	(1,238 )	6,165	796	6,012
Other tax receivable	267	250	226	186
Prepaid expenses	497	1,320	646	2,492
Prepaid expenses – related party	142	4	127	34
Other assets	50	(31)	49	(30)
Accounts payable and accrued liabilities	1,381	(2,821)	2,689	(1,531)
Accounts payable and accrued liabilities – related parties	104	-	20	70
Deferred liabilities	32	(56)	60	(120)
Accrued liability – long-term	-	176	-	254
Operating lease liabilities	(13)	(10)	(18)	(14)
Net cash used in operating activities	(15,362 )	(4,315 )	(22,348 )	(8,579 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>				
Net proceeds from sale of common stock and warrants	15,497	-	27,789	775
Repayments of debt	(5,000 )	-	(7,500 )	(2,500 )
Net cash provided by financing activities	10,497	-	20,289	(1,725 )
Impact on cash from foreign currency translation	86	(13)	(237)	(36)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(4,779 )	(4,328 )	(2,296 )	(10,340 )
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	35,848	52,153	35,848	52,153
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 31,069	\$ 47,825	\$ 33,552	\$ 41,813
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:</b>				
Cash paid for income taxes	\$ -	\$ -	\$ -	\$ -
Cash paid for interest expense	\$ 523	\$ 930	\$ 661	\$ 1,394

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. 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 – GOING CONCERN**

These unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

The Company has incurred significant losses and negative cash flows from operations since inception and expects to incur additional losses until such time that it can generate significant revenue from the commercialization of its product candidates. During the ~~six~~ **nine** months ended ~~June 30, 2024~~ **September 30, 2024**, the Company incurred a net loss of ~~\$20.8~~ **\$32.9** million and had net cash flows used in operating activities of ~~\$15.4~~ **\$22.3** million. Given the Company’s projected operating requirements and its existing cash and cash equivalents, the Company is projecting insufficient liquidity to sustain its operations through one year following the date that the financial statements are issued. These conditions and events raise substantial doubt about the Company’s ability to continue as a going concern.

In response to these conditions, management is currently evaluating different strategies to obtain the required funding of future operations. Financing strategies may include, but are not limited to, the public or private sale of equity, debt financings or funds from other capital sources, such as government funding, collaborations, strategic alliances, divestment of non-core assets, or licensing arrangements with third parties. There can be no assurances that the Company will be able to secure additional financing, or if available, that it will be sufficient to meet its needs or on favorable terms. Because management’s plans have not yet been finalized and are not within the Company’s control, the implementation of such plans cannot be considered probable. As a result, the Company has concluded that management’s plans do not alleviate substantial doubt about the Company’s ability to continue as a going concern.

The unaudited condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

**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 unaudited condensed 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 condensed consolidated interim financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2023, included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 28, 2024.

### ***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.

### **Accounts Receivable and Notes Receivable**

Accounts receivable are presented net of allowances for credit losses. The Company maintains an allowance for credit losses resulting from the inability of its customers to make required payments. At June 30, 2024 September 30, 2024, the Company has a \$590,000 \$545,000 note receivable from a vendor payable quarterly over 2 years including interest payable at prime plus 2% (10.5% (10.0% at June 30, 2024 September 30, 2024). The Company has recorded a full valuation allowance of \$590,000 \$545,000 for the receivable based on the financial condition of the vendor.

### **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 **June 30, 2024** **September 30, 2024** and 2023, the Company had potentially issuable shares as follows:

	June 30,		September 30,	
	2024	2023	2024	2023
Stock options	6,291,807	5,501,000	6,296,807	5,501,000
Warrants	1,602,978	74,074	3,944,238	74,074
<b>Total</b>	<b>7,894,785</b>	<b>5,575,074</b>	<b>10,241,045</b>	<b>5,575,074</b>

### 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 December 2023, the Financial Accounting Standards Board "FASB", issued Accounting Standards Update "ASU", No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09"). The guidance in ASU 2023-09 improves the transparency of income tax disclosures by greater disaggregation of information in the rate reconciliation and income taxes paid disaggregated by jurisdiction. The standard is effective for public companies for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2023-09 may have on its consolidated financial statements and related disclosures.

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280). The amendments in this update expand segment disclosure requirements, including new segment disclosure requirements for entities with a single reportable segment among other disclosure requirements. This update is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements.

## Subsequent Events

The Company evaluates events that have occurred after the balance sheet date of June 30, 2024 September 30, 2024, through the date which the financial statements are issued.

## NOTE 4 – RESEARCH AND DEVELOPMENT ACTIVITY

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 June 30, 2024 September 30, 2024 and December 31, 2023, the Company recorded a research and development tax credit receivable of \$3,143,000 \$1,109,000 and \$1,905,000, respectively, for R&D expenses incurred in Australia. During the six nine months ended June 30, 2024 September 30, 2024 and 2023, the Company received \$0 \$2,475,000 and \$3,763,000, respectively, of R&D tax credit reimbursements from Australia. During July 2024 the Company received a \$2,475,000 R&D tax credit reimbursement 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. During December 2023, the Company initiated a Phase I trial with INKmune in patients with metastatic castration-resistant prostate cancer and has recorded a \$25,000 payable to Immune Ventures as of **June 30, 2024** **September 30, 2024** and December 31, 2023.

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 Beginning on June 26, 2025, the Company has 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

of \$25,000 until first commercial sale. Upon first commercial sale of a product making use of the licensed technology under the PITT Agreement, 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 June 30, 2024 September 30, 2024.

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:

<i>(in thousands)</i>	Total	Quoted Price in Active Market (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total	Quoted Price in Active Market (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>June 30, 2024:</b>								
<b>September 30, 2024:</b>								
Cash equivalents								
Treasury bills	\$ 10,027	\$ 10,027	\$ -	\$ -	\$ 10,146	\$ 10,146	\$ -	\$ -
Money market funds	20,544	20,544	-	-	22,218	22,218	-	-
Total cash equivalents	<u>\$ 30,571</u>	<u>\$ 30,571</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 32,364</u>	<u>\$ 32,364</u>	<u>\$ -</u>	<u>\$ -</u>

<i>(in thousands)</i>	Total	Quoted Price in Active Market (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>December 31, 2023:</b>				
Cash equivalents				
Money market fund	\$ 35,162	\$ 35,162	\$ -	\$ -
Total cash equivalents	<u>\$ 35,162</u>	<u>\$ 35,162</u>	<u>\$ -</u>	<u>\$ -</u>

## 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 2021.

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

<i>(in thousands, except years and rate)</i>	June 30, 2024	December 31, 2023	September 30, 2024	December 31, 2023
Right-of-use asset	\$ 363	\$ 414	\$ 335	\$ 414
Operating lease, current liability	\$ 130	\$ 119	\$ 135	\$ 119
Long-term operating lease liability	\$ 322	\$ 397	\$ 284	\$ 397
Total lease liability	<u>\$ 452</u>	<u>\$ 516</u>	<u>\$ 419</u>	<u>\$ 516</u>
Weighted-average remaining lease term	2.7 years	3.3 years	2.5 years	3.3 years
Weighted-average discount rate	12.0 %	12.0 %	12.0 %	12.0 %

NOTE 7 – RELATED PARTY TRANSACTIONS

UCL

At June 30, 2024 September 30, 2024 and December 31, 2023, the Company recorded \$0\$15,000 and \$112,000, respectively, of prepaid expenses – related party for payments made to UCL in advance of medical research to be provided. At June 30, 2024 and December 31, 2023, the Company recorded \$84,000 and \$0, respectively, of accrued expenses – related party owed to UCL for medical research performed on behalf of the Company. During the six nine months ended June 30, 2024 September 30, 2024 and 2023, the Company paid UCL \$0 \$252,000 and \$209,000 \$334,000, respectively. 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 June 30, 2024 September 30, 2024 and December 31, 2023, the Company owed AmplifyBio \$30,000 and \$10,000, 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 six nine months ended June 30, 2024 September 30, 2024 and 2023, the Company paid AmplifyBio \$233,000 \$324,000 and \$6,000, \$7,000, respectively.

NOTE 8 – DEBT

On June 10, 2021, During June 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, during 2021, and is secured by the Company’s assets.

The term loan and debt discount are as follows as of June 30, 2024 September 30, 2024:

(in thousands)		
Term Loan	\$ 5,000	\$ 2,500
Less: debt discount and financing costs, net	(21)	(6)
Current portion of debt	\$ 4,979	\$ 2,494

For the three and six nine months ended June 30, 2024 September 30, 2024, the Company recognized interest expense of \$250,000 \$145,000 and \$607,000, \$752,000, respectively, related to the Term Loan. For the three and six nine months ended June 30, 2023 September 30, 2023, the Company recognized interest expense of \$631,000 \$568,000 and \$1,243,000, \$1,811,000, 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 June 30, 2023 September 30, 2024, the interest rate was 13.0% 12.5%.

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.

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.

## NOTE 9 – STOCKHOLDERS' EQUITY

### Registered Direct Offerings

During September 2024, the Company entered into securities purchase agreements with investors whereby the Company sold 2,341,260 shares of the Company's common stock and warrants to purchase an additional 2,341,260 shares of the Company's common stock exercisable six months from the issuance date in a registered direct offering in exchange for gross proceeds of \$13.0 million (net proceeds of approximately \$12.0 million). Directors and officers that participated in the offering paid a combined offering price of \$6.50 per share and warrant, and other investors paid \$5.50 per share and warrant. The exercise price of the warrants is \$6.40, and are exercisable beginning on March 16, 2025 and will terminate on March 16, 2030 unless accelerated pursuant to the terms of the warrant agreements. The Company determined the warrants were equity classified. The fair value of the warrants was approximately \$9.1 million and was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 3.41% based on the applicable US Treasury bill rate (2) expected life of 5.5 years, (3) expected volatility of approximately 92% based on the trading history of the Company, and (4) zero expected dividends.

During April 2024, the Company entered into a securities purchase agreement with an investor whereby the Company sold 986,000 shares of the Company's common stock and warrants to purchase an additional 986,000 shares of the Company's common stock in a registered direct offering in exchange for gross proceeds of approximately \$9.7 million (net proceeds of approximately \$8.9 million). The exercise price of the warrants is \$9.84 and the term of the warrants is the earlier of (1) April 29, 2026 or (2) thirty trading days following the reporting of positive top line data in the Phase 2 Alzheimer's program of XPro1595. The Company determined that the warrants were equity classified. The fair value of the warrants was approximately \$5.8 million and was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 4.97% based on the applicable US Treasury bill rate (2) expected life of 2.0 years, (3) expected volatility of approximately 77% based on the trading history of the Company, and (4) zero expected dividends.

During April 2024, the Company entered into securities purchase agreements with investors whereby the Company sold 571,592 shares of the Company's common stock and warrants to purchase an additional 571,592 shares of the Company's common stock in a registered direct offering in exchange for gross proceeds of approximately \$4.8 million (net proceeds of approximately \$4.5 million). Directors and officers that participated in the offering paid a combined offering price of \$8.445 per share and warrant, and other investors paid \$8.32 per share and warrant. The exercise price of the warrants is \$9.152, and the term is the earlier of two years from the issuance of the warrants and thirty trading days following the release of top line data in the Phase 2 Alzheimer's program, provided that directors and officers of the Company that are subject to a blackout with respect to trading in the Company's stock will have an additional 60 days from the termination of the blackout date to exercise the warrant. The Company determined the warrants were equity classified. The fair value of the warrants was approximately \$3.0 million and was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 4.89% based on the applicable US Treasury bill rate (2) expected life of 2.0 years, (3) expected volatility of approximately 78% based on the trading history of the Company, similar companies, and (4) zero expected dividends.

### 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 which the Company set forth amended in the sales agreement. During August 2023, the Company and BTIG entered into Amendment No. 1 to the Sales Agreement. 2023. The Company is was required to pay BTIG a commission of 3% of the gross proceeds from the sale of shares. During the nine months ended September 30, 2024, the Company issued and sold 198,364 shares of common stock at an average price of \$10.56 per share under the ATM program. The aggregate net proceeds were approximately \$2.0 million after BTIG's commission expenses.

During August 2024, the Company entered into an amended and restated at-the-market sales agreement with RBC Capital Markets LLC and BTIG (together, the "Sales Agents") relating to the offer and sale of shares of our common stock with an aggregate offering price of up to \$75.0 million. This amended and restated at-the-market sales agreement replaced the Sales Agreement entered into with BTIG in March 2021, as amended in August 2023. The Company is required to pay the Sales Agents a commission of 3% of the gross proceeds from the sale of shares. During the nine months ended September 30, 2024, the Company issued and sold 48,762 shares of common stock at an average price of \$6.96 per share under the ATM program. The aggregate net proceeds were approximately \$0.3 million after commission expenses. At September 30, 2024, the Company had \$74.7 million of common stock available under the amended and restated at-the-market agreement.

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 June 30, 2024 December 31, 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 equity as a result of potential rescission rights. There have been no claims or demands to exercise such rights. As of September 30, 2024, the rescission rights for these shares shall remain for a period of one year from transaction date. These have lapsed and the shares have been treated as issued and outstanding for financial reporting purposes.

During the six months ended June 30, 2024, the Company issued and sold 198,364 shares of common stock at an average price of \$10.56 per share under the ATM program. The aggregate net proceeds were approximately \$2.0 million after BTIG's commission expenses.

At June 30, 2024, the Company had \$26.7 million of common stock available under the ATM program, reclassified to permanent equity.

### Stock options

During the six nine months ended June 30, 2024 September 30, 2024, the Company granted certain employees, directors and consultants, options to purchase 795,807 832,307 shares of its common stock pursuant to the 2021 Amended and Restated Incentive Stock Plan. The stock options had a fair value of approximately \$6.5 \$6.8 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 4.45% 3.90% – 4.48% based on the applicable US Treasury bill rate (2) expected life of 5.0 – 10.0 years, (3) expected volatility of approximately 101% - 106% based on the trading history of similar companies, and (4) zero expected dividends.

The following table summarizes stock option activity during the **six nine** months ended **June 30, 2024** September 30, 2024:

<i>(in thousands, except share and per share amounts)</i>	Number of Shares	Weighted-average Exercise Price	Weighted-average Remaining Contractual Term (years)	Aggregate Intrinsic Value	Number of Shares	Weighted-average Exercise Price	Weighted-average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at January 1, 2024	5,496,000	\$ 8.73	6.18	\$ 21,509	5,496,000	\$ 8.73	6.18	\$ 21,509
Options granted	795,807	\$ 9.85	10.00	-	832,307	\$ 9.79	10.00	-
Options exercised	-	\$ -	-	-	-	\$ -	-	-
Options cancelled	-	\$ -	-	-	(31,500)	\$ 7.35	-	-
Outstanding at June 30, 2024	6,291,807	\$ 8.87	6.29	\$ 10,655				
Exercisable at June 30, 2024	4,890,811	\$ 8.54	5.51	\$ 10,469				
Outstanding at September 30, 2024					6,296,807	\$ 8.87	5.90	\$ 2,531
Exercisable at September 30, 2024					5,032,843	\$ 8.62	5.19	\$ 2,531

During the three and **six nine** months ended **June 30, 2024** September 30, 2024, the Company recognized stock-based compensation expense of approximately **\$2.3** \$1.7 million and **\$4.1** \$5.8 million, respectively, related to the vesting of stock options. During the three and **six nine** months ended **June 30, 2023** September 30, 2023, the Company recognized stock-based compensation expense of approximately \$1.9 million and **\$3.6** \$5.5 million, respectively, related to the vesting of stock options. As of **June 30, 2024** September 30, 2024, there was approximately **\$11.0 million** \$9.1 million of total unrecognized compensation cost related to non-vested stock options which is expected to be recognized over a weighted-average period of **2.19** 2.33 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 **June 30, 2024** September 30, 2024, 45,386 of these warrants are outstanding and the intrinsic value of these warrants is \$0.

During April 2024, the Company issued 1,557,592 warrants to investors in connection with the sale of common stock. At **June 30, 2024** September 30, 2024, 1,557,592 of these warrants are outstanding and are exercisable for cash at a weighted average price of \$9.59 per share. The intrinsic value of these warrants was \$0 as of **June 30, 2024** September 30, 2024.

During September 2024, the Company issued 2,341,260 warrants to investors in connection with the sale of common stock. At September 30, 2024, 2,341,260 of these warrants are outstanding and are exercisable for cash at a weighted average price of \$6.40 per share. The intrinsic value of these warrants was \$0 as of September 30, 2024.

#### 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 **six three** and **nine** months ended **June 30, 2024** September 30, 2024 and 2023, respectively:

<i>(in thousands)</i>	Three Months Ended June 30, 2024	Three Months Ended June 30, 2023	Six Months Ended June 30, 2024	Six Months Ended June 30, 2023	Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
Research and development	\$ 996	\$ 689	\$ 1,698	\$ 1,338	\$ 677	\$ 705	\$ 2,375	\$ 2,043
General and administrative	1,354	1,174	2,431	2,262	1,042	1,184	3,473	3,446
Total	\$ 2,350	\$ 1,863	\$ 4,129	\$ 3,600	\$ 1,719	\$ 1,889	\$ 5,848	\$ 5,489

#### 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 The Rights Agreement ("Amendment No. 1") was amended in 2021, 2022 and 2023 to extend the expiration of the Rights Agreement to December 30, 2022. On December 9, 2022, the Company date and VStock Transfer, LLC entered into Amendment No. 2 to Rights Agreement ("Amendment No. 2") shall expire on December 30, 2024. 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 June 30, 2024 September 30, 2024, the Company has not received any proceeds pursuant to this grant.

NOTE 11 – COMMITMENTS

Lease

During 2021, the Company signed a 64-month term lease agreement with a third party for office space in Boca Raton, Florida.

Future minimum payments pursuant to the leases are as follows:

(in thousands, except years)		
2024	\$ 94	\$ 47
2025	192	192
2026	198	198
2027	51	51
Total lease payments	535	488
Less: imputed interest	(83)	(69)
Present value of future lease payments	452	419
Less: operating lease, current liability	(130)	(135)
Long-term operating lease liability	\$ 322	\$ 284

During the three and six nine months ended June 30, 2024 September 30, 2024, the Company recognized \$41,000 \$40,000 and \$80,000, \$120,000, 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 six nine months ended June 30, 2023 September 30, 2023, the Company recognized \$39,000 \$41,000 and \$82,000, \$123,000, respectively, in operating lease expense, which is included in general and administrative expenses in the Company’s consolidated statement of operations

Dispute  
The Company has an ongoing dispute with a vendor in which the Company believes that the vendor did not properly provide services for which they have invoiced the Company. As of September 30, 2024, the Company has outstanding invoices with the vendor which aggregate approximately \$1.2 million, of which the Company has recorded approximately \$0.2 million, which is the Company’s estimate of the obligation incurred, and the remaining \$1.0 million has not been recorded by the Company as the Company believes the invoices were sent erroneously. The Company and the vendor are still attempting to resolve the dispute and legal proceedings have not been threatened.

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

##### Description of Business

##### Overview

We are a clinical-stage inflammation and immunology company focused on developing drugs that modify the patient's innate immune system to treat disease. We believe targeting cells of the innate immune system that cause chronic inflammation and are involved in immune dysfunction such as cancer and neurodegenerative diseases may make a therapeutic impact on many diseases. The Company's drugs are in clinical trials and have not been approved by a regulatory authority. The Company has two therapeutic platforms – a dominant-negative TNF platform (“DN-TNF”, “XPro™”, “XPro1595™”, “INB03”, or “pegipanermin”) and a Natural Killer (“NK”, or “INKmune™”) platform. The DN-TNF platform neutralizes soluble TNF (“sTNF”) without affecting trans-membrane TNF (“tmTNF”) or TNF receptors. 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 potent anti-inflammatory strategy that does not cause immunosuppression or demyelination which can occur in the with currently approved non-selective TNF inhibitors and may occur with many other potent anti-inflammatory drugs. 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; 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 immune 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 NK cells of cancer patients lose the ability to bind and kill cancer cells. A INKmune converts the patient's resting NK cells into cancer killing memory like NK cells (mlNK). INKmune improves mlNK killing in the hostile tumor microenvironment in at least three ways: increasing avidity, improving mitochondrial and cellular respiration and allowing the cells to function in the immunosuppressive and hypoxic TME. Avidity is a measure of NK cell binding to cancer cells is avidity, cells. 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. These mechanisms improve the ability of INKmune™ primed NK cells to overcome the immune evasion of the patient's cancer cells. We believe INKmune™ may be best used to eliminate residual disease after the patient has completed other cancer therapies.

Both the DN-TNF platform and the INKmune platform can be used to treat multiple diseases. The DN-TNF platform will be used as an immunotherapy for the treatment of cancer (INB03) and neurodegenerative disease. INKmune™ is being developed to treat NK-resistant hematologic malignancies and solid tumors.

We believe our DN-TNF platform can be used 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”); as a drug to treat many chronic inflammatory diseases; and as a cancer therapy to reduce resistance in immunotherapy. The primary focus of the company’s development efforts for XPro™ is AD which is currently in a Phase 2 trial to determine if reduction of chronic inflammation without immunosuppression makes a difference in cognition. The next indication to be developed with XPro™ will be TRD. **There is a significant pre-clinical program on the use on DN-TNF in cancer.** The drug is named differently for the oncology and CNS indications; INB03™ or XPro, respectively, but it is the same drug product. This novel compound has the same mechanism of action but has novel IP protection. In each case, we believe neutralizing sTNF **without blocking tmTNF or TNF receptors** is a cornerstone to the treatment of these diseases. As an immunotherapy for cancer, we are using 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 express 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 a nude mouse **model, models**, INB03 **may change changes** the immunobiology of the tumor microenvironment (“TME”) by decreasing the number of immunosuppressive myeloid cells, both myeloid derived suppressor cells and tumor active macrophages **and (TAM; phagocytic macrophages)** in the TME. In the TME of immunocompetent mice, INB03 increases the number of cytotoxic lymphocytes modifies **and** the TME by downregulating immune exhaustion markers – PDL-1, TIGIT, LAG3, CTLA4, CD47 and SIRPα. 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 pre-clinical data in MUC4+ expressing tumors and the clinical trial informs the design of a future Phase II trial by demonstrating that INB03 was safe and well tolerated, defined the dose of INB03 to carry into Phase II trials, and demonstrated a pharmacodynamic endpoint. The company does not plan to commence a Phase II trial in patients with advanced MUC4+ expressing cancer until a partner can be found or extra-mural funding is secured.

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. 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 causing** nerve cell loss, synaptic dysfunction and prevents myelin repair - key elements in the development of dementia. In animal models, elimination of sTNF prevents nerve cell dysfunction, reverses synaptic pruning and promotes myelin repair. 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. The endpoints of the trial were 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 brain microstructural changes. CNS.** XPro, at the 1mg/kg/week dose, decreased inflammatory cytokines in the CSF in the brain demonstrating that XPro can decrease neuroinflammation in patients with AD. We also studied downstream benefits of decreasing neuroinflammation by measuring changes in the CSF proteome and **quantifying changes in novel white and gray matter MRI biomarkers, using EEG as a functional measure of brain function.** XPro significantly decreases 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 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 neurogranin, changes that contribute to improved synaptic function. **After 4 weeks of XPro therapy, EEG Alpha power improved in patients with AD suggesting improved brain activity.**

The successful completion of the Phase I trial in AD **has** informed the design of **a the ongoing** blinded randomized, placebo-controlled Phase II trial in patients with early AD with biomarkers of inflammation. Early ADi. Early ADi includes patients **with have mild AD and or MCI who have with** at least one biomarker of **inflammation (ADi and MCI2 respectively), inflammation.** 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 one patients are being 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 or at least one allele of ApoE4. The primary endpoint will be Early/mild Alzheimer’s Cognitive Composite (“EMACC”), a validated cognitive measure that is more sensitive than traditional endpoints used in many studies of **patients patient** with early AD. Although EMACC is a primary endpoint, CDR-SB, a well recognized cognitive test is being used as a secondary endpoint as well. The AD program is **open enrolling patients in the United States,** Australia, Canada, the United Kingdom, France, Germany, Spain, **Poland,** Czech Republic and Slovakia. Because of resource constraints, a planned open-label extension has been stopped.



There are at least 4 clinical milestones associated with the Phase II trial in AD. Enrollment Closing enrollment to screening of 201 patients in the Phase II AD trial is expected to be complete by mid-year. Six was announced at the end of the third quarter of 2024. Approximately seven months after the last patient is enrolled into AD02, top line cognition data with EMACC and CDR will be available. Secondary endpoints which include CDR-SB, blood biomarker, neuroimaging and additional neuropsychiatric endpoints will be available after data-base lock 2-3 months after top line data. Finally, several months after all the data are analyzed, the Company plans an end-of-phase II meeting with the FDA to finalize plans for the pivotal Phase III trial. XPro for treatment of AD may be eligible for one or both accelerated approval pathways. The Company plans to apply for an accelerated pathway during 2024. The Company and plans to submit of Fast Track status in 2024. status. We expect to be eligible for Break Through status after completion of the Phase II trial in 2025.

Effective therapy for TRD is a large unmet need. Twenty percent of patients with Major Depressive Disorder have TRD. Once third of TRD patients have peripheral biomarkers to inflammation (elevated CRP), — the target population of the TRD program. 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 demonstrated the patients have elevated TNF levels and treatment with infliximab treated 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 end-points include both clinical and neuroimaging measures. The final trial design is ongoing and discussions with the FDA are not complete. The Company expects to receive authorization to initiate a clinical trial in TRD in during the 2H24, second half of 2024. The TRD trial is expected to start enrollment after the AD Phase II trial finishes patient enrollment.

Our data show that INKImune improves the ability of the patient’s own NK cells to attack their tumor. INKImune interacts with the patient’s NK cells to convert them from inert resting NK cells into memory-like NK cells that kill the patient’s cancer cells. INKImune 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 INKImune in vitro. INKImune is designed to be given to patients after their immune system has recovered after cytotoxic chemotherapy to target the residual disease that remains after conventional treatment. We have in vitro data suggesting that INKImune can be used to treat numerous hematologic malignancies and solid tumors including leukemia, multiple myeloma, lymphoma, lung, ovary, breast, renal and prostate cancer. The Company had a Phase I trial using INKImune to treat patients with high risk MDS/AML, a form of leukemia. Two patients were treated in the Phase I trial for MDS, three patients have been treated compassionately in AML and another MDS patient is expected to be treated shortly. AML. During March 2024, the Company decided to terminate further enrollment in the MDS/AML trial due to recruitment difficulties in the European trial sites. However, in the patients who were treated, INKImune therapy was shown to be safe, and induced development of cancer killing memory-like NK cells that were found in the patient’s circulation for up to 4 months. The Company initiated a separate Phase I/2 trial of INKImune in a metastatic castrate resistant prostate cancer in 8 trials sites across the US. The open label trial enrolled the first patient in December 2023, opened the second cohort in June 2024, and is on track with recruitment. expects to open the third cohort to patient enrollment in November 2024.

The Phase I/II trial using INKImune™ to treat patients with metastatic castrate resistant prostate cancer (mCPRC) is an open label trial. Biomarker data from the patients will be visible as patients are treated. The Company will report data from each cohort as it becomes available. In addition to clinical data, the Company will communicate when the Phase I portion of the trial has completed follow-up. This is expected The limited immunologic data was reported from the low dose Phase I cohort during the third quarter of 2024 and showed an increase in September 2024, functional memory like NK cells in the patient’s circulation. Because of the modified Bayesian design, the Company estimates the trial enrollment will be completely enrolled 1H25 completed during the first half of 2025 with top-line data available 6 months later. Topline data are divided into immunologic and tumor response variables. The most important immunologic response variable is related to memory like NK cell persistence. This Persistence is how long are the number of mINK cells in patients’ blood compared to baseline. There are 3 important variables to tumor response: i) blood PSA changes; ii) change in PMSA scan and iii) change in circulating tumor DNA (ctDNA). Ideally, the levels of all three variables decrease with treatment, but, in this patient group with advanced disease, absence of progression will be a notable achievement. We do not expect this 6-month trial to provide survival data.

We continue to look for ways to utilize our unique manufacturing and biologic capabilities to optimize clinical application of cell therapies. We believe that we have developed a way to manufacture human mesenchymal stromal cells for the medical research and biotech community that offers large volumes of high-quality, low passage human umbilical cord mesenchymal stromal cells with minimal batch-to-batch variability. We have established a reliable supply of human umbilical cords based on our agreement with the Anthony Nolan Cord Blood Bank in the United Kingdom and may seek additional supplies from US sources in the future. We have developed a validated manufacturing process that reliably produces clinical grade (“cGMP”) quality mesenchymal stromal cells that we call CORDstrom. The manufacturing process is currently performed at a contract manufacturing site under the direction of Mark Lowdell, the Company’s CSO. To date, we are supporting a multicenter academic clinical trial in the UK with CORDstrom. This is a Phase I/IIb trial sponsored by the Great Ormond Street Children’s Hospital in London treating children with the most severe form of Epidermolysis Bullosa (“EB”), a disfiguring and sometimes fatal skin disease that is similar to a second-degree burn. INmune Bio is supplying the clinical product for treatment of these patients. We have identified contract manufacturers in the UK that have the capability to produce cGMP stem cells. We expect the commercial arrangement with academic laboratories or biopharma companies to be a combination of fee-for-service and licensing that does not require additional investment by us. We will be opportunistic in pursuing therapeutic opportunities for our own portfolio with this platform in the future if resources become available. The regulatory path for therapeutic applications of the mesenchymal stem cell products is well established and similar to the regulatory approval process for other cell therapies. We will only be responsible for regulatory compliance related to manufacturing of the mesenchymal stromal cells when the product is being developed by a third party. When developing a therapeutic product for the Company’s commercial portfolio, the Company will be responsible for all aspects of the regulatory process.

We continue to incur significant development and other expenses related to our ongoing operations. As a result, we are not and have never been profitable and have incurred losses in each period since our inception, resulting in substantial doubt in our ability to continue as a going concern. We reported a net loss of \$20.8 million \$32.9 million for the six nine months ended June 30, 2024 September 30, 2024. As of June 30, 2024 September 30, 2024 and December 31, 2023, we had cash and cash equivalents of \$31.1 million \$33.6 million and \$35.8 million, respectively. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues, if any.



Our recurring net losses and negative cash flows from operations raised substantial doubt regarding our ability to continue as a going concern within one year after the issuance of our unaudited condensed consolidated financial statements for the ~~six~~nine months ended ~~June 30, 2024~~September 30, 2024. Until we can generate sufficient revenue from the commercialization of our product candidates, we expect to finance our operations through the public or private sale of equity, debt financings or other capital sources, such as government funding, collaborations, strategic alliances, divestment of non-core assets, or licensing arrangements with third parties. To date, the Company has relied on equity and debt financing to fund its operations.

As a company with less than \$1.235 billion in revenue during our last fiscal year, 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		Six Months Ended	
	June 30,		June 30,	
	2024	2023	2024	2023
External Costs				
DN-TNF - Alzheimer's disease	\$ 4,776	\$ 2,211	\$ 11,130	\$ 4,675
INKmune - High Risk MDS/AML & Prostate cancer	1,067	443	2,254	857
Preclinical and other programs	248	274	361	418
Accrued research and development rebate	(953)	(132)	(1,262)	(269)
Total external costs	5,138	2,796	12,483	5,681
Internal costs	1,915	1,352	3,263	2,600
Total	\$ 7,053	\$ 4,148	\$ 15,746	\$ 8,281
	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2024	2023	2024	2023
External Costs				
DN-TNF - Alzheimer's disease	\$ 7,629	\$ 3,823	\$ 18,759	\$ 8,498
INKmune - High Risk MDS/AML & Prostate cancer	1,214	840	3,468	1,697
Preclinical and other programs	157	214	518	632
Accrued research and development rebate	(262)	(224)	(1,524)	(493)
Total external costs	8,738	4,653	21,221	10,334
Internal costs	1,329	1,332	4,592	3,932
Total	\$ 10,067	\$ 5,985	\$ 25,813	\$ 14,266

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 June 30, 2024 September 30, 2024 and 2023

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

(in thousands)	Three Months Ended June 30,			Three Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
Revenues	\$ -	\$ 46	\$ (46)	\$ -	\$ 43	\$ (43)
Operating expenses:						
Research and development	7,053	4,148	2,905	10,067	5,985	4,082
General and administrative	2,812	2,309	503	2,219	2,586	(367)
Total operating expenses	9,865	6,457	3,408	12,286	8,571	3,715
Loss from operations	(9,865)	(6,411)	(3,454)	(12,286)	(8,528)	(3,758)
Other income (expense), net	119	(90)	209	193	(35)	(228)
Net loss	\$ (9,746)	\$ (6,501)	\$ (3,245)	\$ (12,093)	\$ (8,563)	\$ (3,530)

#### Revenues

The Company had no sales during the three months ended June 30, 2024 September 30, 2024. During the three months ended June 30, 2023 September 30, 2023, the Company sold MSC's Mesenchymal stem cells to one third-party and recognized \$46,000 \$43,000 of revenues.

#### Research and Development

Research and development expenses were approximately \$7.1 million \$10.1 million during the three months ended June 30, 2024 September 30, 2024, compared to approximately \$4.1 million \$6.0 million during the three months ended June 30, 2023 September 30, 2023. The change in research and development expenses during the three months ending June 30, 2024 September 30, 2024 compared to the three months ending June 30, 2023 September 30, 2023 is largely due to incurring \$2.6 million \$3.8 million more expenses with our Alzheimer's clinical program \$0.6 million higher expenses with our INKmun due to the advancement of enrollment in the clinical programs and 0.6 million higher salaries and stock-based compensation, partially offset by a \$0.8 million increase in our accrued research and development rebate accrual. trial.

#### General and Administrative

General and administrative expenses were approximately \$2.8 \$2.2 and \$2.3 million \$2.6 million during the three months ended June 30, 2024 September 30, 2024 and 2023, respectively. The increase decrease in general and administrative expenses was mainly due to a \$0.4 million increase the Company incurring \$0.3 million lower consulting expenses in compensation expense (including stock-based compensation) during 2024.

#### Other Income (Expense), net

The Company's other income, net is higher during the three months ended June 30, 2024 September 30, 2024, due to the Company earning interest income on its money market accounts and incurring less interest expense compared to 2023 due to a reduction in the amount of debt owed.

Comparison of the Six Nine Months Ended June 30, 2024 September 30, 2024 and 2023

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

(in thousands)	Six Months Ended			Nine Months Ended		
	June 30,			September 30,		
	2024	2023	Change	2024	2023	Change
Revenues	\$ 14	\$ 84	\$ (70)	\$ 14	\$ 127	\$ (113)
Operating expenses:						
Research and development	15,746	8,281	7,465	25,813	14,266	11,547
General and administrative	5,150	4,637	513	7,369	7,223	146
Total operating expenses	20,896	12,918	7,978	33,182	21,489	11,693
Loss from operations	(20,882)	(12,834)	(8,048)	(33,168)	(21,362)	(11,806)
Other income (expense), net	111	(203)	314	304	(238)	542
Net loss	\$ (20,771)	\$ (13,037)	\$ (7,734)	\$ (32,864)	\$ (21,600)	\$ (11,264)



## Revenues

During the ~~six~~ nine months ended ~~June 30, 2024~~ September 30, 2024, and 2023, the Company sold ~~MSC's~~ Mesenchymal stem cells to one third-party and recognized \$14,000 and ~~\$84,000~~, ~~\$127,000~~, respectively, of revenues.

## Research and Development

Research and development expenses were approximately ~~\$15.7 million~~ ~~\$25.8 million~~ and ~~\$8.3 million~~ ~~\$14.3 million~~ during the ~~six~~ nine months ended ~~June 30, 2024~~ September 30, 2024 and 2023, respectively. The change in research and development expenses during the ~~six~~ nine months ending ~~June 30, 2024~~ September 30, 2024 compared to the ~~six~~ nine months ending ~~June 30, 2023~~ September 30, 2023 is ~~largely~~ mainly due to the advancement of our clinical trials which include incurring ~~\$6.5 million more~~ ~~\$10.3 million~~ of higher expenses with our Alzheimer's clinical program ~~\$1.4 million~~ as a result of higher enrollment, \$1.8 million of higher expenses with our INKmute clinical programs as a result of progress in our metastatic castration-resistant prostate cancer clinical trial and 0.7 million higher salaries and stock-based compensation, partially offset by a \$1.0 million increase in our accrued research and development rebate accrual.

## General and Administrative

General and administrative expenses were approximately ~~\$5.2 million~~ ~~\$7.4 million~~ and ~~\$4.6 million~~ ~~\$7.2 million~~ during the ~~six~~ nine months ended ~~June 30, 2024~~ September 30, 2024 and 2023, respectively. The ~~\$0.5 million~~ ~~\$0.2 million~~ increase in general and administrative expenses was mainly due to higher compensation (including stock-based compensation) of ~~\$0.3 million~~ and ~~\$0.3 million~~ higher consulting fees, partially offset by ~~\$0.1 million~~ lower travel expenses, expense in 2024.

### Other Income (Expense), net

The Company's other income, net is higher during the ~~six~~ nine months ended ~~June 30, 2024~~ September 30, 2024, due to the Company earning interest income on its money market accounts and incurring less interest expense compared to ~~2023~~ 2024 due to a reduction in the amount of debt owed.

### 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 ~~\$20.8 million~~ \$32.9 million and ~~\$13.0 million~~ \$21.6 million for the ~~six~~ nine months ended ~~June 30, 2024~~ September 30, 2024 and 2023, respectively. Net cash used in operating activities was ~~\$15,362,000~~ \$22,348,000 and ~~\$4,315,000~~ \$8,579,000 for the ~~six~~ nine months ended ~~June 30, 2024~~ September 30, 2024 and 2023, respectively. Since inception, we have funded our operations primarily with proceeds from the sales of our common ~~stock~~, stock and warrants. As of ~~June 30, 2024~~ September 30, 2024, we had cash and cash equivalents of ~~\$31,069,000~~, \$33,552,000. 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.

During the ~~six~~ nine months ending ~~June 30, 2024~~ September 30, 2024, the Company sold ~~198,364~~ 247,126 shares of common stock at an average price of ~~\$10.56~~ \$9.85 for gross proceeds of approximately ~~\$2,095,000~~ \$2.4 million under the ~~ATM offering~~, at the market offerings.

During September 2024, the Company entered into securities purchase agreements with investors whereby the Company sold 2,341,260 shares of the Company's common stock and warrants to purchase an additional 2,341,260 shares of the Company's common stock exercisable six months from the issuance date in a registered direct offering in exchange for gross proceeds of \$13.0 million (net proceeds of approximately \$12.0 million). Directors and officers that participated in the offering paid a combined offering price of \$6.50 per share and warrant, and other investors paid \$5.50 per share and warrant. The exercise price of the warrants is \$6.40, and are exercisable beginning on March 16, 2025 and will terminate on March 16, 2030 unless accelerated pursuant to the terms of the warrant agreements.

On April 24, 2024, the Company entered into a securities purchase agreement with an investor in which the Company sold 986,000 shares of common stock and warrants to purchase 986,000 shares of common stock for gross proceeds of approximately \$9.7 million (net proceeds of approximately \$8.9 million). The exercise price of the warrants is \$9.84, and the term is the earlier of two years from the issuance of the warrants and thirty trading days following the release of top line data in the Phase 2 Alzheimer's program.

On April 19, 2024, the Company entered into securities purchase agreements with purchasers in which the Company sold 571,592 shares of common stock and warrants to purchase 571,592 shares of common stock for aggregate gross proceeds of approximately ~~\$4,771,000~~, \$4.8 million (net proceeds of approximately \$4.5 million). The exercise price of the warrants is \$9.152, and the term is the earlier of two years from the issuance of the warrants and thirty trading days following the release of top line data in the Phase 2 Alzheimer's program, provided that directors and officers of the Company that are subject to a blackout with respect to trading in the Company's stock will have an additional 60 days from the termination of the blackout date to exercise the warrant. Directors and officers that participated in the offering paid a combined offering price of \$8.445 per share and warrant, and other investors paid \$8.32 per share and warrant.

On April 24, 2024, the Company entered into a securities purchase agreement with an investor in which the Company sold 986,000 shares of common stock and warrants to purchase 986,000 shares of common stock for gross proceeds of approximately \$9,702,000. The exercise price of the warrants is \$9.84, and the term is the earlier of two years from the issuance of the warrants and thirty trading days following the release of top line data in the Phase 2 Alzheimer's program.

Our primary uses of capital are, and we expect will continue to be, third-party clinical and preclinical research and development services, costs incurred to manufacture our drugs under development, compensation and related expenses, legal, 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 significant research and development 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 ~~June 30, 2024~~ ~~September 30, 2024~~, the cash balance held by our foreign subsidiaries with currencies other than the United States dollar was approximately ~~\$0.3 million~~ ~~\$0.9 million~~.

Our recurring net losses and negative cash flows from operations, as well as forecast of continued losses and negative cash flows from operations, raised substantial doubt regarding our ability to continue as a going concern within one year after the issuance of our unaudited condensed consolidated financial statements for the year ended ~~June 30, 2024~~ ~~September 30, 2024~~. Until we can generate sufficient revenue from the commercialization of our product candidates, we expect to finance our operations through the public or private sale of equity, debt financing or other capital sources, such as government funding, collaborations, strategic alliances, divestment of non-core assets, or licensing arrangements with third parties. Our cash and cash equivalents were ~~\$31.1 million~~ ~~\$33.6 million~~ and total current assets were ~~\$35.5 million~~ ~~\$35.9 million~~ at ~~June 30, 2024~~ ~~September 30, 2024~~, which the Company is projecting will be insufficient to sustain its operations through one year following the date that the financial statements are issued.

Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development of one or more of our product candidates or cease operations. If we raise additional funds through the issuance of additional debt or equity securities it could result in dilution to our existing stockholders, increased fixed payment obligations and these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license our intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Financing strategies we may pursue include, but are not limited to, the public or private sale of equity, debt financing or funds from other capital sources, such as government or grant funding, collaborations, strategic alliances, divestment of non-core assets, or licensing arrangements with third parties. There can be no assurances additional capital will be available to secure additional financing, or if available, that it will be sufficient to meet our needs on favorable terms. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development of one or more of our product candidates. If we raise additional funds through the public or private sale of equity or debt financings, it could result in dilution to our existing stockholders or increased fixed payment obligations and these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license our intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

#### Cash Flows

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

	Six Months Ended June 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
<i>(in thousands)</i>				
Net cash and cash equivalents (used in) provided by:				
Operating activities	\$ (15,362)	\$ (4,315)	\$ (22,348)	\$ (8,579)
Financing activities	10,497	-	20,289	(1,725)
Change in cash and cash equivalents	(4,865)	(4,315)	(2,059)	(10,304)
Impact on cash from foreign currency translation	86	(13)	(237)	(36)
Cash and cash equivalents, beginning of period	35,848	52,153	35,848	52,153
Cash and cash equivalents, end of period	\$ 31,069	\$ 47,825	\$ 33,552	\$ 41,813

## Operating Activities

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

Operating activities used approximately \$15.4 million \$22.3 million of cash during the six nine months ended June 30, 2024 September 30, 2024, resulting from our loss of \$20.8 million \$32.9 million, partially offset by changes in our net operating assets and liabilities of \$1.2 million \$4.6 million and non-cash stock-based compensation of \$4.1 million \$5.8 million. The change in our net operating assets and liabilities was mainly due to an increase in accounts payable and accrued liabilities of \$1.4 million \$2.7 million, a decrease in research and development tax receivable of \$0.8 million, a decrease in prepaid expenses of \$0.5 million \$0.6 million and a decrease in other tax receivable of \$0.3 million, partially offset by an increase in research and development tax receivable of \$1.2 million \$0.2 million.

Operating activities used approximately \$4.3 million \$8.6 million of cash during the six nine months ended June 30, 2023 September 30, 2023, resulting from our loss of \$13.0 million \$21.6 million, partially offset by changes in our net operating assets and liabilities of \$5.0 million \$7.4 million and non-cash stock-based compensation of \$3.6 million \$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 \$6.2 million \$6.0 million and a decrease in prepaid expenses of \$1.3 million \$2.5 million, partially offset by a decrease in accounts payable and accrued liabilities of \$2.8 million \$1.5 million.

## Financing Activities

During the six nine months ended June 30, 2024 September 30, 2024, the Company sold 198,364 247,126 shares of its common stock under its ATM program programs for net proceeds of approximately \$2.0 million \$2.4 million.

During the six nine months ended June 30, 2024 September 30, 2024, the Company sold 1,557,692 3,898,852 shares of its common stock and 1,557,592 3,898,852 warrants to purchase its common stock in registered direct offerings for net proceeds of approximately \$25.4 million.

During the nine months ended September 30, 2023, the Company sold 75,697 shares of its common stock for net proceeds of approximately \$13.5 million. \$775,000 under the Company's ATM program with BTIG.

During the six nine months ended June 30, 2024 September 30, 2024 and 2023, the Company repaid \$5.0 million \$7.5 and \$2.5 million, respectively, of its debt.

## Critical Accounting Policies and Estimates

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, 2023, and there have been no material changes during the six nine months ended June 30, 2024 September 30, 2024.

**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**

Not required for smaller reporting companies.

### **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**

During the quarter ended **June 30, 2024** **September 30, 2024**, none of the Company's directors or officers adopted, modified, or terminated a Rule 10b5-1 trading arrangement, or a non-Rule 10b5-1 trading arrangement, in each case as defined in Item 408 of Regulation S-K.

Item 6. Exhibits

No.	Description
3.11.1	<a href="#">At-the-Market Sales Agreement, dated August 9, 2024, by and among INmune Bio Inc., RBC Capital Markets, LLC and BTIG, LLC (incorporated by reference to Exhibit 1.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on August 9, 2024)</a>
4.1	<a href="#">First Amendment Form of Warrant (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on September 16, 2024)</a>
10.1	<a href="#">Form of INmune Bio Inc. Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on September 16, 2024)</a>
10.2	<a href="#">Form of Placement Agency Agreement (incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on September 16, 2024)</a>
31.1	<a href="#">Rule 13a-14(a)/ 15d-14(a) Certification of Chief Executive Officer*</a>
31.2	<a href="#">Rule 13a-14(a)/ 15d-14(a) Certification of Chief Financial Officer*</a>
32.1	<a href="#">Section 1350 Certification of Chief Executive Officer**</a>
32.2	<a href="#">Section 1350 Certification of Chief Financial Officer**</a>
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.

Date: August 1, 2024 October 31, 2024

INmune Bio Inc.

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

Date: August 1, 2024 October 31, 2024

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

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Exhibit 3.1

### FIRST AMENDMENT TO BYLAWS OF INMUNE BIO, INC.

WHEREAS, the Board of Directors (the "Board") of INmune Bio, Inc., a Nevada Corporation (the "Company"), has deemed it advisable and in the best interest of the Company and its stockholders, pursuant to the Board's Authority set forth in Article IX, Section 1, of the Bylaws of the Company (the "Bylaws"), to adopt amendments to the Bylaws to change the standard of electing directors to the board from a plurality of votes present at the annual meeting to a majority of votes present at the annual meeting.

NOWHEREFORE, BE IT RESOLVED, that Article II, Section 2 of the Bylaws is deleted and replaced with the following:

"Annual Meetings. The Annual Meetings of Stockholders shall be held on such date and at such time as shall be designated from time to time by the Board of Directors and stated in the notice of the meeting, at which meetings the stockholders shall elect by a majority vote a Board of Directors, and transact such other business as may properly be brought before the meeting. Written notice of the Annual Meeting stating the place, date and hour of the meeting shall be given to each stockholder entitled to vote at such meeting not less than ten nor more than sixty days before the date of the meeting," and be it further

RESOLVED, Article III, Section 1 of the Bylaws is deleted and replaced with the following:

"Number and Election of Directors. The Board of Directors shall consist of one or more members, the exact number of which shall initially be fixed by the Incorporator and thereafter from time to time by the Board of Directors. Except as provided in Section 2 of this Article, directors shall be elected by a majority of the votes cast at Annual Meetings of Stockholders. Any director may resign at any time upon written notice to the Corporation. Directors need not be stockholders."

Except as herein amended, the provisions of the Bylaws shall remain in full force and effect.

AS APPROVED BY THE BOARD OF DIRECTORS EFFECTIVE: May 22, 2024.

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: August 1, 2024 October 31, 2024

/s/ Raymond J. Tesi

Raymond J. Tesi

Chief Executive Officer

(Principal executive officer)

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: August 1, 2024 October 31, 2024

/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 June 30, 2024 September 30, 2024, 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: August 1, 2024 October 31, 2024

/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 June 30, 2024 September 30, 2024, 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: August 1, 2024 October 31, 2024

/s/ David J. Moss

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

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