

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended **September 30, 2024**

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____
Commission File Number: **001-41455**

MAIA BIOTECHNOLOGY, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)
444 West Lake Street, Suite 1700
Chicago, IL
(Address of principal executive offices)

83-1495913
(I.R.S. Employer
Identification No.)

60606
(Zip Code)

(312) 416-8592

(Registrant's telephone number, including area code)

Not Applicable

(Former name or former address and fiscal year, if changed since last report)

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, \$0.0001 par value per share	MAIA	NYSE American

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

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

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

Large accelerated filer	<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 November 12, 2024, the registrant had 25,332,069 shares of common stock, \$0.0001 par value per share, outstanding.

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CAUTIONARY NOTICE ABOUT FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements, which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). This Report contains a number of forward-looking statements that reflect management's current views and expectations with respect to our business, strategies, products, future results and events, and financial performance. All statements other than statements of historical facts contained in this report, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. In some cases, forward-looking statements may be identified by words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could," "would," "expect," "objective," "plan," "potential," "seek," "grow," "target," "if," variations of such words, the negative of these terms and similar expressions intended to identify forward-looking statements. Our actual results may differ materially from those currently anticipated and expressed in such forward-looking statements as a result of a number of factors, including those which we discuss under "Risk Factors," elsewhere in this Quarterly Report on Form 10-Q and in our other filings with the Securities and Exchange Commission (the "SEC").

Readers should not place undue reliance on these forward-looking statements, which are based on management's current expectations and projections about future events, are not guarantees of future performance, are subject to risks, uncertainties and assumptions and apply only as of the date of this Report. Our actual results, performance or achievements could differ materially from historical results as well as from the results expressed in, anticipated or implied by these forward-looking statements. An occurrence of, or any material adverse change in, one or more of the risk factors or risks and uncertainties referred to in this Report or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the U.S. Securities and Exchange Commission could materially and adversely affect our business, prospects, financial condition and results of operations. Except as required by law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Any public statements or disclosures by us following this Report that modify or impact any of the forward-looking statements contained in this Report will be deemed to modify or supersede such statements in this Report.

For a discussion of some of the factors that may affect our business, results and prospects, see "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the Securities and Exchange Commission ("SEC") on March 21, 2024 and in our other reports we file with the SEC, including our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. Readers are also urged to carefully review and consider the various disclosures made by us in this Report and in our other reports we file with the SEC, including our Quarterly Reports on Forms 10-Q and Current Reports on Form 8-K, and those described from time to time in our press releases and other communications, which attempt to advise interested parties of the risks and factors that may affect our business, prospects and results of operations.

Unless the context indicates or otherwise requires, "the Company," "our Company," "we," "us," and "our" refer to MAIA Biotechnology, Inc., a Delaware corporation, and its consolidated subsidiaries.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

MAIA Biotechnology, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets

	September 30, 2024	December 31, 2023
	(unaudited)	
ASSETS		
Current assets:		
Cash	\$ 8,690,784	\$ 7,150,695
Prepaid expenses and other current assets	495,650	268,677
Australia research and development incentives receivable	53,608	144,680
Total current assets	9,240,042	7,564,052
Other assets	2,800	2,800
Total assets	\$ 9,242,842	\$ 7,566,852
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,152,055	\$ 1,638,546
Accrued expenses	2,456,844	3,298,607
Total current liabilities	3,608,899	4,937,153
Long term liabilities:		
Warrant liability	4,015,352	2,152,188
Total liabilities	7,624,251	7,089,341
Commitments and contingencies (Note 6)		
Stockholders' equity		
Preferred stock, \$0.0001 par value, 30,000,000 shares authorized at September 30, 2024 and December 31, 2023, 0 shares issued and outstanding	—	—
Common stock, \$0.0001 par value, 70,000,000 shares authorized at September 30, 2024 and December 31, 2023, 23,966,814 and 16,986,254 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	2,397	1,699
Additional paid-in capital	85,290,791	64,472,249
Accumulated deficit	(83,662,895)	(63,980,177)
Accumulated other comprehensive loss	(11,702)	(16,260)
Total stockholders' equity	1,618,591	477,511
Total liabilities and stockholders' equity	\$ 9,242,842	\$ 7,566,852

See the accompanying notes to the unaudited condensed consolidated financial statements.

MAIA Biotechnology, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development expenses	\$ 2,667,170	\$ 2,599,578	\$ 7,040,145	\$ 7,394,884
General and administrative expenses	1,521,298	2,356,065	4,912,461	6,409,655
Total operating expenses	4,188,468	4,955,643	11,952,606	13,804,539
Loss from operations	(4,188,468)	(4,955,643)	(11,952,606)	(13,804,539)
Other (expense) income:				
Interest expense	(85)	(1)	(85)	(6,863)
Interest income	106,082	3,260	238,583	3,768
Australian research and development incentives	15,198	58,448	51,847	149,457
Change in fair value of warrant liability	1,331,286	18,193	(8,007,505)	141,934
Loss on fair value of warrants over proceeds	—	—	(12,952)	—
Other (expense) income, net	1,452,481	79,900	(7,730,112)	288,296
Net loss	(2,735,987)	(4,875,743)	(19,682,718)	(13,516,243)
Net loss attributable to MAIA Biotechnology, Inc. shareholders	\$ (2,735,987)	\$ (4,875,743)	\$ (19,682,718)	\$ (13,516,243)
Net loss per share				
Basic and diluted	\$ (0.11)	\$ (0.36)	\$ (0.93)	\$ (1.08)
Weighted average common shares outstanding basic and diluted	23,894,980	13,675,802	21,249,725	12,521,264

See the accompanying notes to the unaudited condensed consolidated financial statements.

MAIA Biotechnology, Inc. and Subsidiaries
Condensed Consolidated Statements of Comprehensive Loss
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net loss	\$ (2,735,987)	\$ (4,875,743)	\$ (19,682,718)	\$ (13,516,243)
Foreign currency translation adjustment	10,476	(17,858)	4,558	(43,766)
Comprehensive loss	<u>\$ (2,725,511)</u>	<u>\$ (4,893,601)</u>	<u>\$ (19,678,160)</u>	<u>\$ (13,560,009)</u>

See the accompanying notes to the unaudited condensed consolidated financial statements.

MAIA Biotechnology, Inc. and Subsidiaries
Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit) (Unaudited)

For the Three and Nine Months Ended
September 30, 2024

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance at December 31, 2023	—	\$ —	16,986,254	\$ 1,699	\$ 64,472,249	\$ (63,980,177)	\$ (16,260)	\$ 477,511
Issuance of restricted stock	—	—	12,500	1	11,499	—	—	11,500
Stock-based compensation expense	—	—	—	—	349,965	—	—	349,965
Issuance of common shares in connection with At-The-Market financing, net of \$179,628 of issuance costs	—	—	507,754	51	565,572	—	—	565,623
Issuance of common shares in connection with the Private Placement Offering #1, net of \$50,000 of issuance costs	—	—	2,496,318	250	590,161	—	—	590,411
Issuance of common shares in connection with the Private Placement Offering #2, net of \$47,261 of issuance costs	—	—	578,643	58	90,560	—	—	90,618
Issuance of warrants in connection with the Private Placement Offering #1	—	—	—	—	230,685	—	—	230,685
Foreign currency translation adjustment	—	—	—	—	—	—	(13,786)	(13,786)
Net loss	—	—	—	—	—	(8,067,455)	—	(8,067,455)
Balance at March 31, 2024	—	\$ —	20,581,469	\$ 2,059	\$ 66,310,691	\$ (72,047,632)	\$ (30,046)	\$ (5,764,928)
Exercise of stock options	—	—	101,837	10	185,636	—	—	185,646
Stock-based compensation expense	—	—	—	—	413,948	—	—	413,948
Issuance of common shares in connection with At-The-Market financing, net of \$315,314 of issuance costs	—	—	2,015,122	202	6,801,462	—	—	6,801,664
Issuance of common shares in connection with the Private Placement Offering #3, net of \$5,030 of issuance costs	—	—	494,096	49	162,028	—	—	162,077
Issuance of warrants in connection with the Private Placement Offering #3	—	—	—	—	172,925	—	—	172,925
Exercise of warrants	—	—	545,309	54	3,191,621	—	—	3,191,675
Reclassification of liability classified warrants to equity	—	—	—	—	6,870,296	—	—	6,870,296
Foreign currency translation adjustment	—	—	—	—	—	—	7,868	7,868
Net loss	—	—	—	—	—	(8,879,276)	—	(8,879,276)
Balance at June 30, 2024	—	\$ —	23,737,833	\$ 2,374	\$ 84,108,607	\$ (80,926,908)	\$ (22,178)	\$ 3,161,895
Issuance of restricted stock	—	—	34,602	3	99,997	—	—	100,000
Exercise of stock options	—	—	16,773	2	30,190	—	—	30,192
Stock-based compensation expense	—	—	—	—	455,388	—	—	455,388
Issuance of common shares in connection with At-The-Market financing, net of \$63,810 of issuance costs	—	—	177,606	18	596,609	—	—	596,627
Foreign currency translation adjustment	—	—	—	—	—	—	10,476	10,476
Net loss	—	—	—	—	—	(2,735,987)	—	(2,735,987)
Balance at September 30, 2024	—	\$ —	23,966,814	\$ 2,397	\$ 85,290,791	\$ (83,662,895)	\$ (11,702)	\$ 1,618,591

See the accompanying notes to the unaudited condensed consolidated financial statements.

MAIA Biotechnology, Inc. and Subsidiaries
Condensed Consolidated Statements of Changes in Stockholders' Equity (Unaudited)

For the Three and Nine Months Ended
September 30, 2023

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2022	—	\$ —	10,955,904	\$ 1,096	\$ 52,729,942	\$ (44,207,272)	\$ (15,973)	\$ 8,507,793
Issuance of restricted stock	—	—	40,500	4	164,066	—	—	164,070
Stock-based compensation expense	—	—	—	—	537,522	—	—	537,522
Foreign currency translation adjustment	—	—	—	—	—	—	(9,301)	(9,301)
Net loss	—	—	—	—	—	(4,116,876)	—	(4,116,876)
Balance at March 31, 2023	—	\$ —	10,996,404	\$ 1,100	\$ 53,431,530	\$ (48,324,148)	\$ (25,274)	\$ 5,083,208
Issuance of restricted stock	—	—	96,521	9	324,251	—	—	324,260
Issuance of common shares in connection with follow-on offering, net of \$1,593,016 of issuance costs	—	—	2,555,500	256	4,156,603	—	—	4,156,859
Issuance of warrants to underwriter in connection with follow-on offering	—	—	—	—	241,109	—	—	241,109
Stock-based compensation expense	—	—	—	—	618,932	—	—	618,932
Issuance of stock options to satisfy accrued bonus	—	—	—	—	974,224	—	—	974,224
Foreign currency translation adjustment	—	—	—	—	—	—	(634)	(634)
Net loss	—	—	—	—	—	(4,523,624)	—	(4,523,624)
Balance at June 30, 2023	—	\$ —	13,648,425	\$ 1,365	\$ 59,746,649	\$ (52,847,772)	\$ (25,908)	\$ 6,874,334
Issuance of common shares upon exercise of stock options	—	—	750	1	1,432	—	—	1,433
Issuance of restricted stock	—	—	111,948	11	194,619	—	—	194,630
Stock-based compensation expense	—	—	—	—	570,916	—	—	570,916
Foreign currency translation adjustment	—	—	—	—	—	—	(17,858)	(17,858)
Net loss	—	—	—	—	—	(4,875,743)	—	(4,875,743)
Balance at September 30, 2023	—	\$ —	13,761,123	\$ 1,377	\$ 60,513,616	\$ (57,723,515)	\$ (43,766)	\$ 2,747,712

See the accompanying notes to the unaudited condensed consolidated financial statements.

MAIA Biotechnology, Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine Months Ended	
	September 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (19,682,718)	\$ (13,516,243)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,219,301	1,727,369
Consulting expense for restricted shares issued	111,500	682,962
Change in fair value of warrant liability	8,007,505	(141,934)
Loss on fair value of warrants over proceeds	12,952	—
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(227,368)	134,145
Australia research and development incentives receivable	92,551	174,613
Accounts payable	(488,135)	64,016
Accrued expenses	(841,874)	1,796,502
Net cash used in operating activities	<u>(11,796,286)</u>	<u>(9,078,570)</u>
Cash flows from financing activities:		
Deferred offering costs	—	(153,937)
Proceeds from exercise of stock options	215,838	1,432
Proceeds from sale of common stock in follow-on offering	—	5,749,875
Proceeds from private placement round 1	2,920,696	—
Proceeds from private placement round 2	1,327,990	—
Proceeds from private placement round 3	1,004,999	—
Proceeds from ATM Offerings	8,522,666	—
Payment of offering transactions costs	(661,043)	(1,351,907)
Net cash provided by financing activities	<u>13,331,146</u>	<u>4,245,463</u>
Net effect of foreign currency exchange on cash	5,229	(13,233)
Net increase (decrease) in cash	1,540,089	(4,846,340)
Cash at beginning of period	7,150,695	10,950,927
Cash at end of period	<u>\$ 8,690,784</u>	<u>\$ 6,104,587</u>
Supplemental disclosure of cash flow information:		
Options issued for accrued bonus	<u>\$ —</u>	<u>\$ 974,224</u>
Warrants issued to underwriters in connection with the follow-on offering	<u>\$ —</u>	<u>\$ 241,109</u>
Warrants issued in connection with private placement offering #1	<u>\$ 2,049,600</u>	<u>\$ —</u>
Warrants issued in connection with private placement offering #2	<u>\$ 1,190,111</u>	<u>\$ —</u>
Warrants issued in connection with private placement offering #3	<u>\$ 677,919</u>	<u>\$ —</u>

See the accompanying notes to the unaudited condensed consolidated financial statements.

MAIA Biotechnology, Inc. and Subsidiaries
Notes to Unaudited Condensed Consolidated Financial Statements

1. NATURE OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business, Organization, and Principles of Consolidation

MAIA Biotechnology, Inc. and subsidiaries (collectively, “the Company”) is a biopharmaceutical company that develops oncology drug candidates to improve and extend the lives of people with cancer. MAIA Biotechnology, Inc. (“MAIA”) was incorporated in the state of Delaware on August 3, 2018. These consolidated financial statements include the accounts of MAIA and its subsidiaries, as follows:

- In July 2021, the Company established a wholly owned Australian subsidiary, MAIA Biotechnology Australia Pty Ltd., to conduct various pre-clinical and clinical activities for the development of the Company’s product candidates.
- In April 2022, the Company established a wholly owned Romanian subsidiary, MAIA Biotechnology Romania S.R.L., to conduct various pre-clinical and clinical activities for the development of the Company’s product candidates.

Going Concern Considerations

The accompanying unaudited consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

To date, the Company has incurred recurring losses, negative cash flow from operations and has accumulated a deficit of \$83,662,895 from the Company’s inception through September 30, 2024. As of September 30, 2024, the Company had \$8,690,784 in cash and cash equivalents and working capital of approximately \$5,631,143.

To meet the Company’s future working capital needs, the Company will need to raise additional equity or enter into debt financing. While the Company has historically been able to raise additional capital through issuance of equity and/or debt financing, and while the Company has implemented a plan to control its expenses in order to satisfy its obligations due within one year from the date of issuance of these financial statements, the Company cannot guarantee that it will be able to raise additional equity, raise debt, or contain expenses. Accordingly, there is substantial doubt about the Company’s ability to continue as a going concern within one year after these financial statements are issued.

Basis of Presentation

Basis of Presentation and Consolidation Principles

The accompanying condensed consolidated financial statements have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (“SEC”). Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) have been condensed or omitted pursuant to such rules and regulations. The condensed consolidated financial statements may not include all disclosures required by GAAP; however, the Company believes that the disclosures are adequate to make the information presented not misleading. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and the notes thereto for the fiscal year ended December 31, 2023 included in the Company’s Annual Report on Form 10-K filed with the SEC on March 21, 2024. The condensed consolidated balance sheet as of December 31, 2023 was derived from such audited financial statements.

In the opinion of management, all adjustments, consisting of only normal recurring adjustments that are necessary to present fairly the financial position, results of operations, and cash flows for the interim periods, have been made.

The results of operations for the interim periods are not necessarily indicative of the operating results for the full fiscal year or any future periods.

The unaudited interim condensed consolidated financial statements include the accounts of the Company's wholly owned subsidiaries. All transactions and accounts between and among its subsidiaries have been eliminated. All adjustments and disclosures necessary for a fair presentation of these unaudited interim condensed consolidated financial statements have been included.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company and the Company's chief operating decision-maker, the Company's Chief Executive Officer, view the Company's operations and manage its business as a single operating segment, which is the business of discovering and developing products for the treatment of immunotherapies for cancer.

Use of Estimates

The preparation of the Company's unaudited interim condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The most significant estimates in the Company's financial statements relate to the valuation of the Company's common stock, par value \$0.0001 per share (the "Common Stock"), stock options and warrants, the embedded features in convertible notes, and accruals for outsourced research and development activities. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Certain Risks and Uncertainties

The Company's activities are subject to significant risks and uncertainties including the risk of failure to secure additional funding to properly execute the Company's business plan. The Company is subject to risks that are common to companies in the pharmaceutical industry, including, but not limited to, the development by the Company or its competitors of new technological innovations, dependence on key personnel, reliance on third party manufacturers, protection of proprietary technology, and compliance with regulatory requirements.

Foreign Currency Translation

The financial statements of the Company's foreign subsidiaries, where the local currency is the functional currency, are translated using exchange rates in effect as of the applicable balance sheet dates for assets and liabilities and average exchange rates during the period for results of operations. The resulting foreign currency translation adjustment is included in stockholders' equity as accumulated other comprehensive loss.

Off-Balance Sheet Risk and Concentrations of Credit Risk

The Company has no significant off-balance sheet risks, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Cash accounts are maintained at financial institutions that potentially subject the Company to concentrations of credit risk. As of September 30, 2024 and December 31, 2023, substantially all of the Company's cash was deposited in accounts at two financial institutions. The Company maintains its cash deposits, which at times may exceed the federally insured limits, with a reputable financial institution, and accordingly, the Company believes such funds are subject to minimal credit risk.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with maturities of three months or less to be cash equivalents. As of September 30, 2024 and December 31, 2023, cash includes cash in depository bank accounts. The Company had no cash equivalents as of September 30, 2024 or December 31, 2023.

Fair Value Measurements

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. Accounting Standards Codification (“ASC”) Topic 820, *Fair Value Measurements and Disclosures* (“ASC 820”) establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available.

Under this accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. To increase the comparability of fair value measures, the following hierarchy prioritizes the inputs to valuation methodologies used to measure fair value:

- Level 1 - Valuations based on quoted prices for identical assets and liabilities in active markets.
- Level 2 - Valuations based on observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 - Valuations based on unobservable inputs reflecting our own assumptions, consistent with reasonably available assumptions made by other market participants. These valuations require significant judgment.

Fair value measurements discussed herein are based upon certain market assumptions and pertinent information available to management as of and during the nine months ended September 30, 2024, and as of and during the twelve months ended December 31, 2023. The carrying amount of accounts payable approximated fair value, as they are short term in nature. The fair value of warrants issued for services is estimated based on the Black-Scholes-Merton model during the nine months ended September 30, 2024. The estimated fair value of warrants issued to underwriters represented Level 3 measurements.

General and Administrative

General and administrative expenses primarily consist of costs for corporate functions, including payroll and related expenses, rent, outside legal expenses, insurance costs, and other general and administrative costs.

Research and Development

The Company’s research and development expenses consist primarily of costs associated with the Company’s clinical trials, salaries, payroll taxes, employee benefits, and stock-based compensation charges for those individuals involved in ongoing research and development efforts. Research and development costs are expensed as incurred. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received.

As part of the process of preparing the condensed consolidated financial statements, the Company is required to estimate its accrued expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on the Company’s behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of the actual cost. The majority of the Company’s service providers invoice the Company monthly in arrears for services performed or when contractual milestones are met. The Company makes estimates of its accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to the Company at that time. The Company periodically confirms the accuracy of its estimates with the service providers and makes

adjustments if necessary. The estimates in the Company's accrued research and development expenses are related to expenses incurred with respect to contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), and other vendors in connection with research and development and manufacturing activities.

The Company bases its expense related to CROs and CMOs on its estimates of the services received and efforts expended pursuant to quotations and contracts with such vendors that conduct research and development and manufacturing activities on the Company's behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to the Company's vendors will exceed the level of services provided and result in a prepayment of the applicable research and development or manufacturing expense. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from its estimate, the Company adjusts the accrual or prepaid expense accordingly. Although the Company does not expect its estimates to be materially different from amounts actually incurred, the Company's understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low in any particular period. There have been no material changes in estimates for the periods presented.

Research and Development Incentive

The Company recognizes other income from Australian research and development incentives when there is reasonable assurance that the income will be received, the relevant expenditure has been incurred, and the consideration can be reliably measured. The research and development incentive is one of the key elements of the Australian government's support for Australia's innovation system and is supported by legislative law primarily in the form of the Australian Income Tax Assessment Act 1997, as long as eligibility criteria are met. Under the program, a percentage of eligible research and development expenses incurred by the Company through its subsidiary in Australia are reimbursed.

Management has assessed the Company's research and development activities and expenditures to determine which activities and expenditures are likely to be eligible under the research and development incentive regime described above. At each period end, management estimates the refundable tax offset available to the Company based on available information at the time, and it is included in Australian research and development incentives in the condensed consolidated statements of operations.

Derivative Financial Instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. The Company evaluates all of its financial instruments to determine if such instruments contain features that qualify as embedded derivatives.

Embedded derivatives must be separately measured from the host contract if all the requirements for bifurcation are met. The assessment of the conditions surrounding the bifurcation of embedded derivatives depends on the nature of the host contract. Bifurcated embedded derivatives are recognized at fair value, with changes in fair value recognized in the statement of operations each period.

Stock-Based Compensation

The Company records share-based compensation for awards granted to employees, non-employees, and to members of the board of directors based on the grant date fair value of awards issued, and the expense is recorded on a straight-line basis over the requisite service period. Forfeitures are recognized when they occur.

The Company uses the Black-Scholes-Merton option pricing model to determine the fair value of stock options and warrants. The use of the Black-Scholes-Merton option-pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the Common Stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the Common Stock. The Company has concluded that its historical share option exercise experience does not provide a reasonable basis upon which to estimate expected term. Therefore, the expected term was determined according to the simplified method,

which is the average of the vesting tranche dates and the contractual term. Due to the lack of company specific historical and implied volatility data, the estimate of expected volatility is primarily based on the historical volatility of a group of similar companies that are publicly traded. For these analyses, companies with comparable characteristics, including enterprise value and position within the industry, and with historical share price information sufficient to meet the expected life of the share-based awards, are selected. The Company computes the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of its share-based awards. The risk-free interest rate is determined by reference to U.S. Treasury zero-coupon issues with remaining maturities similar to the expected term of the options. The Company has not paid, and does not anticipate paying, cash dividends on shares of its Common Stock.

Prior to the Company's initial public offering ("IPO") in order to estimate the fair value of shares of the Common Stock, the Company's board of directors considered, among other things, sales of Common Stock to third party investors and valuations of Common Stock, business, financial condition and results of operations, including related industry trends affecting operations; the likelihood of achieving a liquidity event, such as an initial public offering, or sale, given prevailing market conditions; the lack of marketability of our Common Stock; the market performance of comparable publicly traded companies; and U.S. and global economic and capital market conditions.

During the nine months ended September 30, 2024, 47,102 restricted shares of Common Stock were issued for consulting services. During the nine months ended September 30, 2023, 248,969 restricted shares of Common Stock were issued for consulting services. The fair value of restricted stock awards is based on the Common Stock price.

All stock-based compensation costs are recorded in general and administrative or research and development costs in the condensed consolidated statements of operations based upon the underlying individual's role at the Company.

Common Stock Warrants

The Company accounts for Common Stock warrants as either equity instruments or as liabilities in accordance with ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480"), depending on the specific terms of the warrant agreement.

When warrants are issued for services provided by non-employees, under ASC 718, *Compensation – Stock Compensation* ("ASC 718"), the warrants shall be classified as a liability if: (i) the underlying shares are classified as liabilities; or (ii) the entity can be required under any circumstances to settle the warrant by transferring cash or other assets. The measurement of equity-classified non-employee share-based payments is generally fixed on the grant date and are considered compensatory, as defined by ASC 718.

Income Taxes

Income taxes are recorded in accordance with ASC 740, *Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit would more likely than not be realized, assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company recognizes any interest and penalties accrued related to unrecognized tax benefits as income tax expense.

Net Loss Per Share

Basic loss per share of Common Stock is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of Common Stock outstanding for the period. Diluted net loss per share is calculated by adjusting the weighted-average number of shares outstanding for the dilutive effect of Common Stock equivalents outstanding for the period, determined using the treasury-stock method. Diluted loss per share excludes,

when applicable, the potential impact of stock options, unvested shares of restricted stock awards, and common stock warrants because their effect would be anti-dilutive due to our net loss. Gains on warrant liabilities are only considered dilutive when the average market price of the Common Stock during the period exceeds the exercise price of the warrants. Since the Company had a net loss in each of the periods presented, basic and diluted net loss per common share are the same.

The following table summarizes the Company's potentially dilutive securities, in common share equivalents, which have been excluded from the calculation of dilutive loss per share as their effect would be anti-dilutive:

	Nine Months Ended September 30,	
	2024	2023
Shares issuable upon exercise of stock options	9,389,527	7,860,736
Shares issuable upon exercise of warrants	5,442,246	924,760

Recent Accounting Standards

In November 2023, the Financial Accounting Standards Board ("FASB") issued ASU No. 2023-07, *Segment Reporting – Improvements to Reportable Segment Disclosures* ("ASU No. 2023-07"), which provides updates to qualitative and quantitative reportable segment disclosure requirements, including enhanced disclosures about significant segment expenses and increased interim disclosure requirements, among others. ASU No. 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods in fiscal years beginning after December 15, 2024. Early adoption is permitted, and the amendments should be applied retrospectively. We do not expect the amendments in ASU No. 2023-07 to have a material impact on our consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, *Improvements to Income Tax Disclosures* ("ASU No. 2023-09"), which requires disclosure of disaggregated income taxes paid, prescribes standard categories for the components of the effective tax rate reconciliation, and modifies other income tax-related disclosures. ASU No. 2023-09 is effective for fiscal years beginning after December 15, 2024 and allows for adoption on a prospective basis, with a retrospective option. Early adoption is permitted. We do not expect the amendments in ASU No. 2023-09 to have a material impact on our consolidated financial statements.

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

2. RELATED PARTY TRANSACTIONS

10b5-1 Plan

Certain of our directors and executive officers previously adopted written plans, known as Rule 10b5-1 plans, in which they contracted with a broker to buy shares of our Common Stock on a periodic basis. Each of these plans have expired as of the date of this Quarterly Report. Our directors and executive officers may, in the future, adopt Rule 10b5-1 plans in which they contract with a broker to buy or sell shares of our Common Stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer at the time was entered into, without further direction from the director or officer. The director or officer may amend or terminate the plan in limited circumstances. Our directors and executive officers may also buy or sell additional shares of our Common Stock outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information.

Private Placement

The following Company directors participated in the March 2024 private placement as follows: (i) Stan Smith purchased 170,940 shares of our Common Stock and warrants to purchase up to 170,940 shares of our Common Stock for an aggregate purchase price of \$200,000; (ii) Louie Ngar Yee purchased 170,940 shares of our Common Stock and warrants to purchase up to 170,940 shares of our Common Stock for an aggregate purchase price of \$200,000; (iii) Cristian Luput purchased 69,282 shares of our Common Stock and warrants to purchase up to 69,282 shares of our Common Stock for an aggregate purchase price of \$81,060; (iv) Steven Chaouki purchased 34,641 shares of our Common Stock and warrants to purchase up to 34,641 shares of our Common Stock for an aggregate purchase price of \$40,530; and (v) Ramiro Guerrero purchased 6,928 shares of our Common Stock and warrants to purchase up to 6,928 shares of our Common Stock for an aggregate purchase price of \$8,106.

The following Company directors participated in the April 2024 private placement as follows: (i) Stan Smith purchased 147,492 shares of our Common Stock and warrants to purchase up to 147,492 shares of our Common Stock for an aggregate purchase price of \$300,000; (ii) Louie Ngar Yee purchased 19,665 shares of our Common Stock and warrants to purchase up to 19,665 shares of our Common Stock for an aggregate purchase price of \$40,000.

3. ACCRUED EXPENSES

As of September 30, 2024 and December 31, 2023 accrued expenses consisted of the following:

	<u>September 30,</u> <u>2024</u>	<u>December 31,</u> <u>2023</u>
Bonus	\$ 702,928	\$ 786,999
Professional fees	64,874	77,942
Research and development costs	1,160,265	998,838
Accrued severance	214,899	824,435
Other	313,878	610,393
Total accrued expenses	<u>\$ 2,456,844</u>	<u>\$ 3,298,607</u>

4. FAIR VALUE OF FINANCIAL LIABILITIES

Derivative Liability

Financial liabilities consisting of warrant liabilities measured at fair value on a recurring basis are summarized below. The fair value of the warrant liabilities recorded are as follows:

	<u>Fair value at September 30, 2024</u>			
	<u>Total</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Liabilities:				
Warrant liability	\$ 4,015,352	\$ —	\$ —	\$ 4,015,352
Total liabilities	<u>\$ 4,015,352</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 4,015,352</u>

	<u>Fair value at December 31, 2023</u>			
	<u>Total</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Liabilities:				
Warrant liability	\$ 2,152,188	\$ —	\$ —	\$ 2,152,188
Total liabilities	<u>\$ 2,152,188</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,152,188</u>

The table below provides a summary of the changes in fair value of the warrant liabilities measured on a recurring basis using significant unobservable inputs (Level 3):

Warrant liabilities:	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Balance, beginning of period	\$ 5,346,638	\$ 121,600	\$ 2,152,188	\$ 245,341
Issuance of warrants	—	—	3,917,630	—
Exercises of warrants	—	—	(3,191,675)	—
Amendments of warrants	—	—	(6,870,296)	—
Loss (Gain) on fair value of warrant liability	(1,331,286)	(18,193)	8,007,505	(141,934)
Balance, end of period	\$ 4,015,352	\$ 103,407	\$ 4,015,352	\$ 103,407

5. STOCKHOLDERS' EQUITY

Upon the closing of the Company's IPO, the Company's shareholders agreement terminated pursuant to its terms. In connection with the closing of the IPO, the Company amended and restated its Amended and Restated Certificate of Incorporation (the "Amended and Restated Certificate of Incorporation") and amended and restated its Bylaws (the "Amended and Restated Bylaws"). The Amended and Restated Certificate of Incorporation was filed with the Secretary of State of the State of Delaware on August 1, 2022 and became effective on that date, and among other things, increased the authorized number of Common Stock to 70,000,000 shares and decreased the authorized number of preferred stock to 30,000,000 shares.

At-the-Market Equity Offering

On February 14, 2024, the Company entered into an At The Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC ("Wainwright"), to sell shares of its Common Stock, par value \$0.0001 per share, (the "Shares") having an aggregate sales price of up to \$1,445,000, from time to time, through an at-the-market offering program under which Wainwright will act as sales agent. The sales, if any, of the Shares made under the ATM Agreement will be made by any method permitted by law deemed to be an "at-the-market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the "Securities Act"). Effective March 25, 2024, the Company filed a prospectus supplement to amend, supplement and supersede certain information contained in the earlier prospectus and prospectus supplement, which increased the number of Shares the Company may offer and sell under the ATM Agreement to an aggregate offering price of up to \$4,950,000, from time to time. Effective May 15, 2024, the Company filed a prospectus supplement to amend, supplement and supersede certain information contained in the earlier prospectus and prospectus supplement, which increased the number of Shares the Company may offer and sell under the ATM Agreement to an aggregate offering price of up to \$11,280,000 from time to time. The Company will pay Wainwright a commission rate equal to 3.0% of the aggregate gross proceeds from each sale of Shares. As of September 30, 2024, the Company sold 2,700,482 shares of Common Stock at an average price of approximately \$3.16 per share, resulting in aggregate gross proceeds of approximately \$8,522,666, for which it paid Wainwright approximately \$255,680 in commissions, resulting in net proceeds to the Company of approximately \$8,266,986. The Company anticipates that the at-the-market offering will continue throughout the next reporting period.

Share Repurchase Program

On September 28, 2023, the Company announced that its board of directors approved a share repurchase program pursuant to which the Company may repurchase up to \$800,000 of the Company's issued and outstanding shares of Common Stock, par value \$0.0001 per share, through September 2024. The Company expects to fund repurchases by using cash on hand and cash flow expected to be generated in the future. As of September 30, 2024 no shares have been repurchased under the program.

Private Placement

On March 14, 2024, the Company issued and sold 2,496,318 shares of its Common Stock and warrants to purchase 2,496,318 shares of its Common Stock in a private placement to certain accredited investors and Company directors pursuant to securities purchase agreements dated March 11, 2024 at a price per share of \$1.17 for which the

Company received gross proceeds of approximately \$2.92 million. The warrants are exercisable at a price per share of \$1.30, are exercisable commencing six months following issuance, have a term of five years from the initial exercise date, and expiring on September 14, 2029. The securities sold to Company directors participating in the private placement were issued pursuant to the MAIA Biotechnology, Inc. 2021 Equity Incentive Plan (the “MAIA 2021 Plan”).

On March 28, 2024, the Company issued and sold 578,643 shares of its Common Stock and warrants to purchase 578,643 shares of its Common Stock in a private placement to certain accredited investors pursuant to securities purchase agreements dated March 25, 2024 at a price per share of \$2.295 for which the Company received gross proceeds of approximately \$1.33 million. The warrants are exercisable at a price per share of \$2.55, are exercisable commencing six months following issuance, and have a term of five years from the initial exercise date, expiring on September 28, 2029.

On April 25, 2024, the Company issued and sold 494,096 shares of its Common Stock and warrants to purchase 494,096 shares of its Common Stock in a private placement to certain accredited investors and Company directors pursuant to securities purchase agreements dated April 22, 2024 at a price per share of \$2.034 for which the Company received gross proceeds of approximately \$1.0 million. The warrants are exercisable at a price per share of \$2.26, are exercisable commencing six months following issuance, have a term of five years from the initial exercise date, and expiring on October 25, 2029. The securities sold to Company directors participating in the private placement were issued pursuant to the MAIA 2021 Plan.

MAIA Biotechnology, Inc. Restricted Stock Awards

During the nine months ended September 30, 2024, the Company expensed \$111,500 to consulting expense for investor relations related to the grant of 47,102 restricted shares of Common Stock. There are no unvested restricted shares as of September 30, 2024.

During the nine months ended September 30, 2023, the Company expensed \$682,962 to consulting for investor relations related to the grant of 248,969 restricted shares of Common Stock. There were no unvested restricted shares as of September 30, 2023.

MAIA Stock Warrants

Concurrently with the closing of the IPO, the Company issued warrants to purchase an aggregate of up to 100,000 shares of its Common Stock to the representative or its designees, at an exercise price of \$6.25 per share (the “Representative’s Warrants”). The Representative’s Warrants were exercisable beginning on January 23, 2023, and expire on July 27, 2027, pursuant to their terms and conditions. On August 3, 2023, concurrently with the full exercise of the representative’s over-allotment option, the Company issued additional Representative’s Warrants to purchase an aggregate of up to 15,000 shares of its Common Stock to the representative or its designees on the same terms. The Representative’s Warrants are not indexed to the Company’s own stock and therefore meet the definition of a derivative liability. The Representative’s Warrants are liability classified instruments and were initially recorded at a value of \$343,735, which was determined using the Black-Scholes-Merton method using a term of five years, risk free interest rate of 2.82% and volatility of 77.5%. As of September 30, 2024 and December 31, 2023, the Company remeasured the warrant liability resulting in a value of \$140,963 and \$40,211 respectively. The gain on remeasurement of the warrant liability in the amount of \$68,646 and the loss on remeasurement in the amount of \$100,752 was included in other (expense) income for the three and nine months ended September 30, 2024, respectively. The gain on remeasurement of the warrant liability in the amount of \$18,193 and \$141,934 was included in other (expense) income for the three and nine months ended September 30, 2023.

On November 9, 2023, the Company issued warrants to purchase an aggregate of up to 239,234 shares of its Common Stock to Alumni Capital LP (“Alumni”), at an exercise price of \$2.09 per share. The warrants were exercisable beginning on November 10, 2023, and expire on November 10, 2027, pursuant to their terms and conditions. The warrants are not indexed to the Company’s own stock and therefore meet the definition of a derivative liability. On November 13, 2023, 131,578 warrant shares vested in accordance with the terms. The warrants are liability classified instruments and were initially recorded at a value of \$84,251, which was determined using the Black-Scholes-Merton method using a term of 3.87 years, risk free interest rate of 3.93% and volatility of 90.0%. Laidlaw & Company Ltd. acted as the financial advisor to the Company in connection with the warrant and were paid a cash fee of \$13,750. The warrants were exercised on May 22, 2024 in a cashless exercise and Alumni

was issued 54,976 shares of Common Stock. The Company remeasured the warrant liability at the time of the exercise resulting in a value of \$375,705. The warrant liability was removed to reflect the warrants being exercised and equity was increased by the value of \$375,705. As of September 30, 2024 and December 31, 2023, the warrant liability resulted in a value of \$0 and \$84,251, respectively. The loss on remeasurement in the amount of \$0 and \$291,454 was included in other (expense) income for the three and nine months ended September 30, 2024, respectively.

On November 17, 2023, the Company issued warrants concurrently with the Company's registered direct offering to purchase an aggregate of up to 2,424,243 shares of its Common Stock to the investors in the registered direct offering at an exercise price of \$1.86 per share (subject to customary adjustments as set forth in the warrants). The warrants are exercisable six months following issuance and will have a term of five years from the initial exercise date. The warrants contain customary anti-dilution adjustments to the exercise price, including for share splits, share dividends, rights offerings and pro rata distributions. The warrants were not indexed to the Company's own stock and therefore met the definition of a derivative liability. The warrants were liability classified instruments and were initially recorded at a value of \$1,903,915, which was determined using the Black-Scholes-Merton method using a term of 5.38 years, risk free interest rate of 3.85% and volatility of 90.0%. During the nine months ended September 30, 2024, 909,091 warrants were exercised on various dates in cashless exercises and the investor was issued 458,726 shares of Common Stock. The Company remeasured the warrant liability of the exercised warrants at the time of the exercise resulting in a value of \$2,815,970. The warrant liability for the exercised warrants was removed and equity was increased by the value of \$2,815,970. As of September 30, 2024 and December 31, 2023, the warrant liability resulted in a value of \$3,235,441 and \$1,903,915, respectively and the gain on remeasurement in the amount of \$1,067,442 and the loss on remeasurement in the amount of \$4,147,496 was included in other (expense) income for the three months and nine months ended September 30, 2024, respectively.

On November 17, 2023, concurrently with the closing of the Company's registered direct offering, the Company issued warrants to purchase an aggregate of 169,697 shares of its Common Stock to the representative or its designees, at an exercise price of \$2.06 per share. These representative's warrants were exercisable beginning November 15, 2023, and expire on November 15, 2028, pursuant to their terms and conditions. The representative's warrants are not indexed to the Company's own stock and therefore meet the definition of a derivative liability. The representative's warrants are liability classified instruments and were initially recorded at a value of \$123,811, which was determined using the Black-Scholes-Merton method using a term of 4.88 years, risk free interest rate of 3.84% and volatility of 90.0%. As of September 30, 2024 and December 31, 2023 the Company remeasured the warrant liability resulting in a value of \$344,198 and \$123,811 respectively. The gain on remeasurement of the warrant liability in the amount of \$118,277 and the loss on remeasurement of \$220,387 is included in other (expense) income for the three and nine months ended September 30, 2024, respectively.

Concurrently with the closing of the Company's private placement on March 14, 2024, the Company issued warrants to purchase an aggregate of up to 2,496,318 shares of its Common Stock to the investors in the private placement, at an exercise price of \$1.30 per share are exercisable beginning on September 14, 2024, and expire on September 14, 2029. The warrants issued were divided into two groups: warrants issued to directors and warrants issued to non-affiliated investors. The warrants to purchase 452,731 shares of the Company's Common Stock issued to directors were deemed options issued under the MAIA 2021 Plan and are equity classified instruments, and the value of these warrants determined using the Black-Scholes-Merton method was \$230,685 using a term of 5.5 years, risk free interest rate of 4.20% and volatility of 95%. The warrants to purchase 2,043,587 share of the Company's Common Stock issued to non-affiliated investors were not indexed to the Company's own stock and therefore met the definition of a derivative liability. The warrants issued to non-affiliated investors were liability classified instruments when issued and were initially recorded at a value of \$2,049,600, which was determined using the Black-Scholes-Merton method using a term of 5.5 years, risk free interest rate of 4.20% and volatility of 95.0%. In May 2024, the Company amended the warrant agreements to adjust them to be indexed to the Company's own stock, and they were therefore reclassified to equity classified instruments in a non-cash transaction. When the warrant agreements were amended, the Company remeasured the warrant liability resulting in a final warrant value of \$5,089,063. The warrant liability for these warrants was removed and equity was increased by \$5,089,063 to account for the equity classification. The loss on the remeasurement of the warrant liability in the amount of \$0 and \$3,039,463 is included in other (expense) income for the three and nine months ended September 30, 2024, respectively.

Concurrently with the closing of the Company's private placement offering on March 28, 2024, the Company issued warrants to purchase an aggregate of up to 578,643 shares of its Common Stock to the investors in the private placement at an exercise price of \$2.55 per share. The warrants are exercisable beginning on September 28, 2024,

and expire on September 28, 2029. The warrants were not indexed to the Company's own stock and therefore meet the definition of a derivative liability. The warrants were liability classified instruments when issued and were initially recorded at a value of \$1,190,111, which was determined using the Black-Scholes-Merton method using a term of 5.5 years, risk free interest rate of 4.20% and volatility of 95.0%. In May 2024, the Company amended the warrant agreements related to 437,031 warrants to adjust them to be indexed to the Company's own stock, and they were therefore reclassified to equity classified instruments in a non-cash transaction. When the warrants agreements were amended, the Company remeasured the warrant liability resulting in a final warrant value of \$1,011,562. The warrant liability for these 437,031 warrants was removed and equity was increased by \$1,011,562 to account for the equity classification. The loss on the remeasurement of the warrant liability in the amount of \$0 and \$112,708 is included in other (expense) income for the three and nine months ended September 30, 2024, respectively. The remaining 141,612 warrants remain liability classified instruments. As of September 30, 2024 and December 31, 2023, the Company remeasured the warrant liability, resulting in a value of \$294,750 and \$0, respectively. The gain on remeasurement of the warrant liability in the amount of \$76,921 and the loss on remeasurement of \$3,493 is included in other (expense) income for the three and nine months ended September 30, 2024, respectively.

Concurrently with the closing of the Company's private placement offering on April 25, 2024, the Company issued warrants to purchase an aggregate of up to 494,096 shares of its Common Stock to the investors in the private placement at an exercise price of \$2.26 per share. The warrants are exercisable beginning on October 25, 2024, and expire on October 25, 2029. The warrants issued were divided into two groups: warrants issued to directors and warrants issued to non-affiliated investors. The warrants to purchase 167,157 shares of the Company's Common Stock issued to directors were deemed options issued under the MAIA 2021 Plan (as defined below) and are equity classified instruments and the value of these warrants determined using the Black-Scholes-Merton method was \$346,606 using a term of 5.5 years, risk free interest rate of 4.70% and volatility of 95%. The warrants to purchase 326,939 shares of the Company's Common Stock issued to non-affiliated investors were not indexed to the Company's own stock and therefore met the definition of a derivative liability. The warrants were liability classified instruments when issued and were initially recorded at a value of \$677,919, which was determined using the Black-Scholes-Merton method using a term of 5.5 years, risk free interest rate of 4.70% and volatility of 95.0%. In May 2024, the Company amended these warrant agreements to adjust them to be indexed to the Company's own stock, and they were therefore reclassified to equity classified instruments in a non-cash transaction. When the warrant agreements were amended, the Company remeasured the warrant liability resulting in a final warrant value of \$769,671. The warrant liability for these warrants were removed and equity was increased by \$769,671 to account for the equity classification. The loss on the remeasurement of the warrant liability in the amount of \$0 and \$91,752 is included in other (expense) income for the three and nine months ended September 30, 2024, respectively.

	Warrants Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years
Balance at January 1, 2024	3,650,278	\$ 2.82	5.00
Issued	2,949,169	1.65	—
Exercised	(1,157,201)	(1.98)	—
Expired	—	—	—
Balance at September 30, 2024	<u>5,442,246</u>	<u>\$ 2.37</u>	<u>4.62</u>

MAIA Biotechnology, Inc. Stock Option and Equity Incentive Plans

In 2018, the Company adopted the MAIA Biotechnology, Inc. 2018 Stock Option Plan (the "MAIA 2018 Plan"). MAIA's board of directors administers the MAIA 2018 Plan for the purposes of attracting, retaining, and motivating key employees, directors, and consultants of MAIA. The terms of the MAIA 2018 Plan continue to govern the 1,833,857 options outstanding under the plan as of September 30, 2024.

In 2020, the Company adopted the MAIA Biotechnology, Inc. Amended and Restated 2020 Equity Incentive Plan (the "MAIA 2020 Plan"), also administered by the board of directors. The MAIA 2020 Plan permitted awards to take the form of stock options, restricted stock and restricted stock units. The terms of the MAIA 2020 Plan continue

to govern the 3,503,589 options outstanding in the plan as of September 30, 2024. There are no shares reserved for future issuance under the MAIA 2018 Plan or the MAIA 2020 Plan.

On August 1, 2022 the Company approved MAIA 2021 Plan with 1,909,518 shares of Common Stock reserved for issuance. On May 25, 2023 the MAIA 2021 Plan was amended to include an automatic increase to the plan in the amount equal to 10% of the total number of shares of stock outstanding on a fully diluted basis on December 31 of the preceding calendar year (the "Increase Date"); provided that, the board of directors may act prior to any Increase Date to provide that there will be no increase for such year or that the increase for such year will be a lesser number of shares of stock. The amount reserved for issuance under the MAIA 2021 Plan increased by 1,956,993 based on the fully diluted shares outstanding as of December 31, 2022. The amount reserved for issuance under the MAIA 2021 Plan increased by 2,838,668 based on the fully diluted shares outstanding as of December 31, 2023. As of September 30, 2024, there are 2,483,927 shares of Common Stock available for future issuance under the MAIA 2021 Plan and 4,052,081 options are outstanding under the MAIA 2021 Plan.

Stock options are to be granted with an exercise price which is at least equal to the stock's estimated fair value at the date of grant, and with a contractual term of no more than ten years from the date of grant. In the case of an option granted to a 10% stockholder, the exercise price shall be generally no less than 110% of the fair market value per share on the date of grant, and the contractual term shall be seven years. Outstanding options awarded under the MAIA 2021 Plan may, but need not, vest and therefore become exercisable in periodic installments that may, but need not, be equal. The option may be subject to other terms and conditions as to the time or times when it may be exercised (which may be based on performance or other criteria) as the board of directors may deem appropriate. Unexercised options are canceled ninety days after termination of an employee, director, founder, or consultant. Unexercised options are canceled immediately if an employee, director, founder, or consultant is terminated for cause; under certain other circumstances, the period to cancellation may differ as described in the respective plan documents. Certain clauses in the Plans also govern the Company's exercise repurchase rights and various other features of awards granted under the plans.

As of September 30, 2024, only stock options have been awarded pursuant to the MAIA stock option and equity incentive plans.

The following table summarizes the activity and information regarding MAIA's outstanding and exercisable options for the nine months ended September 30, 2024:

	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Balance at January 1, 2024	7,750,152	\$ 2.53	7.29	—
Granted	2,437,516	2.43	—	—
Exercised	(118,610)	(1.82)	—	—
Cancelled/forfeited	(679,531)	(3.62)	—	—
Balance at September 30, 2024	<u>9,389,527</u>	<u>\$ 2.43</u>	<u>6.95</u>	<u>7,041,164</u>
Options exercisable at September 30, 2024	<u>7,232,697</u>	<u>\$ 2.27</u>	<u>6.36</u>	<u>6,336,419</u>

The value of option grants is calculated using the Black-Scholes-Merton option pricing model with the following assumptions for options granted during the nine months ended September 30, 2024 and 2023:

	2024	2023
<i>Risk-free interest rate</i>	3.79%-4.77%	3.64%-4.59%
Expected term (in years)	5 - 6.25	5 - 6.25
Expected volatility	95%-152.5%	99.6%-112.4%
Expected dividend yield	—%	—%

The weighted-average grant date fair value of stock options issued during the nine months ended September 30, 2024 and 2023 was \$2.43 and \$3.12, respectively. As of September 30, 2024, the total unrecognized compensation related to unvested employee and non-employee stock option awards granted was \$2,947,830, which the Company expects to recognize over a weighted average period of approximately 2.54 years.

Stock based compensation related to the Company's stock plans are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
General and administrative	\$ 260,397	\$ 320,456	\$ 748,302	\$ 911,186
Research and development	194,991	250,460	470,999	816,183
Total stock-based compensation	\$ 455,388	\$ 570,916	\$ 1,219,301	\$ 1,727,369

6. COMMITMENTS AND CONTINGENCIES

Legal

From time to time, the Company is involved in legal actions and claims arising in the normal course of business. Management believes there are no matters which will have a material adverse effect on the Company's financial position, operations or cash flows.

Patent Licensing, Sponsored Research, and Patent & Technology Agreements

THIO

In November 2018 and as amended in December 2020, the Company entered into a Global Patent Licensing Agreement ("PLA") titled "Patent and Technology License Agreement AGT. NO. L2264 – MAIA Biotechnology" with the University of Texas Southwestern ("UTSW") to license patent families for a specific compound ("THIO") from UTSW to MAIA (the "UTSW Agreement"). The UTSW Agreement, as amended, has a term of 20 years. The agreement requires MAIA to reimburse UTSW for agreed-upon expenses related to THIO. The UTSW Agreement requires certain payments upon assignment of the license to a third party as well as upon reaching specific milestones, ranging between \$1,000,000 and \$50,000,000, not to exceed a combined milestone payment total of \$112,000,000. As of September 30, 2024, no assignment has occurred and none of the defined milestones have been completed and therefore no payments are due to UTSW related to the milestones. The UTSW Agreement requires royalties MAIA to make royalty payments of: (i) 2-4% (depending on THIO reaching specified sales levels in the respective jurisdictions) on net sales up to \$1,000,000,000; and (ii) 2.5-5% on net sales above \$1,000,000,000.

Also in December 2020, the Company entered into a second license agreement with UTSW titled "Patent and Technology License Agreement AGT. NO. L3648 — MAIA Biotechnology" pursuant to which UTSW is licensing an additional compound to MAIA (the "UTSW2 Agreement"). The UTSW2 Agreement has a term of 20 years and requires the Company to reimburse UTSW for certain agreed-upon expenses. The UTSW2 Agreement requires certain payments upon assignment of the license to a third party as well as upon reaching specific milestones, ranging between \$1,000,000 and \$50,000,000, not to exceed a combined milestone payment total of \$112,000,000. As of September 30, 2024, no assignment has occurred and none of the defined milestones have been completed and therefore no payments are due to UTSW related to the milestones. The UTSW2 Agreement requires MAIA to make royalty payments of: (i) 2-4% (depending on THIO reaching specified sales levels in the respective jurisdictions) on net sales up to \$1,000,000,000; (ii) and 2.5-5% on net sales above \$1,000,000,000.

The Company will also pay UTSW running royalties on a yearly basis as a percentage of Net Sales (as defined in the UTSW2 Agreement) of the Company or its sublicensee. There are single digit royalty rates for licensed products and licensed services covered by a Valid Claim (as defined in the UTSW2 Agreement) and dependent on whether Net Sales are greater than or less than/equal to \$1,000,000,000, with Net Sales above that amount commanding a slightly higher percentage. In each case, the royalty percentage is lower before patent issuance in each jurisdiction. In the event that the licensed product or licensed service is not covered by a Valid Claim, the running royalty rates are reduced by 50%. The royalty obligations continue on a country-by-country basis until the later of expiration of the

last Valid Claim in each country or 10 years after the First Commercial Sale (as defined in UTSW2 Agreement) in each country.

Regeneron

In February 2021, the Company entered into a Drug Supply Agreement (the “Drug Supply Agreement”) with Regeneron Pharmaceuticals, Inc. (“Regeneron”) to perform one clinical trial for the treatment of patients with Non-Small Cell Lung Cancer (NSCLC) involving a Regeneron drug candidate that utilizes one of the Company’s compounds/agents. The Company is responsible for all costs of the study with Regeneron supplying their drug cemiplimab representing a cost savings for the Company, the first phase of which is expected to take approximately two years. The overall term of the agreement is for five years unless earlier terminated for certain reasons as defined in the agreement. Either party may terminate a study plan in the event that patient screening for the clinical study does not commence within 12 months after: (i) the Effective Date (as defined in the Drug Supply Agreement), with respect to the initial study; or (ii) the execution of the applicable study plan, with respect to each other study. If either party terminates a study plan, the Company shall reimburse Regeneron for the Regeneron product it received in connection with such study plan based on the actual out-of-pocket cost to Regeneron of such Regeneron product. As of September 30, 2024, neither party has terminated the agreement.

7. INCOME TAXES

The Company provides for income taxes using the asset and liability approach. Deferred tax assets and liabilities are recorded based on the differences between the financial statement and tax bases of assets and liabilities and the tax rates in effect when these differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The issuance of shares in connection with the Company’s IPO, as well as prior share issuances, may result in limitations on the utilization of the Company’s net operating loss carryforwards under IRS section 382. As of September 30, 2024, and December 31, 2023, the Company had a full valuation allowance against its deferred tax assets.

For the nine months ended September 30, 2024 and 2023, the Company recorded zero income tax expense. No tax benefit has been recorded in relation to the pre-tax losses for the nine months ended September 30, 2024, due to full valuation allowance to offset any deferred tax assets.

8. SUBSEQUENT EVENTS

Issuance of Options

From October 1 to November 7, 2024, the Company issued 10,900 options at a weighted exercise price of \$2.64 to consultants.

Private Placement

On November 1, 2024, the Company issued and sold 1,079,884 shares of its common stock and warrants to purchase 1,079,884 shares of its common stock in a private placement to certain accredited investors and Company directors pursuant to securities purchase agreements dated October 28, 2024 at a price per share of \$2.259 for which the Company received gross proceeds of approximately \$2.44 million. The warrants are exercisable at a price per share of \$2.51, are exercisable commencing six months following issuance, and have a term of five year from the initial exercise date. The securities sold to Company directors participating in the private placement were issued pursuant to the Company’s 2021 Equity Incentive Plan.

Related Party Participation in Private Placement

The following Company directors participated in the aforementioned November 2024 private placement as follows: (i) Stan Smith purchased 100,000 shares of common stock and warrants to purchase up to 100,000 shares of common stock for an aggregate purchase price of approximately \$225,900; (ii) Ramiro Guerrero purchased 88,532 shares of common stock and warrants to purchase up to 88,534 shares of common stock for an aggregate purchase

price of approximately \$200,000; (iii) Steven Chaouki purchased 22,133 shares of common stock and warrants to purchase up to 22,133 shares of common stock for an aggregate purchase price of approximately \$50,000; and (iv) Cristian Luput purchased 22,133 shares of common stock and warrants to purchase up to 22,133 shares of common stock for an aggregate purchase price of approximately \$50,000. In addition, David Smith, the son of Company director Stan Smith purchased 40,000 shares of common stock and warrants to purchase up to 40,000 shares of common stock for an aggregate purchase price of approximately \$90,360

At-The-Market Offering with H.C. Wainwright

Since October 1, 2024, the Company has sold 285,471 shares of its Common Stock at an average price of approximately \$3.22 per share, resulting in aggregate gross proceeds of approximately \$918,284, for which it paid Wainwright approximately \$27,549 in commissions, resulting in net proceeds to the Company of approximately \$890,735. The Company anticipates that the at-the-market offering will continue throughout the next reporting period.

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

You should read the following discussion together with our financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q. This discussion contains forward-looking statements that are based on our current expectations, estimates and projections about our business and operations. Our actual results may differ materially from those currently anticipated and expressed in such forward-looking statements as a result of a number of factors, including those which we discuss under "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q.

Overview

We are a clinical stage biotechnology company engaged in the discovery, development and commercialization of therapies targeting cancer. Our initial disease target is lung cancer, a serious medical condition with an incidence of over 236,000 new cases in the US in 2022, representing 12.3% of all cancers, and over 130,000 deaths, or 21.4% of all cancers. Worldwide, lung cancer incidence is over 2,200,000 per year (ranking second only after breast cancer), and mortality over 1,800,000 (ranking first). Specifically, we are targeting Non-Small Cell Lung Cancer ("NSCLC"), which represents 85% of all lung cancers. THIO (6-thio-dG or 6-thio-2'-deoxyguanosine), our lead asset, is an investigational dual mechanism of action drug candidate incorporating telomere targeting and immunogenicity.

We have accomplished the following key milestones:

- In November 2018, we in-licensed THIO from the University of Texas Southwestern ("UTSW"), in Dallas. The patent license is global and exclusive for the duration of the patients' lives.
- In 2019, we generated the first data for THIO demonstrating complete regression with no recurrence when administered in advance of atezolizumab (TecentriQ®; Genentech), in colorectal and lung cancer preclinical models.
- In the first quarter 2020, we filed a provisional patent application for THIO in sequential combination with checkpoint inhibitors, covering all tumor types. The patent has been allowed as of March 12, 2021, but has not been issued to date. The patent will have an expiration date in 2041, excluding any patent term adjustment or patent extension.
- In the first quarter 2021, we entered into a Drug Supply Agreement with Regeneron. Under the Drug Supply Agreement, Regeneron will provide cemiplimab (Libtayo®; anti-PD-1 checkpoint inhibitor) at no charge for the THIO-101 trials, testing THIO administration for immune activation followed by cemiplimab in NSCLC. The Drug Supply Agreement replaces direct drug purchase expense that we would be otherwise required to incur. In exchange, Regeneron received development exclusivity in NSCLC for the duration of the trial meaning we cannot conduct trials in NSCLC with another checkpoint inhibitor during the time of the trial. All other areas of study and development in any other tumor types remain open.
- In the first quarter 2021, we initiated our clinical supply manufacturing under Good Manufacturing Practices conditions to provide clinical supply for THIO-101 and other development needs.
- In the first half of 2022, we completed a crossover round consisting of sales of 274,840 shares of our common stock, par value \$0.0001 per share (the "Common Stock"), at a price of \$9.00 per shares for gross proceeds of approximately \$2.5 million.
- In the first quarter 2022, THIO received approval by the Bellberry Human Research Ethics Committee ("HREC") in Australia to initiate the THIO-101 Phase 2 clinical study.

- In March 2022, the U.S. Food and Drug Administration (the “FDA”) granted Orphan Drug Designation (“ODD”) to THIO for the treatment of Hepatocellular Carcinoma (“HCC”) (liver cancer), and in May 2022, the FDA granted ODD to THIO for the treatment of small-cell lung cancer. The FDA’s Office of Orphan Products Development may grant orphan designation status to drugs and biologics that are intended for the treatment, diagnosis or prevention of rare diseases, or conditions that affect fewer than 200,000 people in the U.S. ODD provides certain benefits, including financial incentives, to support clinical development and the potential for up to seven years of market exclusivity for the drug for the designated orphan indication in the U.S. if the drug is ultimately approved for its designated indication.
- In May 2022, we entered into a research and collaboration agreement with the Nationwide Children’s Hospital to evaluate the potential of THIO in combination with current standard-of-care therapies for brain cancer. The organizations are conducting preclinical studies to assess the efficacy and safety of THIO in combination with radiotherapy and immune checkpoint inhibitors in vitro and in vivo models.
- In July 2022, we completed our selection process for the clinical sites for our Phase 2 study in Australia and Europe and our application to start the Phase 2 study in Australia has been approved. In July 2022, the first patient was administered with THIO in our Phase 2 human trial (“THIO-101”) in Australia. We have also submitted a similar application to conduct the same Phase 2 study in Europe.
- On July 28, 2022, the Company’s Common Stock began trading on the NYSE American under the symbol MAIA. On August 1, 2022, the Company sold 2,000,000 shares of Common Stock at \$5.00 per share for gross proceeds of \$10,000,000 in an IPO, prior to deducting underwriting discounts, commissions, and other offering expenses. On August 3, 2022, the Company sold an additional 300,000 shares of Common Stock at \$5.00 per share when the underwriter exercised the overallocation for net proceeds of \$1,500,000 prior to deducting underwriting discounts, commissions, and other offering expenses. We believe we have raised sufficient capital to fund the THIO-101 lead-in and preliminary efficacy of the phase 2 THIO-101 trial.
- In November 2022, we completed a pre-investigational new drug meeting with the FDA for the planned U.S. expansion of the THIO-101 Phase 2 trial evaluating THIO, an investigational telomere-targeting agent, in patients with advanced NSCLC.
- In December 2022, regulatory authorities in three European countries, Hungary, Poland, and Bulgaria, approved the implementation of THIO-101, MAIA’s Phase 2 clinical trial. THIO-101 is a critical component of THIO’s clinical development process and it is of the utmost importance that we collaborate with leading cancer institutes in Australia and now in Europe, for a target total of 30 clinical trial sites in six countries.
- In the first week of March 2023, the first two patients were dosed in Europe in MAIA’s Phase 2 clinical trial, THIO-101 evaluating THIO in patients with advanced NSCLC. Following regulatory clearances in Hungary, Poland, and Bulgaria, nine clinical sites have been activated in these three European countries.
- On April 11, 2023, we announced positive topline data related to the completion of Part A, safety lead-in portion of the THIO-101 trial which showed that administration of THIO, at the highest dose of 360 mg/cycle in sequential combination with Regeneron’s anti-PD-1 therapy, Libtayo[®] was well tolerated with no dose-limiting toxicities or significant treatment-related adverse events reported.
- On April 18, 2023, we published data in HCC models: as monotherapy, THIO achieved complete and durable responses in HCC, the dominant histology in primary liver cancer (90%), in in vivo models. When combined with Libtayo[®], duration of response was further potentiated. Upon rechallenge with two times more cancer cells and no additional treatment, tumor growth was completely prevented. Administration of THIO alone and in combination with Libtayo[®] generated anti-cancer immune memory.

- On April 20, 2023, we announced preliminary survival data from Part A of THIO-101. The first two patients enrolled in Part A of the study continue to be alive, approximately 10 and 9 months respectively, from treatment initiation. Both patients have advanced Stage IV metastatic disease and are heavily pretreated, receiving third and fourth line of therapy respectively after previously failing treatment with an immune checkpoint inhibitor. They continue to be progression free following their last dose of THIO, 7 and 6 months respectively, with no new treatment. The current treatment options in patients with advanced relapsed or refractory NSCLC who failed two or more therapy regimens are limited and show minimal benefit. Furthermore, discontinuation of treatment is rapidly followed by physical decline and death, therefore seeing patients with such survival and no disease progression in this clinical setting, is noteworthy. In real-world clinical practice, observed survival in such heavily pretreated patients is typically 3-4 months.
- On April 27, 2023, we closed a follow-on offering and sold 2,555,500 shares of Common Stock at a public offering price of \$2.25 per share, for gross proceeds of approximately \$5.75 million, before deducting underwriting discounts and offering expenses. The shares sold in the offering include the exercise in full by the underwriter of its option to purchase an additional 333,300 shares of Common Stock, in addition to the 2,222,200 shares of Common Stock which the underwriters initially agreed to purchase.
- On June 20, 2023, we announced updates in enrollment in THIO-101 in Europe. To that date, 29 patients had been dosed in THIO-101. With the addition of sites in Hungary, Poland, and Bulgaria in March 2023, THIO-101 has rapidly increased the number of patients enrolled and dosed with THIO. Thirteen sites were activated with another two new additional sites ready to open shortly afterward.
- In July 2023, we announced that the first 2 patients dosed with THIO continue to be alive for approximately 12.2 and 11.5 months respectively, from treatment initiation. They have remained free of disease progression for 10.2 and 8.5 months, respectively, without requiring any additional therapy. We also highlighted that out of the first 11 patients with post-baseline scans, 82% (9 patients) met the disease control primary endpoint at first response assessment. For contrast, in similar heavily treated NSCLC patients, typical disease control rates are in the 25-35% range.
- On August 23, 2023, our universal shelf registration statement on Form S-3 (File No. 333-273984) (“Form S-3”) for possible future offerings was declared effective by the SEC.
- On September 1, 2023, we entered into an at-the-market Sales Agreement (the “Sales Agreement”) with ThinkEquity LLC (the “Sales Agent”), pursuant to which the Company may offer and sell, from time to time, through the Sales Agent, shares of Common Stock having an aggregate offering price of up to \$7,000,000, subject to the terms and conditions of the Sales Agreement. The shares will be offered and sold pursuant to the Company’s prospectus supplement, filed September 1, 2023 with the SEC to the prospectus forming a part of the Form S-3. We terminated the Sales Agreement on November 15, 2023. We sold 758,388 shares of our Common Stock through the Sales Agent for which the Company received net proceeds of approximately \$1,238,688.
- On September 28, 2023, we announced that the Company’s board of directors approved a share repurchase program pursuant to which the Company may repurchase up to \$800,000 of the Company’s issued and outstanding shares of Common Stock through September 2024. The Company expects to fund repurchases by using cash on hand and expected cash flow to be generated in the future. As of September 30, 2023, no repurchases under the program have been executed.
- On October 3, 2023, we announced that the FDA has cleared its investigational new drug application for THIO to be evaluated in the U.S. as part of THIO-101, the Company’s ongoing global phase 2 clinical study in patients with advanced NSCLC. THIO is being tested in sequential combination with Regeneron’s anti PD-1 monoclonal antibody cemiplimab (Libtayo®) to evaluate anti-tumor activity and immune response in NSCLC patients.
- On October 10, 2023, we announced that 49 patients have been dosed in MAIA’s Phase 2 clinical trial, THIO-101, evaluating THIO in sequential combination with an immune checkpoint inhibitor in patients with advanced NSCLC.
- On October 24, 2023, we announced the unprecedented interim disease control rate (“DCR”) of 100% in second-line treatment that far surpasses standard of care (“SoC”) DCR of 53-64%, presented at the

European Society for Medical Oncology Congress 2023. DCR is far stronger than overall response rate (“ORR”) in predicting overall survival benefit, as shown in a recent meta-analysis of 74 clinical trials worldwide in NSCLC.

- On November 10, 2023, we announced that the FDA granted THIO ODD as a treatment for glioblastoma. This is the third orphan drug designation granted to THIO following the receipt of orphan drug designations for HCC and small cell lung cancer (“SCLC”) in 2022.
- On November 17, 2023, we announced the closing of a \$4 million registered direct offering for the issuance and sale of an aggregate of 2,424,243 of its shares of Common Stock at a purchase price of \$1.65 per share. In a concurrent private place, MAIA also issued and sold unregistered warrants to purchase up to an aggregate of 2,424,243 share of its Common Stock.
- On December 19, 2023, we announced dose selection for THIO-101, a Phase 2 clinical trial evaluating its lead asset, THIO, in sequential combination with Regeneron’s anti-PD-1 cemiplimab (Libtayo®) in patients with advanced NSCLC. During the dose-finding stage of THIO-101, patients were administered either 60mg, 180mg, or 360mg of THIO per cycle, followed by 350mg of cemiplimab (Libtayo®). The selected dose, 180mg/cycle, presented better safety profile and outperformed the other doses in the key measures of efficacy for NSCLC trials. Subsequently, all future trial participants will be treated with THIO 180mg/cycle.
- On January 17, 2024, we announced new interim data for our ongoing THIO-101 Phase 2 trial in non-small cell lung cancer (NSCLC). In the latest available data from THIO-101 (November 13, 2023), 60 patients had been dosed with THIO in sequential combination with Libtayo®. The patients received either 60mg, 180mg, or 360mg of THIO per dose, and 42 had at least one post baseline assessment completed. The observed disease control was well sustained compared to previous scans.
- On February 7, 2024, we announced publication of international Patent Cooperation Treaty (“PCT”) application titled “Dinucleotides and Their Use in Treating Cancer.” The new dinucleotides disclosed in the patent application are telomere-targeting molecules, such as THIO fragments or other THIO analogues. These compounds are key next-generation telomere-targeting agents, an important extension of MAIA’s innovative cancer treatment platform. The PCT system streamlines the process for obtaining patent protection globally. Under the PCT, applicants can seek patent protection in a large number of countries.
- On February 14, 2024, we entered into an At The Market Offering Agreement (the “ATM Agreement”) with H.C. Wainwright & Co., LLC (“Wainwright”), to sell shares of our Common Stock having an aggregate sales price of up to \$1,445,000, from time to time, through an “at-the-market offering” program under which Wainwright will act as sales agent. Effective March 25, 2024, the Company filed a prospectus supplement to amend, supplement and supersede certain information contained in the earlier prospectus and prospectus supplement, which increased the number of shares of Common Stock the Company may offer and sell under the ATM Agreement to an aggregate offering price of up to \$4,950,000 from time to time. Effective May 15, 2024, the Company filed a prospectus supplement to amend, supplement and supersede certain information contained in the earlier prospectus and prospectus supplement, which increased the number of Shares the Company may offer and sell under the ATM Agreement to an aggregate offering price of up to \$11,280,000 from time to time. As of the date of this Quarterly Report, we have sold 2,985,953 shares of our Common Stock under the ATM Agreement at an average price of \$3.16 per share, resulting in aggregate gross proceeds of approximately \$9,440,950, for which we paid Wainwright \$283,228 in commissions resulting in net proceeds to us of approximately \$9,157,722.
- On February 22, 2024, we announced completion of enrollment in Phase 2 THIO-101 go-to-market clinical trial. The trial reached the enrollment target of 41 patients for the 180mg/dose on February 19, 2024. As of the latest data available for the trial, 79 patients had received either 60mg (24 patients), 180mg (41 patients) or 360mg (14 patients). The original trial design targeted up to 182 patients, including all patients in the safety lead-in and 41 patients in each of the 3 tested doses (60mg, 180mg, and 360mg). Following the selection of 180 mg/cycle as the optimal dose in December 2023, all patients were subsequently enrolled at the 180mg/cycle dose and trial enrollment was completed ahead of schedule.
- On March 6, 2024, we announced interim efficacy data for THIO-101 Phase 2 trial in NSCLC. In the latest data available (as of January 8, 2024), the ORR, characterized as partial or complete response to therapy,

was 38% (3 out of 8 patients) in the efficacy evaluable population for combination THIO 180mg + cemiplimab (Libtayo®) in third-line treatment for NSCLC patients who failed treatment with immune checkpoint inhibitors in prior lines of therapy, with or without chemotherapy.

- On March 14, 2024, we issued and sold 2,496,318 shares of our Common Stock and warrants to purchase 2,496,318 shares of our Common Stock in a private placement to certain accredited investors and certain of our directors pursuant to securities purchase agreements dated March 11, 2024 at a price per share of \$1.17 for which we received gross proceeds of approximately \$2.92 million. The warrants issued in the private placement have an exercise price of \$1.30, are exercisable six months after issuance and expire 5-years after the initial exercise date. The securities sold to our directors participating in the March 14, 2024 private placement were issued pursuant to the MAIA Biotechnology, Inc. 2021 Equity Incentive Plan (the “MAIA 2021 Plan”).
- On March 28, 2024, we issued and sold 578,643 shares of our Common Stock and warrants to purchase 578,643 shares of our Common Stock in a private placement to certain accredited investors pursuant to securities purchase agreements dated March 25, 2024 at a price per share of \$2.295 for which we received gross proceeds of approximately \$1.33 million. The warrants issued in the private placement have an exercise price of \$2.55, are exercisable six months after issuance and expire 5-years after the initial exercise date.
- On March 27, 2024, MAIA evaluated additional clinical data from its Phase 2 clinical trial, THIO-101. At such time, a total of 68 patients have been dosed and had a post-baseline scan in MAIA’s Phase 2 clinical trial, THIO-101, evaluating THIO in sequential combination with an immune checkpoint inhibitor in patients with advanced NSCLC. Preliminary efficacy across all lines of therapy in this March 2024 data cut were consistent with previous reports including: (i) 75% of patients receiving THIO 180mg as third-line therapy for NSCLC have surpassed the overall survival (“OS”) threshold of 5.8 months; (ii) 88% of patients in the same setting (3L, 180mg) also crossed the 2.5 months progression free survival (“PFS”) threshold and have shown ORR of 38%, greatly improving on current chemo treatment that have ORRs of around 6-10%; and (iii) across all third-line patients, DCR of 85% remained superior to current chemotherapy options, which ranges from 25-35% DCR.
- On April 25, 2024, we issued and sold 494,096 shares of our Common Stock and warrants to purchase 494,096 shares of our Common Stock in a private placement to certain accredited investors and Company directors pursuant to securities purchase agreements dated April 22, 2024 at a price per share of \$2.034, for which we received gross proceeds of approximately \$1.0 million. The warrants issued in the private placement have an exercise price of \$2.26, are exercisable six months after issuance and expire 5-years after the initial exercise date. The securities sold to our directors participating in the April 25, 2024 private placement were issued pursuant to the MAIA 2021 Plan.
- On June 4, 2024, we announced new preliminary efficacy data from the Phase 2 THIO-101 clinical trial. The updated included that as of April 30, 2024: (i) all evaluable patients had completed ≥ 1 post-baseline assessment; (ii) third-line treatment across all doses had shown DCR of 85% for THIO, 65% of patients crossed the 5.8-month OS threshold identified in literature, 85% of patients crossed the 2.5-month PFS threshold, median survival follow-up time was 9.1 months; and (iii) third-line treatment with THIO 180mg had shown median PFS of 5.5 months, 78% OS rate at 6 months, 38% ORR, 75% of patients crossed the 5.8-month OS threshold, 88% of patients crossed the 2.5-month PFS threshold and median survival follow-up time observed was 9.1 months.
- On June 6, 2024, we announced Company highlights and key achievements year-to-date, including: (i) exceptional measures of efficacy by lead drug THIO in Phase 2 clinical trial, with 38% ORR in third-line (3L) setting (THIO 180mg) compared to ~6% for currently available treatments in a similar population and 5.5 months median progression-free survival (PFS) (3L, THIO 180mg); and (ii) secured continued insider investment through independent board members’ participation in private placement equity financings, with funding of more than \$12M year-to-date.
- On June 7, 2024, we announced the validation of clinical and regulatory pathways for viable therapies leveraging the cell’s telomeric functions as evidenced by the FDA approval of imetelstat, a treatment for low- to intermediate-risk hematologic malignancies (myelodysplastic syndromes) from Geron Corporation, illuminating the role of telomere targeting as a viable therapeutic strategy for cancer treatment.

- On July 23, 2024, we announced treatment updates from our Phase 2 clinical trial of THIO. As of June 12, the latest clinical cut-off date: (i) 6 patients remain on treatment following at least 12 months of therapy; (ii) treatment with THIO followed by cemiplimab has been well tolerated throughout the trial, with lower toxicity compared to standard-of-care treatments; and (iii) the longest-treated patients have completed 21 cycles of THIO sequenced with cemiplimab.
- On September 10, 2024, we announced updates from our lead clinical candidate THIO, in our Phase 2 clinical trial, THIO-101. The updates included: (i) As of August 1, 2024, 16 patients had survival follow-up surpassing 12 months, including 9 in third line treatment (3L); (ii) Interim median survival follow-up in 3L was 10.6 months.; and (iii) THIO's substantial survival benefit in third line surpasses comparable standard-of-care overall survival of 5.8 months.
- On October 15, 2024, we announced that an abstract related to the Company's second generation of proprietary telomere-targeting THIO prodrugs was accepted for poster presentation at the 36th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, taking place October 23-25, 2024, in Barcelona, Spain. MAIA's presentation included results of preclinical studies for its new THIO-based prodrugs, designated as MAIA-2021-20 and MAIA-2022-12, which are lipid-conjugated compounds derived from THIO. The preclinical studies were designed to evaluate the efficacy of the new molecules alone and in combination with or without immune checkpoint-blocking antibodies (anti-PD-L1).
- On November 1, 2024, we issued and sold 1,079,784 shares of our common stock and warrants to purchase 1,079,784 shares of our common stock in a private placement to certain accredited investors and Company directors pursuant to securities purchase agreements dated October 28, 2024 at a price per share of \$2.259 for which we received gross proceeds of approximately \$2.44 million. The warrants issued in the private placement have an exercise price of \$2.51, are exercisable six months after issuance and expire 5-years after the initial exercise date. The securities sold to our directors participating in the private placement were issued pursuant to our 2021 Equity Incentive Plan.
- On November 5, 2024, we announced that a late-breaking abstract (LBA) detailing new updates from its Phase 2 THIO-101 clinical trial was selected for oral and poster presentation at the 2024 Annual Meeting of the Society for Immunotherapy of Cancer (SITC), being held November 6-10, 2024, in Houston, Texas. The updates include new data on efficacy and safety from its clinical trial evaluating THIO sequenced with Regeneron's immune checkpoint inhibitor cemiplimab (Libtayo®) in patients with advanced NSCLC who have failed two or more standard-of-care therapy regimens.
- In addition to NSCLC, we plan to conduct clinical trials evaluating THIO in sequential combination with an immune checkpoint inhibitor in several other cancer indications. THIO-102 is a Phase 2 clinical trial planned to target: (i) colorectal cancer, in which THIO demonstrated 100% complete response in pre-clinical setting, with no tumor recurrence after long-term follow-up; (ii) HCC (90% of primary liver cancers), a deadly cancer indication to which MAIA holds an ODD awarded by the FDA in April 2022; (iii) SCLC, the deadliest type of lung cancer, MAIA was also awarded ODD for this indication in August 2022; and (iv) solid tumors, such as breast, prostate, gastric, pancreatic and ovarian cancers. THIO-103 is a Phase 2 clinical trial planned to evaluate treatment with THIO in first-line patients for both NSCLC and SCLC.

Impact of the War in Ukraine and War in Israel on Our Operations

The short and long-term implications of war in Ukraine and war in Israel are difficult to predict at this time. The imposition of sanctions and counter sanctions may have an adverse effect on the economic markets generally and could impact our business, financial condition, and results of operations. Because of the highly uncertain and dynamic nature of these events, the Company terminated any planned research activities in the impacted areas.

Results of Operations for the Three and Nine Months Ended September 30, 2024 and 2023

Comparison of Three Months Ended September 30, 2024 and 2023

	Three Months Ended September 30,		Change	
	2024	2023	Dollars	Percentage
Operating expenses:				
Research and development expenses	\$ 2,667,170	\$ 2,599,578	\$ 67,592	3%
General and administrative expenses	1,521,298	2,356,065	(834,767)	(35)%
Total operating costs and expenses	4,188,468	4,955,643	(767,175)	(15)%
Loss from operations	(4,188,468)	(4,955,643)	767,175	(15)%
Other (expense) income:				
Interest expense	(85)	(1)	(84)	8400%
Interest income	106,082	3260	102,822	3154%
Australian research and development incentives	15,198	58,448	(43,250)	(74)%
Change in fair value of warrant liability	1,331,286	18,193	1,313,093	7218%
Loss on fair value of warrants over proceeds	—	—	—	100%
Other income, net	1,452,481	79,900	1,372,581	1718%
Net loss	(2,735,987)	(4,875,743)	2,139,756	(44)%
Net loss attributable to MAIA Biotechnology, Inc. shareholders	\$ (2,735,987)	\$ (4,875,743)	\$ 2,139,756	(44)%

Operating Costs and Expenses

Research and development expenses

Research and development expenses increased by approximately \$67,000 (or approximately 3%), from approximately \$2,600,000 for the three months ended September 30, 2023 to approximately \$2,667,000 for the three months ended September 30, 2024. The increase was primarily related to an increase in scientific research and clinical research of approximately \$293,000, offset by a decrease in payroll expense of approximately \$171,000 and a decrease in stock-based compensation costs of approximately \$55,000.

General and administrative expenses

General and administrative expenses decreased by approximately \$835,000 (or approximately 35%) from approximately \$2,356,000 for the three months ended September 30, 2023, to approximately \$1,521,000 for the three months ended September 30, 2024. The decrease was primarily related to a decrease in professional fees of approximately \$507,000, a decrease in other expenses of approximately \$258,000, a decrease in stock-based compensation of approximately \$60,000, and a decrease of approximately \$10,000 payroll expense.

Other income, net

Other income, net increased by approximately \$1,373,000 (or approximately 1718%) from other income of approximately \$80,000 for the three months ended September 30, 2023, to other income of approximately \$1,452,000 for the three months ended September 30, 2024. The increase was primarily related to the change in the fair value of the warrant liability of approximately \$1,313,000, a net increase in interest income of approximately \$103,000, and a reduction in the Australian research and development incentives of approximately \$43,000.

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

	Nine Months Ended September 30,		Change	
	2024	2023	Dollars	Percentage
Operating expenses:				
Research and development expenses	\$ 7,040,145	\$ 7,394,884	\$ (354,739)	(5)%
General and administrative expenses	4,912,461	6,409,655	(1,497,194)	(23)%
Total operating costs and expenses	11,952,606	13,804,539	(1,851,933)	(13)%
Loss from operations	(11,952,606)	(13,804,539)	1,851,933	(13)%
Other (expense) income:				
Interest expense	(85)	(6,863)	6,778	(99)%
Interest income	238,583	3,768	234,815	6232%
Australian research and development incentives	51,847	149,457	(97,610)	(65)%
Change in fair value of warrant liability	(8,007,505)	141,934	(8,149,439)	(5742)%
Loss on fair value of warrants over proceeds	(12,952)	—	(12,952)	100%
Other (expense) income, net	(7,730,112)	288,296	(8,018,408)	(2781)%
Net loss	(19,682,718)	(13,516,243)	(6,166,475)	46%
Net loss attributable to MAIA Biotechnology, Inc. shareholders	\$ (19,682,718)	\$ (13,516,243)	\$ (6,166,475)	46%

Operating Costs and Expenses

Research and development expenses

Research and development expenses decreased by approximately \$355,000 (or approximately 5%) from approximately \$7,395,000 for the nine months ended September 30, 2023, to approximately \$7,040,000 for the nine months ended September 30, 2024. The decrease was primarily related to a decrease in payroll expense of approximately \$1,120,000 related to the decreased headcount of research and development employees and the reversal of the accrued bonus, decrease in stock-based compensation costs of approximately \$345,000, and a decrease in other expenses of approximately \$37,000, offset by an increase in scientific research and clinical research of approximately \$1,147,000.

General and administrative expenses

General and administrative expenses decreased by approximately \$1,497,000 (or approximately 23%) from approximately \$6,409,000 for the nine months ended September 30, 2023, to approximately \$4,912,000 for the nine months ended September 30, 2024. The decrease was primarily related to a decrease in payroll expense of approximately \$535,000 relating to the reversal of the accrued bonus, a decrease in professional fees of approximately \$418,000, a decrease in other expenses of approximately \$381,000 related to lower insurance expenses, and a decrease in stock-based compensation of approximately \$163,000.

Other expense, net

Other expense, net increased by approximately \$8,018,000 (or approximately 2781%) from other income, net of approximately \$288,000 for the nine months ended September 30, 2023, to other expense, net of approximately \$7,730,000 for the nine months ended September 30, 2024. The increase was primarily related to the change in the fair value of the warrant liability of approximately \$8,149,000, a loss on fair value of warrants over proceeds of approximately \$13,000, a reduction in the Australia research and development incentives of approximately \$98,000 and a net increase of interest income of approximately \$242,000.

Liquidity and Capital Resources

Our Ability to Continue as a Going Concern

As of September 30, 2024, our cash totaled approximately \$8,691,000 which represented an increase of approximately \$1,540,000 compared to December 31, 2023. As of September 30, 2024, we had working capital of approximately \$5,631,000 which represents an increase of approximately \$3,004,000 compared to December 31, 2023. We have generated no revenues as of September 30, 2024. Our current operating plan indicates that we will continue to incur losses from operations and generate negative cash flows from operating activities given ongoing expenditures related to the completion of its ongoing clinical trials and our lack of revenue generating activities. Based on our cash reserves as of September 30, 2024 of \$8,691,000 and current financial condition as of the date of this Quarterly Report, the accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

To meet the Company's future working capital needs, we will need to raise additional equity or enter into debt financing. While we have historically been able to raise additional capital through issuance of equity and/or debt financing, and we have implemented a plan to control its expenses in order to satisfy its obligations due within one year from the date of issuance of these financial statements, we cannot guarantee that it will be able to raise additional equity, raise debt, or contain expenses. Accordingly, there is substantial doubt about our ability to continue as a going concern within one year after these financial statements are issued.

Sales of Common Stock

On March 14, 2024, we issued and sold 2,496,318 shares of our Common Stock and warrants to purchase 2,496,318 shares of our Common Stock in a private placement to certain accredited investors and to our participating directors pursuant to securities purchase agreements dated March 11, 2024 at a price \$1.17 per share, for which we received gross proceeds of approximately \$2.92 million. The securities sold to our directors participating in the March 14, 2024 private placement were issued pursuant to the MAIA 2021 Plan.

On March 28, 2024, we issued and sold 578,643 shares of our Common Stock and warrants to purchase 578,643 shares of our Common Stock in a private placement to certain accredited investors pursuant to securities purchase agreements dated March 25, 2024 at a price of \$2.295 per share, for which we received gross proceeds of approximately \$1.33 million.

Between February 14, 2024 and March 31, 2024, we sold 507,754 shares of Common Stock at an average price of approximately \$1.47 per share, resulting in aggregate gross proceeds of approximately \$745,251 under the ATM Agreement dated February 14, 2024, for which we paid Wainwright approximately \$22,357 in commissions resulting in net proceeds to us of approximately \$722,894. Between April 1, 2024 and June 30, 2024, we sold 2,015,122 shares of our Common Stock at an average price of \$3.53 per share, resulting in aggregate gross proceeds of approximately \$7,116,978 under the ATM Agreement dated February 14, 2024 with Wainwright, for which we paid Wainwright \$213,509 in commissions, resulting in net proceeds of approximately \$6,903,469. Between July 1, 2024 and September 30, 2024, we sold 177,606 shares of Common Stock at an average price of approximately \$3.72 per share, resulting in aggregate gross proceeds of approximately \$660,437 under the ATM Agreement dated May 15, 2024, for which we paid Wainwright approximately \$19,813 in commissions, resulting in net proceeds to us of approximately \$640,624.

On April 25, 2024, we issued and sold 494,096 shares of our Common Stock and warrants to purchase 494,096 shares of our Common Stock in a private placement to certain accredited investors and to our participating directors pursuant to securities purchase agreements dated April 25, 2024 at a price of \$2.034 per share, for which we received gross proceeds of approximately \$1.0 million. The securities sold to our directors participating in the April 25, 2024 private placement were issued pursuant to the MAIA 2021 Plan.

We will need to raise additional capital to fund our operations, to develop and commercialize THIO, and to develop, acquire or in-license other products. We may seek to fund our operations through public equity, private equity, or

debt financings, as well as other sources. We cannot make any assurances that additional financings will be available to us and, if available, on acceptable terms or at all. This could negatively impact our business and operations and could also lead to the reduction of our operations.

Cash Flows

Cash Flows for the Nine Months ended September 30, 2024 and 2023

	Nine Months Ended September 30,	
	2024	2023
Net cash flows used in operating activities	\$ (11,796,286)	\$ (9,078,570)
Net cash flows provided by financing activities	13,331,146	4,245,463
Effect of foreign currency exchange rate changes on cash	5,229	(13,233)
Net increase in cash and cash equivalents	<u>\$ 1,540,089</u>	<u>\$ (4,846,340)</u>

Operating Activities

For the nine months ended September 30, 2024, net cash used in operating activities was approximately \$11,796,000, which consisted of a consolidated net loss of approximately \$19,683,000 offset by non-cash charges of approximately \$1,219,000 in stock-based compensation, approximately \$112,000 of non-cash expense to issue stock to consultants, the remeasurement of the warrant liability of approximately \$8,008,000, and the loss on fair value of warrants over proceeds of approximately \$13,000. Total changes in operating assets and liabilities of approximately \$1,465,000 were driven by an approximate \$1,330,000 net decrease in accounts payable and accrued expenses, an approximate \$93,000 increase in the Australia research and development incentives receivable, and an approximate \$227,000 decrease in prepaid expense and other assets.

For the nine months ended September 30, 2023, net cash used in operating activities was approximately \$9,079,000, which consisted of a net loss of approximately \$13,516,000 offset by non-cash charges of approximately \$1,727,000 in stock-based compensation, approximately \$683,000 of non-cash expense to issue stock to consultants, and the remeasurement of the warrant liability of approximately \$142,000. Total changes in operating assets and liabilities of approximately \$2,169,000 were driven by an approximate \$1,861,000 increase in accounts payable and accrued liabilities, an approximate increase of \$134,000 in prepaid expenses and other assets and an approximate increase of \$134,000 in Australia research and development incentives receivables.

For the nine months ended September 30, 2024 the effect of foreign currency exchange rate changes on cash increased the cash balance as of September 30, 2024 by approximately \$5,000 versus a decrease of approximately \$13,000 for the nine months ended September 30, 2023.

Investing Activities

For the nine months ended September 30, 2024 and 2023, we did not have any cash provided by or used in investing activities.

Financing Activities

Net cash provided by financing activities was approximately \$13,331,000 and \$4,245,000 for the nine months ended September 30, 2024 and 2023, respectively. Total net cash provided by financing activities for the nine months ended September 30, 2024 consisted primarily of approximately \$5,254,000 gross proceeds from private placement offerings, proceeds from the at-the-market offering of approximately \$8,523,000, proceeds from the exercise of stock options of \$216,000, and were offset by approximately \$661,000 of offering costs.

Net cash provided by financing activities for the nine months ended September 30, 2023 consisted primarily of approximately \$5,750,000 of gross proceeds from the sales of Common Stock in a follow-on offering, offset by approximately \$1,352,000 of offering costs and approximately \$154,000 of deferred offering costs.

Off-Balance Sheet Arrangements

None.

Critical Accounting Policies and Significant Judgments and Estimates

Our condensed consolidated financial statements are prepared in accordance with GAAP. These accounting principles require us to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities as of the date of the financial statements. We believe that the estimates, judgments and assumptions are reasonable based upon information available to us at the time that these estimates, judgments and assumptions are made. To the extent there are material differences between these estimates, judgments or assumptions and actual results, our financial statements will be affected. For a discussion of our critical accounting estimates, please read Part II, Item 7 — Management’s Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 21, 2024. There have been no material changes to the critical accounting estimates previously disclosed in such report.

Recently Issued Accounting Standards Not Yet Effective or Adopted

Management does not believe that any recently issued, but not yet effective accounting pronouncements, if adopted, would have a material impact on the accompanying unaudited condensed consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company and are not required to provide the information otherwise required under this item.

Item 4. Controls and Procedures.**Evaluation of Disclosure Controls and Procedures**

Under the supervision of and with the participation of our management, including our Chief Executive Officer, who is our principal executive officer, and our Head of Finance, who is our principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of September 30, 2024, the end of the period covered by this Quarterly Report. The term “disclosure controls and procedures,” as set forth in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, (the “Exchange Act”) means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected. Based on the evaluation of our disclosure controls and procedures as of September 30, 2024, our Chief Executive Officer and Head of Finance concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the period covered by this Quarterly Report that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

We are not party to any material legal proceedings. From time to time, we may be involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 1A. Risk Factors.

Factors that could cause our actual results to differ materially from those in this Quarterly Report are any of the risks described in “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the Securities and Exchange Commission on March 21, 2024. Any of these factors could result in a significant or material adverse effect on our results of operations or financial condition. Additional risk factors not presently known to us or that we currently deem immaterial may also impair our business or results of operations. As of the date of this Quarterly Report, except as set forth below, there are no additional risk factors added to the risk factors disclosed in our Annual Report on Form 10-K.

If we are unable to comply with the continued listing requirements of the NYSE American, then our Common Stock would be delisted from the NYSE American, which would limit investors’ ability to effect transactions in our Common Stock and subject us to additional trading restrictions.

Our Common Stock is currently listed on the NYSE American and the continued listing of our Common Stock on the NYSE American is contingent on our continued compliance with a number of listing requirements. If we are unable to comply with the continued listing requirements of the NYSE American, our Common Stock would be delisted from the NYSE American, which would limit investors’ ability to effect transactions in our Common Stock and subject us to additional trading restrictions. In order to maintain our listing, we must maintain certain share prices, financial and share distribution targets, including maintaining a minimum amount of stockholders’ equity and a minimum number of public stockholders, as well as satisfy other listing requirements of the NYSE American. In addition to these objective standards, NYSE American may delist the securities of any issuer for other reasons involving the judgment of NYSE American.

While our stockholders’ equity was approximately \$1.62 million as of September 30, 2024, and while we have had losses from continuing operations and/or net losses in each of our fiscal years ended December 31, 2021, 2022 and 2023, we are nevertheless currently in compliance with the NYSE American continued listing standards as we satisfy alternate compliance standards provided in Section 1003(a) of the NYSE American Company Guide since: (i) the total value of our market capitalization is at least \$50,000,000; and (ii) we have at least 1,100,000 shares publicly held, a market value of publicly held shares of at least \$15,000,000 and 400 round lot shareholders. There is no assurance that we will be able to maintain compliance with the NYSE American continued listing standards and/or continue our listing on the NYSE American in the future.

If the NYSE American delists our Common Stock from trading on its exchange and we are not able to list our securities on another national securities exchange, we expect the Common Stock would qualify to be quoted on an over-the-counter market. If this were to occur, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- substantially impair our ability to raise additional funds;
- the loss of institutional investor interest and a decreased ability to issue additional securities or obtain additional financing in the future;

- a determination that our Common Stock is a “penny stock,” which will require brokers trading in our Common Stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage; and
- potential breaches of representations or covenants of our agreements pursuant to which we made representations or covenants relating to our compliance with applicable listing requirements, which, regardless of merit, could result in costly litigation, significant liabilities and diversion of our management’s time and attention and could have a material adverse effect on our financial condition, business and results of operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Recent sales of unregistered securities

On September 20, 2024, the Company entered into a Services Agreement with IRTH Communications LLC (“IRTH”) pursuant to which IRTH will provide investor relations, communications and consulting services. In consideration of IRTH's undertaking of the services agreement and provision of services thereunder, the Company agreed to issue IRTH shares of its Common Stock having a value of \$100,000 with the number of shares (the “Shares”) determined by dividing \$100,000 by the Company's closing price on the date of execution of the agreement, or 34,602 shares based on the \$2.89 closing price for the Company's common stock on September 20, 2024. The Shares are to be issued based on the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”).

No underwriters were involved in the foregoing issuance of securities. The securities described above were issued in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. The recipient of securities in the transaction described above represented that it was an accredited investor and was acquiring the securities for its own account for investment purposes only, and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time and appropriate legends were affixed to the instruments representing such securities issued in such transactions

Purchases of equity securities by the issuer and affiliated purchasers.

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

10b5-1 Trading Plans

During the fiscal quarter ended September 30, 2024, no Section 16 director or officer adopted, modified, or terminated a “Rule 10b5-1 trading arrangement” (as defined in Item 408 of Regulation S-K of the Exchange Act).

There were no “non-Rule 10b5-1 trading arrangements” (as defined in Item 408 of Regulation S-K of the Exchange Act) adopted, modified or terminated during the fiscal quarter ended September 30, 2024 by our directors and Section 16 officers.

Item 6. Exhibits.

3.1	<u>Amended and Restated Certificate of Incorporation of MAIA Biotechnology, Inc., filed as Exhibit 3.1 to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 1, 2022 and incorporated herein by reference.</u>
3.2	<u>Amended and Restated Bylaws of MAIA Biotechnology, Inc., filed as Exhibit 3.2 to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 1, 2022 and incorporated herein by reference.</u>
31.1*	<u>Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2*	<u>Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
32.1**	<u>Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
32.2**	<u>Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101.INS***	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL 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 (embedded within the Inline XBRL document)

* Filed herewith.

** These certifications are furnished to the SEC pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such filing.

*** Furnished herewith. Pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act or Section 18 of the Exchange Act and otherwise are not subject to liability under those sections.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

MAIA Biotechnology Inc.

Date: November 12, 2024

By: _____
/s/ Vlad Vitoc
Vlad Vitoc
Chief Executive Officer
(Principal Executive Officer)

Date: November 12, 2024

By: _____
/s/ Jeffrey C. Himmelreich
Jeffrey C. Himmelreich
Head of Finance
(Principal Financial Officer)

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

I, Vlad Vitoc, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of MAIA Biotechnology, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2024

By: /s/ Vlad Vitoc

Vlad Vitoc
Chairman and Chief Executive Officer
(Principal Executive Officer)

**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 MAIA Biotechnology, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Vlad Vitoc, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2024

By: */s/ Vlad Vitoc*

Vlad Vitoc

Chairman and Chief Executive Officer

(Principal Executive Officer)

**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 MAIA Biotechnology, Inc. (the "Company") on Form 10-Q or the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jeffrey C. Himmelreich, Head of Finance of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2024

By: */s/ Jeffrey C. Himmelreich*

Jeffrey C. Himmelreich
Head of Finance
(Principal Financial Officer)