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, 2023

OR

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

For the transition period from _____ to _____

Commission File Number: 001-41455

MAIA BIOTECHNOLOGY, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**83-1495913**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
444 West Lake Street, Suite 1700 Chicago, IL	**60606**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (312) 416-8592

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

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

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

As of November 7, 2023, the registrant had 14,213,511 shares of common stock, $0.0001 par value per share, outstanding.

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NOTE ABOUT FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. 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," 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").

We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

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, 2023	December 31, 2022
	(unaudited)	
ASSETS		
Current assets:		
Cash	$ 6,104,587	$ 10,950,927
Prepaid expenses and other current assets	414,120	554,321
Australia research and development incentives receivable	114,426	302,789
Total current assets	6,633,133	11,808,037
Deferred offering costs	365,140	211,203
Other assets	2,800	2,800
Total assets	$ 7,001,073	$ 12,022,040
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,226,101	$ 1,165,505
Accrued expenses	2,923,853	2,103,401
Total current liabilities	4,149,954	3,268,906
Long term liabilities:		
Warrant liability	103,407	245,341
Total liabilities	4,253,361	3,514,247
Commitments and contingencies (Note 6)		
Stockholders' equity (deficit)		
Preferred stock, $0.0001 par value, 30,000,000 shares authorized at September 30, 2023 and December 31, 2022, 0 shares issued and outstanding	—	—
Common stock, $0.0001 par value, 70,000,000 shares authorized at September 30, 2023 and December 31, 2022, 13,761,123 and 10,955,904 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	1,377	1,096
Additional paid-in capital	60,513,616	52,729,942
Accumulated deficit	(57,723,515)	(44,207,272)
Accumulated other comprehensive loss	(43,766)	(15,973)
Total stockholders' equity	2,747,712	8,507,793
Total liabilities and stockholders' equity	$ 7,001,073	$ 12,022,040

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

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

	For the Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development expenses	$ 2,599,578	$ 2,343,154	$ 7,394,884	$ 6,539,948
General and administrative expenses	2,356,065	1,653,072	6,409,655	4,341,880
Ratchet share expense	—	1,099,360	—	1,099,360
Total operating expenses	4,955,643	5,095,586	13,804,539	11,981,188
Loss from operations	(4,955,643)	(5,095,586)	(13,804,539)	(11,981,188)
Other (expense) income:				
Interest expense	(1)	(1,716)	(6,863)	(1,820)
Interest income	3,260	348	3,768	1,249
Australian research and development incentives	58,448	65,111	149,457	230,188
Change in fair value of warrant liability	18,193	128,030	141,934	128,030
Other income, net	79,900	191,773	288,296	357,647
Net loss	(4,875,743)	(4,903,813)	(13,516,243)	(11,623,541)
Deemed dividend on warrant modification	—	—	—	(450,578)
Net loss attributable to MAIA Biotechnology, Inc. shareholders	$ (4,875,743)	$ (4,903,813)	$ (13,516,243)	$ (12,074,119)
Net loss per share				
Basic and diluted	$ (0.36)	$ (0.48)	$ (1.08)	$ (1.39)
Weighted average common shares outstanding basic and diluted	13,675,802	10,165,622	12,521,264	8,713,570

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,	
	2023	**2022**	**2023**	**2022**
Net loss	$ (4,875,743)	$ (4,903,813)	$ (13,516,243)	$ (12,074,119)
Foreign currency translation adjustment	(17,858)	(47,501)	(43,766)	(51,646)
Comprehensive loss	$ (4,893,601)	$ (4,951,314)	$ (13,560,009)	$ (12,125,765)

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	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 Changes in Stockholders' Equity (Unaudited)

For the Three and Nine Months Ended
September 30, 2022

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	7,584,980	$ 758	$ 37,618,438	$ (28,437,993)	$ —	$ 9,181,203
Issuance of common shares upon exercise of stock options	26,500	3	47,697	—	—	47,700
Issuance of common shares upon exercise of warrants	61,111	6	109,994	—	—	110,000
Issuance of common shares in connection with Equity Financing	263,729	27	2,373,534	—	—	2,373,561
Stock-based compensation expense	—	—	713,330	—	—	713,330
Modification of warrant in equity	—	—	450,478	—	—	—
Deemed dividend on modification of warrant	—	—	(450,478)	—	—	—
Foreign currency translation adjustment	—	—	—	—	1,721	1,721
Net loss	—	—	—	(3,413,845)	—	(3,413,845)
Balance at March 31, 2022	7,936,320	794	40,862,993	(31,851,838)	1721	9,013,670
Issuance of common shares upon exercise of warrants	468,601	47	275,353	—	—	275,400
Issuance of common shares in connection with Equity Financing	11,111	1	99,998	—	—	99,999
Stock-based compensation expense	—	—	584,768	—	—	584,768
Foreign currency translation adjustment	—	—	—	—	(5,866)	(5,866)
Net loss	—	—	—	(3,305,883)	—	(3,305,883)
Balance at June 30, 2022	8,416,032	$ 842	$ 41,823,112	$ (35,157,721)	$ (4,145)	$ 6,662,088
Issuance of common shares upon exercise of stock options	10,000	1	17,999	—	—	18,000
Issuance of common shares in connection with initial public offering, net of $2,749,905 issuance cost	2,300,000	230	8,749,865	—	—	8,750,095
Issuance of ratchet share	219,872	22	1,099,338	—	—	1,099,360
Stock-based compensation expense	—	—	532,438	—	—	532,438
Foreign currency translation adjustment	—	—	—	—	(47,501)	(47,501)
Net loss	—	—	—	(4,903,813)	—	(4,903,813)
Balance at September 30, 2022	10,945,904	$ 1,095	$ 52,222,752	$ (40,061,534)	$ (51,646)	$ 12,110,667

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,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (13,516,243)	$ (11,623,541)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,727,369	1,830,536
Issuance of ratchet shares	—	1,099,360
Consulting expense for restricted shares issued	682,962	—
Change in fair value of warrant liability	(141,934)	(128,030)
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	134,145	(412,124)
Australia research and development incentives receivable	174,613	(230,188)
Other assets	—	322
Accounts payable	64,016	64,788
Accrued expenses	1,796,502	252,487
Net cash used in operating activities	(9,078,570)	(9,146,390)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of transaction costs	—	2,473,560
Deferred offering costs	(153,937)	—
Proceeds from exercise of stock options	1,432	65,700
Proceeds from exercise of warrants	—	385,400
Proceeds from sale of common stock in initial public offering	—	11,500,000
Payment of initial public offering transaction costs	—	(1,754,586)
Proceeds from sale of common stock in follow-on offering	5,749,875	—
Payment of follow-on offering transactions costs	(1,351,907)	—
Net cash provided by financing activities	4,245,463	12,670,074
Net effect of foreign currency exchange on cash	(13,233)	(34,334)
Net decrease in cash	(4,846,340)	3,489,350
Cash at beginning of period	10,950,927	10,574,292
Cash at end of period	$ 6,104,587	$ 14,063,642
Supplemental disclosure of cash flow information:		
Previously paid issuance costs in connection with the initial public offering	—	651,582
Warrants issued to underwriters in connection with the initial public offering	—	343,735
Options issued for accrued bonus	$ 974,224	—
Warrants issued to underwriters in connection with the follow-on offering	$ 241,109	—

See the accompanying notes to the 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:

- THIO Therapeutics, Inc. ("THIO"), incorporated in the state of Delaware on November 26, 2018. On August 13, 2021, MAIA and THIO completed a plan of reorganization in which THIO merged with and into MAIA. Prior to the merger, MAIA owned 93.3% of the outstanding shares of THIO common stock, which were canceled in connection with the merger. The remaining 6.7% minority stockholder of THIO received one share of MAIA common stock for each share of THIO common stock owned prior to the merger.

- DGD Pharmaceuticals Corporation ("DGD"), incorporated in the state of Delaware of April 1, 2019. In July 2020, the board of directors approved the dissolution of DGD, and shortly thereafter also approved a special dividend/return of capital to its stockholders. On August 13, 2021, DGD was officially dissolved via a filing of a Certificate of Dissolution with the state of Delaware.

- MAIA Drug Development Corporation ("MAIA DD") incorporated in the state of Texas on September 10, 2018, and was 100% owned by MAIA, until MAIA DD was legally dissolved in July 2021. The operations of MAIA DD were nominal.

- 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 $57,723,515 from the Company’s inception through September 30, 2023. As of September 30, 2023, the Company had $6,104,587 in cash and cash equivalents and working capital of approximately $2,483,179.

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, 2022 included in the Company's Annual Report on Form 10-K filed on March 24, 2023. The condensed consolidated balance sheet as of December 31, 2022 was derived from the 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 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, 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. At September 30, 2023 and December 31, 2022, substantially all of the Company's cash was deposited in accounts at one financial institution. 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, 2023 and December 31, 2022, cash includes cash in a depository bank account; the Company had no cash equivalents as of September 30, 2023 or December 31, 2022.

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, 2023, and as of and during the twelve months ended December 31, 2022. 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, 2023. The estimated fair value of warrants issued to underwriters and embedded features, 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 CROs, 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 are selected, 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. 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 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, 2023, 248,969 restricted shares of common stock were issued for consulting services. There were no issuances of restricted stock awards during the nine months ended September 30, 2022. 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 1) the underlying shares are classified as liabilities or 2) 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.

Deferred Offering Costs

Deferred offering costs are included in other assets and consist of legal, accounting, underwriting fees and other costs. Deferred offering costs as of the December 31, 2022 balance sheet date are directly related to the follow-on offering and were charged to additional paid-in capital upon the completion of the follow-on offering on April 27, 2023. Deferred offering costs incurred through the September 30, 2023 balance sheet are directly related to a proposed follow-on offerings that will be charged to additional paid-in capital upon the completion of the offering.

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,	
	2023	**2022**
Shares issuable upon exercise of stock options	7,860,736	6,511,910
Shares issuable upon exercise of warrants	924,760	796,985

Recent Accounting Standards

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board 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 have 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 Report. Our directors and executive officers may also adopt future 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 when entering into the plan, 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.

3. ACCRUED EXPENSES

As of September 30, 2023 and December 31, 2022, accrued expenses consisted of the following:

	September 30, 2023	December 31, 2022
Bonus	$ 819,290	$ 1,094,582
Professional fees	659,111	332,589
Research and development costs	1,035,481	516,961
Other	409,971	159,269
Total accrued expenses	$ 2,923,853	$ 2,103,401

Accrued Bonus

On May 31, 2023, the 2022 accrued bonus for current employees and officers was settled by the issuance of 511,225 stock options with a total fair value of $974,224.

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:

	Fair value at September 30, 2023			
	Total	Level 1	Level 2	Level 3
Liabilities:				
Warrant liability	103,407	—	—	103,407
Total liabilities	$ 103,407	$ —	$ —	$ 103,407

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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Warrant liabilities:	2023	2022	2023	2022
Balance, beginning of period	$ 121,600	$ —	$ 245,341	$ —
Gain on fair value of warrant liability	(18,193)	—	(141,934)	—
Balance, end of period	$ 103,407	$ —	$ 103,407	$ —

5. STOCKHOLDERS' EQUITY

Upon the closing of the Company's initial public offering, the Company's shareholders agreement terminated pursuant to its terms. In connection with the closing of the Company's initial public offering, 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.

Sales of MAIA Common Stock

During January and February 2022, the Company sold 263,729 shares of common stock at $9.00 per share for gross proceeds of $2,373,561 with no transaction costs. During May 2022, the Company sold 11,111 shares of common stock at $9 per share for gross proceeds of $99,999 with no transaction costs. The Company issued these shareholders additional shares ("Ratchet Shares") upon the closing of the Company's initial public offering such that the $9.00 price per share they paid was equal to the price per share in the Company's initial public offering of $5.00. The number of Ratchet Shares were calculated using the $5.00 per share price in the Company's initial public offering and 219,872 shares of common stock were issued on August 1, 2022 to the investors in the Recent Private Rounds. The Ratchet shares were determined to be a freestanding instrument that was classified as a liability when the right was granted and subsequently reclassified to equity when shares were issued. The Ratchet Shares were valued at $1,099,360, based on the $5 price of the initial public offering and were recorded as expense included in operating expense in the 2022 Consolidated Statement of Operations.

Initial Public Offering

On July 28, 2022 the Company's shares of 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 initial public offering prior to deducting underwriting discounts, commissions, and other offering expenses. ThinkEquity LLC ("ThinkEquity") served as underwriter in the offering. On August 3, 2022, the Company sold an additional 300,000 shares of common stock at $5.00 per share when ThinkEquity exercised its over-allotment option in full for gross proceeds of $1,500,000 prior to deducting underwriting discounts, commissions, and other offering expenses. After deducting the underwriting discount and other offering expenses payable by the Company, the total net proceeds for the initial public offering and the over-allotment were $9,093,830.

Follow-on Offering

On April 27, 2023, the Company sold 2,555,500 shares of the Company's common stock at a price of $2.25 per share in an underwritten public offering, including the full exercise by the underwriter of its overallotment option. ThinkEquity LLC served as underwriter in the offering. The total net proceeds of the offering were approximately $4,398,000, after deducting underwriting discounts, commissions, and other offering expenses.

At-the-Market Equity Offering

On September 1, 2023, the Company 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 (the "Shares") of the Company's common stock, par value $0.0001 per share (the "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 (the "Prospectus Supplement"), filed September 1, 2023 with the Securities and Exchange Commission (the "SEC"), to the prospectus forming a part of the Company's shelf Registration Statement on Form S-3 (File No. 333-273984) filed by the Company with the SEC on August 15, 2023 and declared effective by the SEC on August 23, 2023. As of September 30, 2023, no sales have been executed.

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 expected cash flow to be generated in the future. As of September 30, 2023 no shares have been repurchased.

MAIA Biotechnology, Inc. Restricted Stock Awards

During the nine months ended September 30, 2022, MAIA recognized $52,500 of stock compensation expense related to 29,168 of MAIA's restricted shares granted to the founders.

During the nine months ended September 30, 2023, the company expensed $682,962 for investor relation services related to the grant of 248,969 restricted shares of common stock. There are no unvested restricted shares as of September 30, 2023.

MAIA Stock Warrants

In January 2022, the Company and certain warrant holders executed waivers related to the acceptance and approval of an amendment to the holders' warrant agreements originally issued between May 6, 2020 and February 26, 2021 in connection with the Company's issuance of convertible notes. The amendment removed the IPO expiration provision from the warrant agreements, and the warrants are now only to be exercisable, in whole or in part, during the exercise period ending on the earliest to occur of: (a) various dates in 2028 as stated within the warrant agreements; or (b) immediately prior to the closing of a change of control. The value of the warrant modification to the 144,497 warrants was calculated using the Black-Scholes-Merton option pricing model. The incremental fair value attributable to the modified awards compared to the original awards immediately prior to the modification was calculated at $450,578 and was treated as a deemed dividend for the nine months ended September 30, 2022 and is reflected as "Deemed dividend on warrant modification" in the accompanying statement of operations.

During January 2022, warrants were exercised, resulting in the issuance of 61,111 shares of MAIA common stock for proceeds of $110,000. During May 2022, warrants were exercised, resulting in the issuance of 153,000 shares of common stock for proceeds of approximately $275,400. Another 394,501 warrants were exercised with a cashless exercise assuming the fair market value of $9.00 per share resulting in the issuance of 315,601 shares of common stock.

On August 1, 2022 at the closing of the initial public offering, 20,520 warrants with an exercise price of $5.00 per share expired.

Concurrently with the closing of the Company's initial public offering, 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 are exercisable beginning on January 23, 2023, and expire on July 27, 2027, pursuant to the terms and conditions of the Representative's Warrants. On August 3, concurrently with the full exercise of the Underwriter'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 as $343,735, which was the value 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, 2023 and December 31, 2022 the Company remeasured the warrant liability resulting in a value of $103,407 and $245,341 respectively. The gain on remeasurement of the warrant liability in the amount of $141,934 was included in other income for the nine months ended September 30, 2023.

Concurrently with the closing of the Company's follow-on offering, the Company issued warrants to purchase an aggregate of up to 127,775 shares of its common stock to the Representative or its designees, at an exercise price of $2.81 per share (the "Follow-On Representative's Warrants"). The Follow-On Representative's Warrants are exercisable beginning on October 24, 2023, and expire on April 24, 2028, pursuant to the terms and conditions of the Follow-On Representative's Warrants. The Follow-On Representative's Warrants are equity classified instruments and the value of the Follow-On Representative's Warrants determined using the Black-Scholes-Merton method was $241,009 using a term of five years, risk free interest rate of 4.09% and volatility of 86.3%.

	Warrants Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years
Balance at January 1, 2023	796,985	$ 6.04	5.16
Issued	127,775	2.81	
Exercised	—	—	
Expired	—	—	
Balance at September 30, 2023	924,760	$ 5.59	4.43

MAIA Biotechnology, Inc. Stock Award Plans

In 2018, the Company adopted the MAIA Biotechnology, Inc. 2018 Stock Option Plan (the "MAIA 2018 Plan"). MAIAs board of directors administers the MAIA 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 1,924,500 options outstanding in the plan as of September 30, 2023.

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 3,935,000 options outstanding in the plan as of September 30, 2023. There are no shares reserved for future issuance in the MAIA 2018 Plan or the MAIA 2020 Plan.

On August 1, 2022 the Company approved the MAIA Biotechnology, Inc. 2021 Equity Incentive Plan (the "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 and automatic increase to the plan in the amount equal to ten percent (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, 2021. As of September 30, 2023 there are 1,912,548 shares of common stock available for future issuance under the MAIA 2021 Plan and 2,001,236 options are outstanding in 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, 2023, only stock options have been awarded pursuant to the MAIA stock award plans.

The following table summarizes the activity and information regarding MAIA's outstanding and exercisable options for the nine months ended September 30, 2023:

	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Balance at January 1, 2023	6,545,628	$ 2.55	7.59	—
Granted	1,398,881	3.12		
Exercised	(750)	1.91		
Cancelled/forfeited	(83,023)	6.92		
Balance at September 30, 2023	7,860,736	$ 2.62	7.52	2,130,148
Options exercisable at September 30, 2023	6,623,957	$ 2.36	7.25	2,068,490

During the nine months ended September 30, 2023, the fair value of our common stock is based on the closing price of the common stock in the public market.

During the nine months ended September 30, 2022, the fair value of the Company's common stock was estimated for financial reporting purposes from January 1 to January 26, 2022 based on valuations of $8.87 per share as of December 31, 2021. For our valuations of common stock performed, we used a hybrid method of the Option Pricing Method ("OPM") and the Probability-Weighted Expected Return Method ("PWERM"). PWERM considers various potential liquidity outcomes. Our approach included the use of an initial public offering scenario, a scenario assuming continued operation as a private entity, and a dissolution scenario. Under the hybrid OPM and PWERM, the per share values calculated under the OPM and PWERM are weighted based on expected exit outcomes and the quality of the information specific to each allocation methodology to arrive at a final estimated fair value per share of the common stock before a discount for lack of marketability is applied. From January 27 to May 31, 2022 the fair value of the Company's common stock was estimated for financial reporting purposes at $9 per share based on the sale of common stock from January 27, 2022 to May 31, 2022. From June 1 to September 30, 2022 the fair value of the Company's common stock was estimated for financial reporting purposes at $5 per share based on the price paid in the initial public offering.

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, 2023 and 2022:

	2023	2022
Risk-free interest rate	3.64% - 4.59%	2.14% - 3.74%
Expected term (in years)	5 - 6.25	5 - 6.25
Expected volatility	99.6% - 112.4%	71.9% - 79.5%
Expected dividend yield	—%	—%

The weighted-average grant date fair value of stock options issued during the nine months ended September 30, 2023 and 2022 was $3.12 and $5.97, respectively. As of September 30, 2023, the total unrecognized compensation

related to unvested employee and non-employee stock option awards granted was $3,995,070, which the Company expects to recognize over a weighted average period of approximately 2.9 years.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
General and administrative	$ 320,456	$ 345,568	$ 911,186	$ 1,144,440
Research and development	250,460	186,870	816,183	686,096
Total stock-based compensation	$ 570,916	$ 532,438	$ 1,727,369	$ 1,830,536

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 agreement, as amended, has a term of 20 years. The agreement requires MAIA to reimburse UTSW for agreed-upon expenses related to THIO. The 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, 2023, 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 agreement requires royalties of 2-4% (depending on THIO reaching specified sales levels in the respective jurisdictions) royalty payments on net sales up to $1,000,000,000, and 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 agreement has a term of 20 years and requires the Company to reimburse UTSW for certain agreed-upon expenses. The 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, 2023, 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 agreement requires royalties of 2-4% (depending on THIO reaching specified sales levels in the respective jurisdictions) royalty payments on net sales up to $1,000,000,000, 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 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 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 fifty percent (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 ten (10) years after the First Commercial Sale (as defined in UTSW2 Agreement) in each country.

Regeneron – In February 2021, the Company reached an 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 twelve (12) months after (a) the Effective Date, with respect to the initial study, or (b) 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, 2023 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, 2023, and December 31, 2022, the Company had a full valuation allowance against its deferred tax assets.

For the nine months ended September 30, 2023 and 2022, 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, 2023, due to full valuation allowance to offset any deferred tax assets.

8. SUBSEQUENT EVENT

Subsequent to the end of the reporting period September 30, 2023, the Company initiated an at-the-market offering of common stock, pursuant to a previously established equity distribution agreement with ThinkEquity LLC. As of the date of this filing, the Company has sold 452,388 shares of common stock at an average price of $2.32 per share, resulting in aggregate gross proceeds of approximately $1,051,000. The Company anticipates that the at-the-market offering will continue throughout the next reporting period.

These subsequent events may have a material impact on the Company's financial position, results of operations, and cash flows in future periods, and they are disclosed here for informational purposes. Investors should consider the potential impact of these events on their assessments of the Company's financial condition and performance.

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 NSCLC, which represents 85% of all lung cancers.

We accomplished the following key milestones:

- In November 2018, we in-licensed THIO from University of Texas Southwestern, 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 not been allowed to date, but if it is allowed 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 Pharmaceuticals, Inc. Under this agreement, Regeneron will provide cemiplimab (LibtayoÒ; anti-PD-1 checkpoint inhibitor) at no charge for the THIO-101 trials, testing THIO administration for immune activation followed by cemiplimab in NSCLC. This 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 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 (FDA) granted Orphan Drug Designation (ODD) to THIO for the treatment of hepatocellular carcinoma, 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 shares of 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 initial public offering 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 overallotment 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 Non-Small Cell Lung Cancer (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, LibtayoÒ was well tolerated with no dose-limiting toxicities or significant treatment-related adverse events reported.
- On April 18, 2023, we published data in Hepatocellular Carcinoma ("HCC") (liver cancer) 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 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.
- In July 2023**,** MAIA 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) (the "From S-3") for possible future offerings was declared effective by the SEC. As of September 30, 2023, no securities have been issued pursuant to the Form S-3.
- On September 1, 2023, the Company 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 the Company's 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 (the "Prospectus Supplement"), filed September 1, 2023 with the SEC to the prospectus forming a part of the Form S-3. As of September 30, 2023, no sales have been executed.
- 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 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 have been executed.
- On October 3, 2023, the Company announced that the FDA has cleared its IND 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, the Company 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.

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.

Financial Operations Overview and Analysis for the Three and Nine Months Ended September 30, 2023 and 2022

Comparison of three months ended September 30, 2023 and 2022

	Three Months Ended September 30,		Change	
	2023	2022	Dollars	Percentage
Operating expenses:				
Research and development expenses	$ 2,599,578	$ 2,343,154	$ 256,424	11%
General and administrative expenses	2,356,065	1,653,072	702,993	43%
Ratchet share expense	—	1,099,360	(1,099,360)	-100%
Total operating costs and expenses	4,955,643	5,095,586	(139,943)	-3%
Loss from operations	(4,955,643)	(5,095,586)	139,943	-3%
Other (expense) income:				
Interest expense	(1)	(1,716)	1,715	-100%
Interest income	3,260	348	2,912	837%
Australian research and development incentives	58,448	65,111	(6,663)	-10%
Change in fair value of warrant liability	18,193	128,030	(109,837)	-86%
Other income, net	79,900	191,773	(111,873)	-58%
Net loss	(4,875,743)	(4,903,813)	28,070	-1%
Net loss attributable to MAIA Biotechnology, Inc. shareholders	$ (4,875,743)	$ (4,903,813)	$ 28,070	-1%

Operating Expenses

Research and development expenses

Research and development expenses increased by approximately $256,000 or 11%, from approximately $2,343,000 for the three months ended September 30, 2022 to approximately $2,600,000 for the three months ended September 30, 2023. The increase was primarily related to an increase in scientific research of approximately $519,000 and an increase in stock-based compensation costs of approximately $64,000, offset by a decrease in clinical expenses of approximately $126,000, a decrease in payroll and bonus expenses of approximately $120,000 related to the decreased headcount of additional research and development employees, a decrease in consulting of approximately $46,000, and a decrease of approximately $35,000 in other expenses.

General and administrative expenses

General and administrative expenses increased by approximately $703,000, or 43% from approximately $1,653,000 for the three months ended September 30, 2022 to approximately $2,356,000 for the three months ended September 30, 2023. The increase was primarily related to an increase in professional fees of approximately $522,000 relating to the write-off of deferred offering costs, an increase in other expenses of approximately $200,000 related to the new investor relation contract, and an increase in payroll expense of approximately $6,000, offset by a decrease in stock-based compensation of approximately $25,000.

Ratchet Expense

Ratchet expense decreased by approximately $1,099,000 or 100% from approximately $1,099,000 for the three months ended September 30, 2022 to $0 for the three months ended September 30, 2023. The decrease is due to the fact that the ratchet share issuance was a one-time event at the time of the IPO and thus no ratchet share issuance this quarter.

Other expense, net

Other income, net decreased by approximately 112,000 or 58% from other income of approximately $192,000 for the three months ended September 30, 2022 to other income of approximately $80,000 for the three months ended September 30, 2023. The decrease was primarily related to the change in the fair value of the warrant liability of approximately $110,000, a reduction in the Australia research and development incentives of approximately $7,000 and a net increase of interest income of approximately $5,000.

Comparison of nine months ended September 30, 2023 and 2022

	Nine Months Ended September 30,		Change	
	2023	2022	Dollars	Percentage
Operating expenses:				
Research and development expenses	$ 7,394,884	$ 6,539,948	$ 854,936	13%
General and administrative expenses	6,409,655	4,341,880	2,067,775	48%
Ratchet share expense	—	1,099,360	(1,099,360)	-100%
Total operating costs and expenses	13,804,539	11,981,188	1,823,351	15%
Loss from operations	(13,804,539)	(11,981,188)	(1,823,351)	15%
Other (expense) income:				
Interest expense	(6,863)	(1,820)	(5,043)	277%
Interest income	3,768	1,249	2,519	202%
Australian research and development incentives	149,457	230,188	(80,731)	-35%
Change in fair value of warrant liability	141,934	128,030	13,904	11%
Other income, net	288,296	357,647	(69,351)	-19%
Net loss	(13,516,243)	(11,623,541)	(1,892,702)	16%
Deemed dividend on warrant modifications	—	(450,578)	450,578	-100%
Net loss attributable to MAIA Biotechnology, Inc. shareholders	$ (13,516,243)	$ (12,074,119)	$ (1,442,124)	12%

Operating Expenses

Research and development expenses

Research and development expenses increased by approximately $855,000 or 13%, from approximately $6,540,000 for the nine months ended September 30, 2022 to approximately $7,395,000 for the nine months ended September 30, 2023. The increase was primarily related to an increase in scientific research of approximately $1,181,000, an increase in payroll related expenses and bonus expense of approximately $538,000 related to an increase in payroll, bonus expense and benefits due to an increased headcount of development employees, an increase in stock-based compensation of approximately $130,000, an increase of approximately $5,000 in other expenses, offset by decrease in other clinical expenses of approximately $778,000 and a decrease in professional fees of approximately $221,000.

General and administrative expenses

General and administrative expenses increased by approximately $2,068,000 or 48% from approximately $4,342,000 for the nine months ended September 30, 2022 to approximately $6,410,000 for the nine months ended September 30, 2023. The increase was primarily attributable to the increased costs to create additional infrastructure to support our operations as a public company. Increases included an increase in other expenses of approximately $1,508,000 primarily related to investor relations and insurance required to operate as a public company, an increase

in payroll, bonus expenses and benefits due to an increase headcount of operational employees approximately $418,000, and an increase in professional fees of approximately $375,000, offset by a decrease in stock-based compensation expense of approximately $233,000 related to lower Board of Directors compensation.

Ratchet Expense

Ratchet expense decreased by approximately $1,099,000 or 100% from approximately $1,099,000 for the nine months ended September 30, 2022 to $0 for the nine months ended September 30, 2023. The decrease is due to the fact that the ratchet share issuance was a one-time event at the time of the IPO and thus no ratchet share issuance this quarter.

Other expense, net

Other income expense, decreased by approximately $69,000 or 19% from approximately $358,000 of other income for the nine months ended September 30, 2022 to approximately $288,000 of other income for the nine months ended September 30, 2023. The change in other income, net was primarily the result of approximately $81,000 decrease of income related to the Australian research and development incentive, a net increase in interest expense of approximately $2,000, offset by approximately $14,000 related to the change in fair value of the warrant liability for the nine months ended September 30, 2023.

Liquidity and Capital Resources

Our Ability to Continue as a Going Concern

As of September 30, 2023, our cash totaled $6,104,587 which represented a decrease of approximately $4,846,000 compared to December 31, 2022. As of September 30, 2023, we had working capital of approximately $2,483,000 which represents a decrease of approximately $6,316,000 compared to December 31, 2022. We have generated no revenues as of September 30, 2023. The Company's current operating plan indicates that it 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 the Company's lack of revenue generating activities. Based on the Company's cash reserves as of September 30, 2023 of $6,104,587 and current financial condition as of the date of the Quarterly Report on Form 10-Q, 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, 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.

Sales of Common Stock

During January and February 2022, the Company sold 263,729 shares of common stock at $9.00 per share for gross proceeds of $2,373,561 before transaction costs and expenses.

Between April 22, 2022 and May 3, 2022, warrant holders exercised warrants, resulting in the issuance of 153,000 shares of common stock for proceeds of approximately $275,400.

On May 19, 2022, the Company sold 11,111 shares of common stock at $9.00 per share for gross proceeds of $99,999 with no transaction costs.

On August 1, 2022, the Company sold 2,000,000 shares of common stock at $5 per share for gross proceeds of $10,000,000 in an initial public offering. On August 3, 2022, the Company sold an additional 300,000 shares of common stock at $5 per share for gross proceeds of $1,500,000 per the overallotment option for the underwriter. Concurrently with the closing of the Company's initial public offering, 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 warrants are exercisable beginning on January 23, 2023, and expire on July 27, 2027, pursuant to the terms and conditions of the warrants. On August 3, concurrently with the full exercise of the Underwriter's over-allotment option, the Company issued additional 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.

On April 27, 2023, the Company sold 2,555,500 shares of the Company's common stock at a price of $2.25 per share in an underwritten public offering. ThinkEquity served as underwriter of the offering. The aggregate net proceeds of the offering were approximately $4.4 million, after deducting underwriting discounts and offering expenses. Concurrently with the closing of the public offering, the Company also issued warrants to purchase an aggregate of up to 127,775 shares of its common stock to ThinkEquity or its designees, at an exercise price of $2.8125 per share. The warrants are exercisable beginning on October 24, 2023, and expire on April 24, 2028, pursuant to the terms and conditions of the warrants

On September 1, 2023, the Company 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 the Company's 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 (the "Prospectus Supplement"), filed September 1, 2023 with the SEC to the prospectus forming a part of the Form S-3. As of September 30, 2023, no sales have been executed.

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 nine months ended September 30, 2023 and 2022

	Nine Months Ended September 30,	
	2023	**2022**
Net cash flows used in operating activities	$ (9,078,570)	$ (9,146,390)
Net cash flows provided by financing activities	4,245,463	12,670,074
Effect of foreign currency exchange rate changes on cash	(13,233)	(34,334)
Net increase in cash and cash equivalents	$ (4,846,340)	$ 3,489,350

Operating Activities

For the nine months ended September 30, 2023, net cash used in operating activities was approximately $9,079,000, which consisted of a consolidated net loss of approximately $13,516,000 offset by non-cash charges of approximately $1,727,000 in stock-based compensation, and approximately $683,000 of non-cash expense to issue stock to consultants, offset by 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 net increase in accounts payable and accrued expenses, an approximate $175,000 increase in the Australia research and development incentives receivable, and an approximate $134,000 increase in prepaid expense and other assets.

For the nine months ended September 30, 2022, net cash used in operating activities was approximately $9,146,000, which consisted of a net loss of approximately $11,624,000 offset by non-cash charges of approximately $1,831,000

in stock-based compensation, approximately $1,099,00 non-cash charges for issuance of ratchet shares, offset by the remeasurement of the warrant liability of approximately $128,000. Total changes in operating assets and liabilities of approximately $325,000 were driven by an approximate $317,000 increase in accounts payable and accrued liabilities, offset by an approximate $412,000 decrease in prepaid expenses and other assets and an approximate decrease of $230,000 in Australia research and development incentives receivables.

For the nine months ended September 30, 2023 the effect of foreign currency exchange rate changes on cash decreased the cash balance as of September 30, 2023 by approximately $13,000 versus approximately $34,000 for the nine months ended September 30, 2022.

Financing Activities

Net cash provided by financing activities was approximately $4,245,000 and $12,670,000 for the nine months ended September 30, 2023 and 2022, respectively. Total net cash provided by financing activities for the nine months ended September 30, 2023 consisted primarily of approximately $5,750,000 gross proceeds from the follow-on offering and proceeds from exercise of stock options of approximately $1,000, offset by an approximate $1,352,000 of follow-on offering costs and an approximate $154,000 decrease in deferred offering costs. Total net cash provided by financing activities for nine months ended September 30, 2022 consisted of proceeds from the sale of common stock in the initial public offering of approximately $11,500,000, proceeds from the issuance of common stock net of transactions costs totaling approximately $2,474,000, proceeds from the exercise of warrants of $385,000, proceeds from exercise of stock options of approximately $66,000, offset by an approximate $1,755,000 payment of initial public offering cost.

Critical Accounting Policies and Significant Judgments and Estimates

Our condensed consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles (U.S. 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, 2022 filed with the SEC on March 24, 2023. There have been no material changes to the critical accounting estimates previously disclosed in such report.

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 Chief Financial Officer, who is our principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of September 30, 2023 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, or 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, 2023, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There 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 on Form 10-Q 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 our Annual Report on Form 10-K filed under the heading "*Risk Factors"* and filed with the SEC on March 24, 2023. 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, the following additional risk factor has been added to the risk factors disclosed in our Annual Report on Form 10-K.

We cannot guarantee that our share repurchase program will be utilized to the full value approved, or that it will enhance long-term stockholder value and repurchases we consummate could increase the volatility of the price of our common stock and could have a negative impact on our available cash balance.

Our board of directors authorized a share repurchase program pursuant to which we may repurchase up to $800,000 of our common stock through September 2024. The manner, timing and amount of any share repurchases may fluctuate and will be determined based on a variety of factors, including the market price of our common stock, our priorities for the use of cash to support our business operations and plans, general business and market conditions, tax laws, and alternative investment opportunities. The share repurchase program authorization does not obligate us to acquire any specific number or dollar value of shares. Further, our share repurchases could have an impact on our share trading prices, increase the volatility of the price of our common stock, or reduce our available cash balance such that we will be required to seek financing to support our operations. Our share repurchase program may be modified, suspended, or terminated at any time, which may result in a decrease in the trading prices of our common stock. Even if our share repurchase program is fully implemented, it may not enhance long-term stockholder value.

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

Recent sales of unregistered securities

On August 15, 2023, the Company entered into an agreement with Laidlaw & Company for investor services, pursuant to which we issued 12,500 shares of restricted common stock on August 15, 2023 and have agreed to issue an additional 12,500 shares of restricted common stock to be issued 180 days following the date of the agreement.

On September 21, 2023, the Company entered into a twelve-month agreement with IRTH Communications, LLC for investor relation services, pursuant to which we issued $100,000 worth of restricted shares of common stock, with the number of shares of the Company determined by dividing $100,000 by the average closing price of the Company's common stock for the ten trading days immediately prior to the execution of the agreement.

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

Use of Proceeds

On August 1, 2022, we consummated the initial public offering of our common stock pursuant to which we issued and sold 2,000,000 shares of our common stock at a price to the public of $5.00 per share, for aggregate approximate net proceeds of $7,706,000, after deducting underwriting discounts and commissions and estimated 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 overallotment option in full. In connection with the underwriter's exercise of its overallotment, we received net proceeds of $1,387,500, after deducting underwriting discounts and commissions and estimated offering expenses. All of the shares of common stock issued and sold in our initial public offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-266453), which was declared effective by the SEC on July 27, 2022. None of the expenses incurred by us were direct or indirect payments to any of (i) our directors or officers or their associates, (ii) persons owning 10% or more of our common stock, or (iii) our affiliates. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on July 29, 2022 pursuant to Rule 424(b)(4). ThinkEquity acted as sole book-running manager for the initial public offering.

On April 27, 2023, the Company sold 2,555,500 shares of the Company's common stock at a price of $2.25 per share in an underwritten public offering. ThinkEquity served as underwriter of the offering. The aggregate net proceeds of the offering were approximately $5.1 million, after deducting underwriting discounts and expenses. The shares of common stock were offered, issued and sold to the public pursuant to the Registration Statement on Form S-1, as amended from time to time (File No. 333-269606).

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.

None

Item 6. Exhibits.

The following exhibits are included, or incorporated by reference, in this Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 (and are numbered in accordance with Item 601 of Regulation S-K).

Exhibit Number	Description
3.1[(1)]	Amended and Restated Certificate of Incorporation of MAIA Biotechnology, Inc.
3.2[(1)]	Amended and Restated Bylaws of MAIA Biotechnology, Inc.
10.1[(2)]	Sales Agreement, dated September 1, 2023, by and between MAIA Biotechnology, Inc. and ThinkEquity LLC.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – 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.

(1) Filed as an exhibit to our Current Report on Form 8-K filed with the SEC on August 1, 2022.
(2) Filed as an exhibit to our Current Report on Form 8-K filed with the SEC on September 1, 2023.

SIGNATURES

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

MAIA Biotechnology Inc.

Date: November 7, 2023 By: /s/ Vlad Vitoc

Vlad Vitoc
Chief Executive Officer
(Principal Executive Officer)

Date: November 7, 2023 By: /s/ Joseph McGuire

Joseph McGuire
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

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

I, 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)) 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) [Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313];

   (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 7, 2023

By: */s/ Vlad Vitoc*

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

Exhibit

31.2

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

I, Joseph F. McGuire, 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)) 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) [Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313];

   (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 7, 2023

By: */s/ Joseph F. McGuire*

Joseph F. McGuire Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of MAIA Biotechnology, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, 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 7, 2023

By: */s/ Vlad Vitoc*
Vlad Vitoc
Chairman and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of MAIA Biotechnology, Inc. (the "Company")on Form 10-Q or the period ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph F. McGuire, Chief Financial 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 7, 2023

By: */s/ Joseph F. McGuire*
Joseph F. McGuire
Chief Financial Officer
(Principal Financial Officer)