UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q/A

(Amendment No. 1)

(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, 2022

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	**06060**
(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 8, 2022 the registrant had 10,945,904 shares of common stock, $0.0001 par value per share, outstanding.

EXPLANATORY NOTE

This Amendment No. 1 on Form 10-Q/A (the "Amendment") amends the Quarterly Report on Form 10-Q as of and for the three and nine month periods ended September 30, 2022 (the "Original Report") of MAIA Biotechnology, Inc. (the "Company"), as originally filed with the U.S. Securities and Exchange Commission (the "SEC") on November 9, 2022.

Background of Restatement

On February 3, 2023, the audit committee of the board of directors of the Company (the "Audit Committee") concluded, after discussion with the Company's management, that it is appropriate to restate the Company's previously issued unaudited condensed consolidated balance sheet as of September 30, 2022, and unaudited condensed consolidated statements of operations, unaudited condensed consolidated statements of comprehensive loss and unaudited condensed consolidated statements of stockholders' equity for the three and nine months ended September 30, 2022, and the unaudited condensed consolidated statement of cash flows for the nine months ended September 30, 2022 included in the Company's previously filed Quarterly Report on Form 10-Q with the SEC (the "Q3 Form 10-Q" and, the financial statements included in the Q3 Form 10-Q, the "Non-Reliance Financial Statements"). Considering the restatement of such financial statements, the Company concluded that the Non-Reliance Financial Statements should no longer be relied upon. This Amendment includes restatements of the Non-Reliance Financial Statements.

In connection with SEC pronouncements related to Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 480, Distinguishing Liabilities from Equity ("ASC 480"), the Company re-evaluated its accounting for the Issuance of Ratchet shares and warrants to Underwriters in connection with the IPO. As a result, the Company determined that the ratchet shares had improperly been treated as a deemed dividend instead of operating expense and the warrants were improperly classified as equity instead of a liability.

Effects of Restatement

As a result of the factors described above, the Company has included in this Amendment a restatement of its unaudited condensed consolidated financial statements for the periods affected by the Non-Reliance Financial Statements. See Note 2 to the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Amendment for additional information on the restatement and the related financial statement effects. These changes do not impact the Company's cash position.

Internal Control Considerations

The Company's management has concluded that in light of the classification error described above, a material weakness exists in the Company's internal control over financial reporting and that the Company's disclosure controls and procedures were not effective. For a discussion of management's consideration of the material weakness identified, see Part I, Item 4, Controls and Procedures of this Amendment.

Items Amended in this Form 10-Q/A

This Form 10-Q/A presents the Original Report, amended and restated with modifications as necessary to reflect the restatements. The following items have been amended to reflect the restatement:
Part I, Item 1. Financial Statements
Part I, Item 4, Controls and Procedures
Part II, Item 1A. Risk Factors

In addition, the Company's Principal Executive Officer and Principal Financial and Accounting Officer has provided new certifications dated as of the date of this filing in connection with this Form 10-Q/A (Exhibits31.1, 31.2, 32.1 and 32.2).

Except as described above, this Form 10-Q/A does not amend, update or change any other items or disclosures in the Original Report and does not purport to reflect any information or events subsequent to the filing thereof. As such, this Form 10-Q/A speaks only as of the date the Original Report was filed, and we have not undertaken herein to amend, supplement or update any

information contained in the Original Report to give effect to any subsequent events. Accordingly, this Form 10-Q/A should be read in conjunction with our filings made with the SEC subsequent to the filing of the Original Report, including any amendment to those filings.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

MAIA Biotechnology, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets

	September 30, 2022 (As Restated) (unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash	$ 14,063,642	$ 10,574,292
Prepaid expenses and other current assets	460,917	54,537
Australia research and development incentives receivable	255,306	43,666
Total current assets	14,779,865	10,672,495
Deferred offering costs	—	651,582
Other assets	2,800	3,122
Total assets	$ 14,782,665	$ 11,327,199
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,019,093	$ 960,401
Accrued expenses	1,437,200	1,185,595
Total current liabilities	2,456,293	2,145,996
Warrant liability	215,705	—
Total current liabilities and long term liabilities	2,671,998	2,145,996
Commitments and contingencies		
Stockholders' equity (deficit)		
Preferred stock, $0.0001 par value, 30,000,000 and 70,000,000 shares authorized at September 30, 2022 and December 31, 2021 respectively, 0 shares issued and outstanding	—	—
Common stock, $0.0001 par value, 70,000,000 and 30,000,000 shares authorized at September 30, 2022 and December 31, 2021 respectively, 10,945,904 and 7,584,980 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	1,095	758
Additional paid-in capital	52,222,752	37,618,438
Accumulated deficit	(40,061,534)	(28,437,993)
Accumulated other comprehensive income (loss)	(51,646)	—
Total stockholders' equity	12,110,667	9,181,203
Total liabilities and stockholders' equity	$ 14,782,665	$ 11,327,199

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022 (As Restated)	**2021**	**2022 (As Restated)**	**2021**
Operating expenses:				
Research and development expenses	$ 2,343,154	$ 1,081,705	$ 6,539,948	$ 1,988,450
General and administrative expenses	1,653,072	1,151,542	4,341,880	2,798,766
Ratchet share expense	1,099,360	—	1,099,360	—
Total operating costs and expenses	5,095,586	2,233,247	11,981,188	4,787,216
Loss from operations	(5,095,586)	(2,233,247)	(11,981,188)	(4,787,216)
Other income (expense):				
Interest expense	(1,716)	(451,306)	(1,820)	(827,539)
Interest income	348	708	1,249	1,501
Australian research and development incentives	65,111	—	230,188	—
Change in fair value of embedded features	—	(96,000)	—	(203,000)
Change in fair value of warrant liability	128,030	(100,780)	128,030	(1,546,280)
Loss on extinguishment of convertible notes and convertible notes, related parties	—	(2,322,943)	—	(2,322,943)
Other income (expense), net	191,773	(2,970,321)	357,647	(4,898,261)
Net loss	(4,903,813)	(5,203,568)	(11,623,541)	(9,685,477)
Net loss attributable to noncontrolling interests	—	(7,130)	—	(74,331)
Deemed dividend on warrant modification	—	—	(450,578)	—
Net loss attributable to MAIA Biotechnology, Inc. shareholders	$ (4,903,813)	$ (5,196,438)	$ (12,074,119)	$ (9,611,146)
Net loss per share				
Basic and diluted	$ (0.48)	$ (1.02)	$ (1.39)	$ (2.06)
Weighted average common shares outstanding Basic and diluted	10,165,622	5,119,121	8,713,570	4,668,635

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,	
	2022 (As Restated)	2021	2022 (As Restated)	2021
Net loss attributable to MAIA Biotechnology, Inc. shareholders	$ (4,903,813)	$ (5,196,438)	$ (12,074,119)	$ (9,611,146)
Foreign currency translation adjustment	(47,501)	—	(51,646)	—
Comprehensive loss to MAIA Biotechnology, Inc. shareholders	$ (4,951,314)	$ (5,196,438)	$ (12,125,765)	$ (9,611,146)

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

For the Three and Nine Months Ended
September 30, 2022

	Preferred Stock		Common Stock							
	Shares	Amount	Shares	Amount	Additional Paid-In Capital (As Restated)	Accumulated Deficit (As Restated)	Accumulated other comprehensive income (loss)	Total MAIA Equity (As Restated)	Noncontrolling Interest	Total Stockholders' Equity (As Restated)
Balance at December 31, 2021	—	$ —	7,584,980	$ 758	$ 37,618,438	$ (28,437,993)	$ —	$ 9,181,203	$ —	$ 9,181,203
Issuance of common shares upon exercise of stock options	—	—	26,500	3	47,697	—	—	47,700	—	47,700
Issuance of common shares upon exercise of warrants	—	—	61,111	6	109,994	—	—	110,000	—	110,000
Issuance of common shares in connection with Equity Financing	—	—	263,729	27	2,373,534	—	—	2,373,561	—	2,373,561
Stock-based compensation expense	—	—	—	—	713,330	—	—	713,330	—	713,330
Modification of warrant in equity	—	—	—	—	450,578	—	—	450,578	—	450,578
Deemed dividend on modification of warrant	—	—	—	—	(450,578)	—	—	(450,578)	—	(450,578)
Foreign currency translation adjustment	—	—	—	—	—	—	1,721	1,721	—	1,721
Net loss	—	—	—	—	—	(3,413,845)	—	(3,413,845)	—	(3,413,845)
Balance at March 31, 2022	—	—	7,936,320	794	40,862,993	(31,851,838)	1,721	9,013,670	—	9,013,670
Issuance of common shares upon exercise warrants	—	—	468,601	47	275,353	—	—	275,400	—	275,400
Issuance of common shares in connection with Equity Financing	—	—	11,111	1	99,998	—	—	99,999	—	99,999
Stock-based compensation expense	—	—	—	—	584,768	—	—	584,768	—	584,768
Foreign currency translation adjustment	—	—	—	—	—	—	(5,866)	(5,866)	—	(5,866)
Net loss	—	—	—	—	—	(3,305,883)	—	(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	-	6,662,088
Issuance of common shares upon exercise of stock options	—	—	10,000	1	17,999	—	—	18,000	—	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	—	8,750,095
Issuance of ratchet share	—	—	219,872	22	1,099,338	—	—	1,099,360	—	1,099,360
Stock-based compensation expense	—	—	—	—	532,438	—	—	532,438	—	532,438
Foreign currency translation adjustment	—	—	—	—	—	—	(47,501)	(47,501)	—	(47,501)
Net loss	—	—	—	—	—	(4,903,813)	—	(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	$ —	$ 12,110,667

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

MAIA Biotechnology, Inc. and Subsidiaries
Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit) (Unaudited)
For the three months ended September 30, 2021

For the Three and Nine Months Ended
September 30, 2021

	Preferred Stock		Common Stock							
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Subscription Receivable	Total MAIA Equity (Deficit)	Noncontrolling Interest	Total Stockholders' (Deficit) Equity
Balance at December 31, 2020	—	$ —	4,433,644	$ 443	$ 12,599,585	$ (15,934,113)	$ (2,002)	$ (3,336,087)	$ 1,719,787	$ (1,616,300)
Issuance of restricted common shares	—	—	15,278	2	27,498	—	—	27,500	—	27,500
Cancellation of restricted common shares	—	—	(5,557)	(1)	—	—	—	(1)	—	(1)
Issuance of common shares upon exercise of stock options	—	—	3,000	—	5,400	—	—	5,400	—	5,400
Receipt of stock subscription receivable	—	—	—	—	-	—	2,002	2,002	—	2,002
Stock-based compensation expense - MAIA	—	—	—	—	408,608	—	—	408,608	—	408,608
Stock-based compensation expense - DGD	—	—	—	—	—	—	—	—	64,584	64,584
Stock-based compensation expense - THIO	—	—	—	—	—	—	—	—	52,500	52,500
Net loss	—	—	—	—	—	(1,488,060)	—	(1,488,060)	(37,525)	(1,525,585)
Balance at March 31, 2021	—	—	4,446,365	444	13,041,091	(17,422,173)	—	(4,380,638)	1,799,346	(2,581,292)
Issuance of stock options to satisfy accrued bonus	—	—	—	—	786,531	—	—	786,531	—	786,531
Issuance of stock options to satisfy deferred compensation	—	—	—	—	285,418	—	—	285,418	—	285,418
Stock-based compensation expense - MAIA	—	—	—	—	660,048	—	—	660,048	—	660,048
Stock-based compensation expense - DGD	—	—	—	—	—	—	—	—	64,584	64,584
Stock-based compensation expense - THIO	—	—	—	—	—	—	—	—	52,500	52,500
Net loss	—	—	—	—	—	(2,926,648)	—	(2,926,648)	(29,676)	(2,956,324)
Balance at June 30, 2021	—	—	4,446,365	444	14,773,088	(20,348,821)	—	(5,575,289)	1,886,754	(3,688,535)
Issuance of common shares upon conversion of convertible notes	—	—	1,375,228	138	11,001,136	—	—	11,001,274	—	11,001,274
Issuance of common shares upon conversion of SAFE	—	—	5,208	—	25,000	—	—	25,000	—	25,000
Issuance of common shares in connection with Equity Financing	—	—	725,563	73	5,804,430	—	(320,000)	5,484,503	—	5,484,503
Transaction costs incurred in connection with Equity Financing	—	—	—	—	(118,332)	—	—	(118,332)	—	(118,332)
Reclassification of warrant liability to equity	—	—	—	—	1,952,000	—	—	1,952,000	—	1,952,000
Issuance of restricted common shares to Jerry Shay pursuant to THIO Merger Agreement	—	—	700,000	70	(70)	—	—	—	—	-
Stock-based compensation expense - MAIA	—	—	—	—	746,253	—	—	746,253	—	746,253
Stock-based compensation expense - DGD	—	—	—	—	—	—	—	—	32,291	32,291
Stock-based compensation expense - THIO	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	(5,196,438)	—	(5,196,438)	(7,130)	(5,203,568)
Dissolution of DGD	—	—	—	—	1,098,110	—	—	1,098,110	(1,098,110)	—
Dissolution of THIO pursuant to Merger Agreement	—	—	—	—	813,805	—	—	813,805	(813,805)	—
Balance at September 30, 2021	—	$ —	7,252,364	$ 725	$ 36,095,420	$ (25,545,259)	$ (320,000)	$ 10,230,886	$ —	$ 10,230,886

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,	
	2022 (As Restated)	**2021**
Cash flows from operating activities:		
Net loss, including noncontrolling interests	$ (11,623,541)	$ (9,685,477)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,830,536	2,108,868
Loss on extinguishment of convertible notes	—	2,322,943
Loss on settlement of bonus	—	6,531
Change in fair value of embedded features	—	203,000
Issuance of ratchet shares	1,099,360	—
Change in fair value of warrant liability	(128,030)	1,546,280
Amortization of debt discount	—	596,954
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(412,124)	(1,290)
Australia research and development incentives receivable	(230,188)	—
Other assets	322	(520,648)
Accounts payable	64,788	342,369
Accrued expenses	252,487	344,940
Due to related parties	—	(7,037)
Accrued interest	—	226,909
Net cash used in operating activities	(9,146,390)	(2,515,658)
Cash flows from financing activities:		
Proceeds from issuance of convertible notes, warrants, and embedded conversion features	—	7,369,000
Proceeds from Paycheck Protection Program loan	—	62,500
Collections of subscriptions receivable	—	2,002
Proceeds from issuance of common stock, net of transaction costs	2,473,560	5,366,170
Proceeds from exercise of stock options	65,700	5,400
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)	—
Payment on loan payable to officer	—	(367)
Net cash provided by financing activities	12,670,074	12,804,705
Net effect of foreign currency exchange on cash	(34,334)	—
Net increase in cash	3,489,350	10,289,047
Cash at beginning of period	10,574,292	663,457
Cash at end of period	$ 14,063,642	$ 10,952,504
Supplemental disclosure of cash flow information:		
Conversion of convertible notes and accrued interest into MAIA common stock	$ —	$ 8,249,587
Conversion of SAFE into MAIA common stock	$ —	$ 25,000
Subscription receivable for issuance of MAIA common stock	$ —	$ (320,000)
Options issued for accrued bonus	$ —	$ 786,531
Options issued for deferred compensation	$ —	$ 285,418
Reclassification of warrant liability to equity	$ —	$ 1,952,000
Issuance of convertible note for payment on loan to officer	$ —	$ (21,000)
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	$ —

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.

Liquidity

At September 30, 2022, the Company had working capital of $12,323,572, accumulated deficit of $40,061,534, cash of $14,063,642 and current liabilities of $2,456,293. Since inception the Company has experienced net losses and negative cash flows from operations each fiscal year. The Company has no revenues and expects to continue to incur operating losses for the foreseeable future, and may never become profitable. The Company is dependent on its ability to continue to raise equity and/or debt financing to continue operations, until the attainment of profitable operations.

During January and February 2022, the Company sold 263,729 shares of common stock at $9 per share for gross proceeds of $2,373,561. During May 2022, the company sold 11,111 shares of common stock at $9 per share for gross proceeds of $99,999. The Company completed an initial public offering on August 1, 2022 and has commenced trading on the NYSE American under the ticker symbol "MAIA." The Company sold 2,000,000 shares of common stock at $5 per share for gross proceeds of $10,000,000 in the 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. After deducting $2,406,170 for cash issuance costs, net proceeds from the offering and overallotment were $9,093,830.

The Company will require significant funding to perform the necessary clinical trials, and to meet the Company’s long-term development and commercialization goals. The Company plans to meet its capital requirements primarily through issuances of equity securities, or debt financings, as well as other sources. The Company cannot make any assurances that additional financings will be available, on acceptable terms or at all. If the Company is unable to raise the necessary funding, management will undertake cost cutting measures to reduce compensation and reduce

the scope of or delay its clinical programs. This could negatively impact the Company's business and could also lead to the reduction of the Company's operations.

Impact of the COVID-19 Pandemic on our Operations

On January 30, 2020, the World Health Organization ("WHO") announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (the "COVID-19 Outbreak") and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, the WHO classified the COVID-19 Outbreak as a pandemic, based on the rapid increase in exposure globally.

The full impact of the COVID-19 Outbreak continues to evolve as of the date of this report. As a result, we cannot estimate the full magnitude that the pandemic will have on our business. If the COVID-19 Outbreak continues, it may have a material adverse effect on our financial condition, liquidity, and future results of operations for the future. We are actively monitoring the impact of the global pandemic on our financial condition, liquidity, operations, industry, and workforce. Given the daily evolution of the COVID-19 Outbreak and the global responses to curb its spread, we are not able to estimate the effects of the COVID-19 Outbreak on our results of operations, financial condition, or liquidity for the future. One of our initial clinical studies is taking place in Australia, which initially imposed one of the strictest COVID-19-related measures, including lock-downs. While we are not currently experiencing any delays or increased costs as a result of these measures, we may do so in the future.

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, 2021 included in the Company's final prospectus for its initial public offering dated July 27, 2022 and filed with the SEC on July 29, 2022. The condensed consolidated balance sheet as of December 31, 2021 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.

Reclassification

Certain 2021 amounts have been reclassified to conform to the 2022 presentation.

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, accruals for outsourced research and development activities, and the valuation allowance of deferred tax assets. 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 shareholders' 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, 2022 and December 31, 2021, 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, 2022 and December 31, 2021, cash includes cash in a depository bank account; the Company has no cash equivalents as of September 30, 2022 and December 31, 2021.

Fair Value Measurements

ASC 820, *Fair Value Measurements*, provides guidance on the development and disclosure of fair value measurements. 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, 2022, and as of and during the twelve months ended December 31, 2021. 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

model during the nine months ended September 30, 2021 and the nine months ended September 30, 2022 . The carrying value of notes payable and convertible notes payable approximated the estimated fair values due to their recent issuances. The estimated fair value of the warrants issued with the convertible notes, 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, depreciation and amortization, 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 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 significant 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 options 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, 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.

There were no issuances of common stock as it relates to DGD or THIO during nine months ended September 30, 2021. 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 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 to 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 were included in other assets and consisted of legal, accounting, underwriting fees and other costs incurred through the balance sheet date that are directly related to the initial public offering and were charged to additional paid-in capital upon the completion of the initial public offering on August 1, 2022.

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,	
	2022	**2021**
Shares issuable upon exercise of stock options	6,511,910	5,666,267
Shares issuable upon exercise of warrants	796,985	1,594,733
Unvested restricted stock awards	—	58,333

Recent Accounting Standards

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that

the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

2. RESTATEMENT OF PREVIOUSLY ISSUED FINANCIAL STATEMENTS

During February 2023, the Company identified errors in its previously issued financial statements. Specifically, (i) ratchet shares should have been be treated as a liability-classified free standing instrument instead of an embedded feature of the Company's common shares, and (ii) the warrants issued to the Underwriters in connection with the Company's IPO should have been liability classified instead of equity classified.

Due to these changes in the treatment of issuance of the ratchet shares and the warrants issued to the Underwriter in connection with the IPO, the Company corrected its financial statements as of and for the three and nine months ended September 30, 2022. As a result, the following items have been restated, (i) warrant liability which is included in total liabilities, (ii) additional paid-in capital, and (iii) accumulated deficit as of September 30, 2022, and (iv) change in fair value of warrant liability, (v) operating expense, and (vi) net loss and net loss per share for the three and nine months ended September 30, 2022.

The table below represents the balances of the affected accounts on the Condensed Consolidated Balance Sheet as of September 30, 2022, the Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2022, Statement of Changes in Condensed Consolidated Statements of Comprehensive Loss for the three and nine months Ended September 30, 2022**,** Condensed Consolidated Statement of Stockholders' Equity for the three and nine months ended September 30, 2022, and the Condensed Consolidated Statement of Cash Flows for the nine months ended September 30, 2022. The accompanying notes to the unaudited consolidated interim financial statements have been restated as applicable.

	As Previously Reported	Adjustment	As Restated
Balance Sheet as of September 30, 2022			
Warrant liability	$ —	$ 215,705	$ 215,705
Total current and long term liabilities	$ 2,456,293	$ 215,705	$ 2,671,998
Additional paid-in capital	$ 51,467,127	$ 755,625	$ 52,222,752
Accumulated deficit	$ (39,090,204)	$ (971,330)	$ (40,061,534)
Total stockholders equity	$ 12,326,372	$ (215,705)	$ 12,110,667
Statement of Operations, Three Months Ended September 30, 2022			
Ratchet share expense	$ —	$ 1,099,360	$ 1,099,360
Loss from operations	$ (3,996,226)	$ (1,099,360)	$ (5,095,586)
Change in fair value of warrant liability	$ —	$ 128,030	$ 128,030
Other income (expense) net	$ 63,743	$ 128,030	$ 191,773
Net Loss	$ (3,932,483)	$ (971,330)	$ (4,903,813)
Deemed dividend on ratchet shares	$ (1,099,360)	$ 1,099,360	$ —
Net loss attributable to MAIA Biotechnology, Inc. shareholders	$ (5,031,843)	$ 128,030	$ (4,903,813)
Net loss per share; basic and diluted	$ (0.49)	$ 0.01	$ (0.48)
Statement of Operations, Nine Months Ended September 30, 2022			
Ratchet share expense	$ —	$ 1,099,360	$ 1,099,360
Loss from operations	$ (10,881,828)	$ (1,099,360)	$ (11,981,188)
Change in fair value of warrant liability	$ —	$ 128,030	$ 128,030
Other income (expense) net	$ 229,617	$ 128,030	$ 357,647
Net loss	$ (10,652,211)	$ (971,330)	$ (11,623,541)
Deemed dividend on ratchet shares	$ (1,099,360)	$ 1,099,360	$ —
Net loss attributable to MAIA Biotechnology, Inc. shareholders	$ (12,202,149)	$ 128,030	$ (12,074,119)
Net Loss per share; basic and diluted	$ (1.40)	$ 0.01	$ (1.39)
Statement of Changes in Condensed Consolidated Statement of Comprehensive Loss Three Months Ended September 30, 2022			
Net loss attributable to MAIA Biotechnology, Inc. shareholders	$ (5,031,843)	$ 128,030	$ (4,903,813)
Comprehensive loss to MAIA Biotechnology, Inc. shareholder	$ (5,079,344)	$ 128,030	$ (4,951,314)
Statement of Changes in Condensed Consolidated Statement of Comprehensive Loss Nine Months Ended September 30, 2022			
Net loss attributable to MAIA Biotechnology, Inc. shareholders	$ (12,202,149)	$ 128,030	$ (12,074,119)
Comprehensive loss to MAIA Biotechnology, Inc. shareholder	$ (12,253,795)	$ 128,030	$ (12,125,765)
Statement of Changes in Stockholders' Equity (Deficit), Three Months Ended September 30, 2022			

Deemed dividend on ratchet shares	$ (1,099,360)	$ 1,099,360	$ —
Net loss	$ (3,932,483)	$ (971,330)	$ (4,903,813)
Additional paid-in capital at September 30, 2022	$ 51,467,127	$ 755,625	$ 52,222,752
Accumulated deficit at September 30, 2022	$ (39,090,204)	$ (971,330)	$ (40,061,534)
Total equity at September 30, 2022	$ 12,326,372	$ (215,705)	$ 12,110,667
Statement of Cash Flows, Nine Months Ended September 30, 2022			
Net loss, including noncontrolling interests	$ (10,652,211)	$ (971,330)	$ (11,623,541)
Change in fair value of warrant liability	$ —	$ (128,030)	$ (128,030)
Issuance of ratchet shares	$ —	$ 1,099,360	$ 1,099,360
Net cash used in operating activities	$ (9,146,390)	$ 0	$ (9,146,390)

3. ACCRUED EXPENSES

As of September 30, 2022 and December 31, 2021, accrued expenses consisted of the following:

	September 30, 2022	December 31, 2021
Bonus	$ 781,647	$ 384,750
Professional fees	70,922	380,277
Research and development costs	514,676	268,140
Deferred compensation to former officers	32,594	111,271
Other	37,361	41,157
Total accrued expenses	$ 1,437,200	$ 1,185,595

4. 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 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.

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. 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 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 overallotment were approximately $9.1 million.

MAIA Biotechnology, Inc. Restricted Stock Awards

During the nine months ended September 30, 2021, MAIA recognized $202,500 of stock compensation expense related to 112,500 of MAIA's restricted shares granted to the founders. On August 13, 2021, upon the dissolution of THIO and merger into MAIA (see Note 1), a founder's 612,500 fully vested THIO restricted shares were canceled and the founder was issued 612,500 MAIA restricted shares. Additionally, in accordance with the founder's original award, the founder was also issued 87,500 MAIA restricted shares which vested ratably each quarter through April 1, 2022 to replace the equivalent number of unvested THIO restricted shares. There are no unvested shares as of September 30, 2022 related to the founder's restricted shares.

	Shares	Weighted Average Grant Date Fair Value
Unvested balance at January 1, 2022	58,333	$ 1.80
Vested	(58,333)	1.80
Unvested balance at September 30, 2022	—	$ —

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 three months ended March 31, 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 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 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 warrants are not indexed to the Company's own stock and therefore meet the definition of a derivative liability. The warrants are liability classified instruments and were initially recorded as $343,735, which was the value determined using the Black-Scholes method using a term of five years, risk free interest rate of 2.82% and volatility of 77.5%. As of September 30, 2022 the Company remeasured the warrant liability resulting in a value of $215,705. The gain on remeasurement of the warrant liability in the amount of $128,030 was included in other income (expense) net.

	Warrants Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years
Balance at January 1, 2022	1,311,117	$ 4.03	7.30
Issued	115,000	6.25	
Exercised	(608,612)	1.80	
Expired	(20,520)	5.00	
Balance at September 30, 2022	796,985	$ 6.03	5.41

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 of September 30, 2022.

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 3,993,023 options outstanding in the plan as of September 30, 2022. 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. As of September 30, 2022 there are 1,315,131 available for future issuance under the MAIA 2021 Plan and 594,387 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, 2022, 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, 2022:

	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Balance at January 1, 2022	5,797,185	$ 2.22	8.59	—
Granted	768,113	4.84		
Exercised	(36,500)	1.80		
Cancelled/forfeited	(16,888)	1.82		
Balance at September 30, 2022	6,511,910	$ 2.53	7.34	$ 8,536,318
Options exercisable at September 30, 2022	5,443,036	$ 2.19	7.82	$ 7,664,470

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 19, 2022. From June 1, 2022 to August 1, 2022 the fair value of the Company's common stock was estimated for financial reporting purpose at $5 per share based on the price paid in the initial public offering.

During the nine months ended September 30, 2021, the fair value of the Company's common stock was estimated for financial reporting purposes based on valuations. From January 1, 2021 to February 28, 2021 a valuation of $1.80 was used. During the period of March 1, 2021 to June 6, 2021, the fair value of the Company's common stock was estimated for financial reporting purposes based on valuations of $1.83 per share in February and April 2021 due to the lack of any single specific event that would have indicated a definitive change in the value of the Company. The February and April 2021 valuations used the income approach and the market approach in estimating the fair value of our common stock. The market approach utilized guideline public companies in estimating fair value of our stock. The income approach estimates enterprise value based on the estimated present value of future cash flows the business is expected to generate over its remaining life. The estimated present value is calculated using a discount rate reflective of the risks associated with an investment in a similar company in a similar industry or having a similar history of revenue growth. The market approach measures the value of a business through an analysis of recent sales or offerings of comparable investments or assets, and in our case, focused on comparing us to a group of our peer companies. In applying this method, valuation multiples are derived from historical and projected operating data of the peer company group. We then apply the selected multiples to our operating data to arrive at a range of indicated enterprise values of the Company. We then subtracted the net debt to determine equity value.

The value of option grants is calculated using the Black-Scholes option pricing model with the following assumptions for options granted during the nine months ended September 30, 2022 and 2021:

	2022	2021
Risk-free interest rate	2.14% - 3.74%	0.35% - 1.05%
Expected term (in years)	5 – 6.25	5 – 6.50
Expected volatility	71.9% - 79.5%	73.4% - 81.5%
Expected dividend yield	—	—

The weighted-average grant date fair value of stock options issued during the nine months ended September 30, 2022 and 2021 was $3.11 and $2.57, respectively. As of September 30, 2022, the total unrecognized compensation related to unvested employee and non-employee stock option awards granted was $3,829,045, which the Company expects to recognize over a weighted average period of approximately 3.4 years.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
General and administrative	$ 345,568	$ 464,360	$ 1,144,440	$ 1,399,498
Research and development	186,870	314,184	686,096	709,370
Total stock-based compensation	$ 532,438	$ 778,544	$ 1,830,536	$ 2,108,868

5. 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, 2022, 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, 2022, 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, 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.

MJC13 — In January 2019, MAIA entered into a Global PLA and SRA for Collaborative Research and Jointly Owned Intellectual Property for the MJC13 Family of Compounds for the Treatment of Prostate Cancer with UTEP. The SRA requires MAIA to reimburse UTEP for research program expenditures up to $46,000. As amended, the SRA extended the research program to June 2020, since which point it has continued on an at-will basis.

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, 2022 neither party has terminated the agreement.

6. 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, 2022, and December 31, 2021, the Company had a full valuation allowance against its deferred tax assets.

For the nine months ended September 30, 2022 and 2021, the Company recorded zero income tax expense. No tax benefit has been recorded in relation to the pre-tax losses for nine months ended September 30, 2022 and 2021, due to a full valuation allowance to offset any deferred tax assets.

7. SUBSEQUENT EVENTS

Employee Retirement Plan

The Company created MAIA's 401(k) plan (the“Plan”), which became effective on October 1, 2022. All employees who have attained the age of 21 are eligible to participate in the Plan as the first entry date, as defined, following the employment date. Each eligible employee can contribute a percentage of compensation up to a maximum of the statutory limits per year. The Company will make a “safe harbor” matching contribution and deferrals will be determined on an annual basis.

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

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 235,000 new cases in the US in 2021, representing 12.4% of all cancers, and over 131,000 deaths, or 21.7% of all cancers. Worldwide, lung cancer incidence is over 2,200,000 per year (ranking second only after breast cancer), and mortality over 1,800,000 (ranking first). Specifically, we are targeting Non-Small Cell Lung Cancer (NSCLC), which represents 85% of all lung cancers.

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 completed a common stock seed round in the amount of $2 million.
- 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 was allowed in the US in the First Quarter 2021 and expires in 2041.
- In the First Quarter 2021, we entered into a Drug Supply Agreement with Regeneron Pharmaceuticals, Inc. Under this agreement, Regeneron will provide cemiplimab (LIBTAYO; anti-PD-1 checkpoint inhibitor) at no charge for the THIO-101 trials, testing THIO administration for immune activation followed by cemiplimab in NSCLC. 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 which is expected to be two years, 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 (CMC) under Good Manufacturing Practices (GMP) conditions to provide clinical supply for THIO-101 and other development needs.
- In the Second Quarter 2021, we completed a convertible note funding round in the amount of approximately $8 million.
- In the Third Quarter 2021 and Fourth Quarter 2021, we sold common shares of MAIA for total proceeds of approximately $6.2 million.
- In the First Quarter 2022, we completed the Crossover Round for total proceeds of approximately $2.4 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. Orphan Drug Designation 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 completed the Additional Round for total proceeds of approximately $99,999.
- 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 will conduct 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 net 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.

Impact of the COVID-19 Pandemic on Our Operations

On January 30, 2020, the World Health Organization ("WHO") announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (the "COVID-19 Outbreak") and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, the WHO classified the COVID-19 Outbreak as a pandemic, based on the rapid increase in exposure globally.

The full impact of the COVID-19 Outbreak continues to evolve as of the date of this report. As a result, we cannot estimate the full magnitude that the pandemic will have on our business. If the COVID-19 Outbreak continues, it may have a material adverse effect on our financial condition, liquidity, and future results of operations for the future. We are actively monitoring the impact of the global pandemic on our financial condition, liquidity, operations, industry, and workforce. Given the daily evolution of the COVID-19 Outbreak and the global responses to curb its spread, we are not able to estimate the effects of the COVID-19 Outbreak on our results of operations, financial condition, or liquidity for the future. One of our initial clinical studies is taking place in Australia, which initially imposed one of the strictest COVID-19-related measures, including lock-downs. While are not currently experiencing any delays or increased costs as a result of these measures, we may do so in the future.

Impact of the War in Ukraine on Our Operations

The short and long-term implications of Russia's invasion of Ukraine 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 Russia.

Financial Operations Overview and Analysis for the Three Months Ended September 30, 2022 and 2021

Comparison of the three months ended September 30, 2022 and 2021

	Three Months Ended September 30,		Change	
	2022 (As Restated)	2021	Dollars	Percentage
Operating expenses:				
Research and development expenses	$ 2,343,154	$ 1,081,705	$ 1,261,449	117%
General and administrative expenses	1,653,072	1,151,542	501,530	44%
Ratchet share expense	1,099,360	—	$ 1,099,360	100%
Total operating costs and expenses	5,095,586	2,233,247	2,862,339	128%
Loss from operations	(5,095,586)	(2,233,247)	(2,862,339)	128%
Other income (expense):				
Interest expense	(1,716)	(451,306)	449,590	(100)%
Interest income	348	708	(360)	(51)%
Australian research and development incentives	65,111	—	65,111	100%
Change in fair value of embedded features	—	(96,000)	96,000	(100)%
Change in fair value of warrant liability	128,030	(100,780)	228,810	(227)%
Loss on extinguishment of convertible notes and convertible notes, related parties	—	(2,322,943)	2,322,943	(100)%
Other income (expense), net	191,773	(2,970,321)	3,162,094	(106)%
Net loss	(4,903,813)	(5,203,568)	299,755	(6)%
Net loss attributable to noncontrolling interests	—	(7,130)	7,130	(100)%
Net loss attributable to MAIA Biotechnology, Inc. shareholders	$ (4,903,813)	$ (5,196,438)	$ 292,625	(6)%

Operating Expenses

Research and development expenses

Research and development expenses increased by approximately $1,261,000 or 117%, from approximately $1,082,000 for the three months ended September 30, 2021 to approximately $2,343,000 for the three months ended September 30, 2022. The increase was primarily related to the increase in clinical expenses related to the clinical preparation and startup of THIO 101 trial of approximately $667,000, an increase in payroll and bonus expenses of approximately $610,000 related to increased headcount of additional research and development employees, an increase of approximately $111,000 in professional fees and other expenses, offset by a decrease in stock-based compensation costs of approximately $127,000.

General and administrative expenses

General and administrative expenses increased by approximately $502,000, or 44% from approximately $1,152,000 for the three months ended September 30, 2021 to approximately $1,653,000 for the three months ended September 30, 2022. The increase was primarily related to an increase in payroll expense of approximately $228,000, an increase in other expenses of approximately $472,000 related to the costs of operating as a public company, offset by a decrease in stock-based compensation of approximately $119,000 and professional fees of approximately $79,000.

Ratchet Expense

Ratchet expense increased by approximately $1,099,000 or 100% for the three months ended September 30, 2022 due to the issuance of ratchet shares to certain investors.

Other expense, net

Other expense, net decreased by approximately $3,162,000 or 106% from other expense of approximately $2,970,000 for the three months ended September 30, 2021 to other expense of approximately $192,000 for the three months ended September 30, 2022. The change in other income (expense), net was primarily the result of the following expenses in the three months ended September 30, 2021: approximately $2,323,000 expense related to the loss on extinguishment of convertible notes, approximately $451,000 expense related to the interest for convertible notes, the change in the fair value of warrant liability expense of approximately $101,000 related to interest for convertible notes, approximately $96,000 of expense for the change in fair value of the bifurcated embedded feature, and by the increase of approximately $65,000 of income related to the Australian research and development incentives, and remeasurement of the warrant liability of $128,000, for the three months ended September 30, 2022. This was offset by approximately net $1,000 of interest for the three months ended September 30, 2022.

Comparison of nine months ended September 30, 2022 and 2021

	Nine Months Ended September 30,		Change	
	2022 (As Restated)	2021	Dollars	Percentage
Operating expenses:				
Research and development expenses	$ 6,539,948	$ 1,988,450	$ 4,551,498	229%
General and administrative expenses	4,341,880	2,798,766	1,543,114	55%
Ratchet share expense	1,099,360	—	$ 1,099,360	100%
Total operating costs and expenses	11,981,188	4,787,216	7,193,972	150%
Loss from operations	(11,981,188)	(4,787,216)	(7,193,972)	150%
Other income (expense):				
Interest expense	(1,820)	(827,539)	825,719	(100)%
Interest income	1,249	1,501	(252)	(17)%
Australian research and development incentives	230,188	—	230,188	100%
Change in fair value of embedded features	—	(203,000)	203,000	(100)%
Change in fair value of warrant liability	128,030	(1,546,280)	1,674,310	(108)%
Loss on extinguishment of convertible notes and convertible notes, related parties	—	(2,322,943)	2,322,943	(100)%
Other income (expense), net	357,647	(4,898,261)	5,255,908	(107)%
Net loss	(11,623,541)	(9,685,477)	(1,938,064)	20%
Net loss attributable to noncontrolling interests	—	(74,331)	74,331	(100)%
Deemed dividend on warrant modifications	(450,578)	—	(450,578)	100%
Net loss attributable to MAIA Biotechnology, Inc. shareholders	$ (12,074,119)	$ (9,611,146)	$ (2,462,973)	26%

Operating Expenses

Research and development expenses

Research and development expenses increased by approximately $4,551,000 or 229%, from approximately $1,988,000 for the nine months ended September 30, 2021 to approximately $6,540,000 for the nine months ended September 30, 2022. The increase was primarily related to an increase in clinical expenses of approximately $2,721,000 due to an increase in payments to clinical research organizations and payments to consultants primarily related to the THIO 101 trial start-up and pre-clinical activities, an increase in payroll related expenses and bonus expense of approximately $1,470,000 related to increased headcount of eight research and development employees during the nine months ended September 30, 2022, an increase of approximately $190,000 in professional fees, and an increase in other expenses of approximately $193,000, offset by a decrease in stock-based compensation of approximately $23,000.

General and administrative expenses

General and administrative expenses increased by approximately $1,543,000 or 55% from approximately $2,799,000 for the nine months ended September 30, 2021 to approximately $4,342,000 for the nine months ended September 30, 2022. 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 payroll, bonus expenses and benefits of approximately $583,000 related to an increase in headcount over the same period last year, an increase in professional fees for approximately $623,000, and an increase in other expenses of approximately $592,000, offset by a decrease in stock-based compensation expense of approximately $255,000 primarily due to the 2021 expense related to founders' stock-based compensation expense.

Ratchet Expense

Ratchet expense increased by approximately $1,099,000 or 100% for the nine months ended September 30, 2022 due to the issuance of ratchet shares to certain investors.

Other expense, net

Other income expense, decreased by approximately $5,255,000 or 107% from approximately $4,898,000 of other expenses for the nine months ended September 30, 2021 to approximately $358,000 of other expense for the nine months ended September 30, 2022. The change in other expense, net was primarily the result of approximately $2,323,000 expense related to loss of extinguishment of convertible notes, the approximately $1,546,000 of expense for the change in fair value of the warrant liability, the change in the fair value of bifurcated embedded feature of $203,000, and expense related to approximately $828,000 related to interest for convertible notes for the nine months ended September 30, 2021 . Other income increased by approximately $230,000 of income related to the Australian research and development incentives, increased by $128,000 for the remeasurement of the warrant liability and offset by approximately $1,000 of interest expense for nine months ended September 30, 2022 .

Liquidity and Capital Resources

As of September 30, 2022, our cash totaled approximately $14,064,000 which represented an increase of approximately $3,489,000 compared to December 31, 2021. As of September 30, 2022, we had working capital of approximately $12,324,000 which represents an increase of approximately $3,797,000 compared to December 31, 2021. We have generated no revenues and we expect to continue to incur operating losses for the foreseeable future and may never become profitable. We are dependent on our ability to continue to raise equity and/or debt financing to continue operations, until the attainment of profitable operations.

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.

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 additional public 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. We believe that we currently have sufficient funds to support funding of the THIO-101 lead-in and preliminary efficacy of the phase 2 THIO-101 through the next 12 months from the date of this filing. If the Company is unable to raise the necessary funding, management will undertake cost cutting measures to reduce compensation and reduce the scope of or delay its clinical programs. This could negatively impact the Company's business and could also lead to the reduction of the Company's operations.

Cash Flows

Cash Flows nine months ended September 30, 2022 and 2021

	Nine Months Ended September 30,	
	2022	**2021**
Net cash flows used in operating activities	$ (9,146,390)	$ (2,515,658)
Net cash flows provided by financing activities	12,670,074	12,804,705
Effect of foreign currency exchange rate changes on cash	(34,334)	—
Net increase in cash and cash equivalents	$ 3,489,350	$ 10,289,047

Operating Activities

For the nine months ended September 30, 2022, net cash used in operating activities was approximately $9,146,000, which consisted of a consolidated net loss of approximately $11,624,000 offset by non-cash charges of approximately $1, 831,000 in stock-based compensation., remeasurement of the warrant liability of approximately $128,000 and expense related to the issuance of ratchet shares of approximately $1,099,000. Total changes in operating assets and liabilities of approximately $325,000 were driven by an approximate $412,000 increase in prepaid expense and other assets, and an approximate $230,000 increase in the Australia research and development incentives receivable offset by an increase of approximately $317,000 in other accounts payable and accrued expenses.

For the nine months ended September 30, 2021, net cash used in operating activities was approximately $2,516,000, which consisted of a net loss of approximately $9,685,000 offset by non-cash charges of approximately $6,785,000 which primarily includes approximately $2,109,000 in stock-based compensation, $2,323,000 loss on extinguishment of convertible notes, $203,000 related to the change in fair value of embedded features, $597,000 amortization of debt discount on convertible notes, a changes in the fair value of the warrant liability of approximately $1,546,000, and approximately $7,000 loss on settlement of bonus. Total changes in operating assets and liabilities of approximately $385,000 were primarily driven by an approximate $345,000 increase in accrued expenses, an approximate increase of $342,000 in accounts payable and an approximate increase in accrued interest of $227,000 offset by and an approximate increase in prepaid expenses and other assets of $522,000 and an approximate decrease in amounts due to related parties of $7,000.

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

Financing Activities

Net cash provided by financing activities was approximately $12,670,000 and $12,805,000 for the nine months ended September 30, 2022 and 2021, respectively. Net cash provided by financing activities for the nine months ended September 30, 2022 consisted primarily of gross proceeds from the sale of common stock in the initial public offering of approximately $11,500,000, net proceeds from issuance of common stock of approximately of $2,474,000 in a crossover round, and proceeds from issuance of common stock upon exercise of warrants of

approximately $385,000 and stock options of approximately $66,000 offset by approximately $1,755,000 of the offering costs paid in the nine months ended September 30, 2022. Total Net cash provided by financing activities for nine months ended September 30, 2021 consisted of proceeds from issuance of convertible notes totaling approximately $7,369,000, proceeds for issuance of common stock net of transactions costs totaling approximately $5,366,000, collections of subscriptions receivable of approximately $2,000, proceeds from the paycheck protection program loan totaling approximately $63,000, and proceeds from exercise of stock options of approximately $5,000.

Critical Accounting Policies and Significant Judgments and Estimates

Management's discussion and analysis of our financial condition and results of our operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us 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, accruals for outsourced research and development activities, and the valuation allowance of deferred tax assets. 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.

We define our critical accounting policies as those accounting principles that require it to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. While our significant accounting policies are more fully described in Note 1 to our financial statements, we believe the following are the critical accounting policies used in the preparation of its financial statements that require significant estimates and judgments.

Fair value of common stock

For all periods prior to the initial public offering, there was no public market for our common stock. The Company sold shares of its common stock to third parties beginning in September 2018 through June 2019 at $1.80 per share. Subsequent to July 2019 the fair value of the shares of common stock underlying our stock-based awards was estimated by our board of directors based in part on valuations until we began selling shares of our common stock to third parties beginning on July 15, 2021 through October 15, 2021 at $8.00 per share and beginning on January 27, 2022 through February 27, 2022 at $9.00 per share. To determine the fair value of our common stock underlying annual option grants to officers and directors, our board of directors considered, among other things, input from management, valuations of our common stock valuation firms in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, and our board of directors' assessment of additional objective and subjective factors that it believed were relevant, and factors that may have changed from the date of the most recent valuation through the date of the grant.

These factors included, but were not limited to:

- our results of operations and financial position, including our levels of available capital resources;
- our stage of development and material risks related to our business;
- our business conditions and projections;
- the valuation of publicly traded companies in the life sciences industry sectors, as well as recently completed mergers and acquisitions of peer companies;
- the lack of marketability of our common stock as a private company;
- the likelihood of achieving a liquidity event for our security holders, such as an initial public offering or a sale of our company, given prevailing market conditions;
- the hiring of key personnel and the experience and expertise of management;
- trends and developments in our industry; and
- external market conditions affecting the life sciences industry sectors.

Our valuation as of February 28, 2021 indicated a fair value of our common stock of $1.83 per share. For grants of stock awards and stock option awards during the period February 28, 2021 through July 12, 2021, management set

the exercise prices for those awards based on the February 28, 2021 valuation until the Company initiated the sale of common stock at $8.00 per share which was first competed on July 18, 2021 and followed by additional sales through September 26, 2021. The Company set the exercise price of awards granted from July 18, 2021 through October 30, 2021 at $8.00 per share.

In evaluating the fair value of our common stock during the period March 2021 through May 2021, management evaluated events and their potential impact on the estimated fair value per share of the common stock. We considered events during this period which would have an effect on the fair value of our common stock such as milestones related to the clinical development and operations of our drug substances and advances in the production of drug substances and our drug product, however, there were no specific events that would indicate a definitive change in the value of the Company.

Given that there were no specific events that caused the change in fair value of our common stock from the indicated value of $1.83 as of February 28, 2021 to the $8.00 per share realized from the sale of common stock initiated in mid July, we performed a retrospective valuation of our common stock as of April 30, 2021. The retrospective valuation as of April 30, 2021 also indicated a fair value of our common stock of $1.83. In estimating the fair value of stock and stock option awards, we used an estimated fair value of $1.83 for awards granted from February 28, 2021 through May 31, 2021, based on the February 28, 2021 and April 30, 2021 valuations. From June 1, 2021 through October 30, 2021, we used an estimated of fair value of our common stock of $8.00 in valuing our stock and stock option awards. We believe the fair values based on the valuations materially represents the fair value of our common stock during the period February 28, 2021 through May 31, 2021 since no single intervening specific event indicated a definitive change in the value of the Company.

The February 28, 2021 and the April 30, 2021 valuations used the income approach and the market approach in estimating the fair value of our common stock. The market approach utilized guideline public companies in estimating fair value of our stock. The income approach estimates enterprise value based on the estimated present value of future cash flows the business is expected to generate over its remaining life. The estimated present value is calculated using a discount rate reflective of the risks associated with an investment in a similar company in a similar industry or having a similar history of revenue growth. The market approach measures the value of a business through an analysis of recent sales or offerings of comparable investments or assets, and in our case, focused on comparing us to a group of our peer companies. In applying this method, valuation multiples are derived from historical and projected operating data of the peer company group. We then apply the selected multiples to our operating data to arrive at a range of indicated enterprise values of the Company. We then subtracted the net debt to determine equity value.

During November 2021 and December 2021, the fair value of the Company’s common stock was determined to be $8.69 and $8.87, respectively. For our valuations of common stock performed November 2021 and December 2021, 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 value 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.

In the First Quarter of 2022, the Company made further progress in its clinical programs, which included the approval of THIO by the Bellberry Human Research Ethics Committee (HREC) in Australia to initiate the THIO-101 Phase 2 clinical study. Additionally, the Company completed its selection process for the clinical sites for its Phase 2 study in Australia and Europe and its application to start the Phase 2 study in Australia was approved. The Company also submitted a similar application in the second quarter of 2022, to conduct the same Phase 2 study in Europe.

The events above resulted in the Company being able to complete sales of its common stock to unrelated third-party investors beginning in January 27, 2022, through February 28, 2022, of 263,729 shares of common stock at a price of $9.00 per share resulting in aggregate proceeds of approximately $2.4 million. In May 2022, the Company

completed additional sales of its common stock at a price of $9.00 per share resulting in aggregate proceeds of approximately $0.1 million. Due to the lack of any single specific event that would have indicated a definitive change in the value of the Company, the fair value of the Company's common stock from January 27, 2022 through May 31, 2022, was determined based on sales of the Company's shares at arm's length to unrelated third parties at $9.00 per share. The fair value for common stock for June 2022 was determined based on the $5.00 per share for common stock initial public offering price.

Following the initial public offering, the fair value of our common stock, is based on the closing price of the common stock in the public market.

Stock-based compensation

Our stock-based awards are classified as equity (restricted stock awards, stock options, and warrants). We recognize related stock-based compensation expense based on the grant date fair value of the awards. The fair value of restricted stock awards is based on our common stock price. We estimate the fair value of stock options and warrants using the Black-Scholes-Merton valuation model which requires the use of subjective assumptions that could materially impact the estimation of fair value and related compensation expense to be recognized. One of these assumptions include the expected volatility of our stock price. Developing this assumption requires the use of judgment. The Company lacks company-specific historical and implied volatility information. Therefore, we estimate our expected stock volatility based on the historical volatility of a publicly traded set of peer companies. These estimates are highly subjective and now that the initial public offering is completed these estimates will no longer be necessary since the fair value will be based on the trading value of the Company's common stock.

Two of the assumptions used in the Black-Scholes-Merton valuation model are historical volatility and fair value of common stock, both of which are subject to uncertainty. Historical volatility is subject to uncertainty due to changes in the market over time. The fair value of our common stock is subject to uncertainty due to the possibility of changes in the results of our clinical trials, which could impact the fair value of our common stock. The total expense related to stock options is material to our financial statements on an annual basis, and significant fluctuations in the volatility assumption or the fair value of our common stock could result in material changes in related compensation expense to be recognized.

Prepaid and Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our prepaid and accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our prepaid and accrued research and development expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at the time. We confirm the accuracy of estimates with the service providers and make adjustments if necessary. Examples of estimated prepaid and accrued research and development expenses include expenses for:

- Clinical Research Organizations (CROs) in connection with clinical studies;
- Investigative sites in connection with clinical studies;
- Vendors in connection with preclinical development activities; and
- Vendors related to product manufacturing, development and distribution of clinical materials.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. The scope of services under these contracts can be modified and some of the agreements may be canceled by either party upon written notice. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical study milestones. In accruing service fees, we estimate 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 our estimate, we adjust the accrual or prepaid accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed we may report amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates and the amount actually incurred.

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.

Management's Evaluation of our 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, 2022, 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, 2022, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were not effective at the reasonable assurance level due to material weaknesses in internal control over financial reporting.

Material weaknesses were initially identified at December 31, 2021 as previously disclosed in our Form S-1, as amended, filed on July 21, 2022 and related to the effectiveness of controls over our review and approval procedures with respect to financial information generated to prepare our consolidated financial statements, coupled with a lack of segregation of duties. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be presented or detected on a timely basis.

Specifically, the Company did not maintain an effective control environment as there was an insufficient complement of personnel within the finance and accounting function with appropriate degree of knowledge, experience and training in the application of U.S. generally accepted accounting principles ("U.S. GAAP). In addition, the Company did not have an effective risk assessment process that defined clear financial reporting objectives and elevated risks, including fraud risks, at a sufficient level of detail to identify all relevant risks of material misstatement including the risks associated with the use of outsourced consultants in the preparation of schedules supporting balances within the consolidated financial statements. These factors contributed to the following additional material weaknesses.

We failed to design, implement and maintain effective controls regarding:

- the accounting for stock-based compensation and other stock-based financial instruments in accordance with U.S. GAAP. Specifically, we did not design and maintain controls to timely identify transactions requiring a valuation of our common stock and to review in sufficient detail, the valuation model assumptions used in determining the fair value of our common stock which is used as an input in accounting for stock-based compensation provided to employees and other stock-based financial instruments;
- the calculation of earnings per share in accordance with U.S. GAAP; and
- the reconciliation and review of significant account balances, authorization over cash disbursements, stock-based compensation calculations and related valuation models including inputs, period end financial reporting, risks associated with segregation of duties, and certain other entity level controls.

In addition, as of September 30, 2022, we failed to design implement and maintain effective controls regarding:

- the application of U.S. generally accepted accounting principles ("U.S. GAAP") to effectively evaluate the accounting treatment for complex financial instruments.

Changes in Internal Control over Financial Reporting

During the quarter ended September 30, 2022, there were no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, other than material weakness identified relating to the application of U.S. generally accepted accounting principles ("U.S. GAAP") to effectively evaluate the accounting treatment for complex financial instruments. In light of the material weakness discussed above, we are taking steps to remediate the material weakness including the hiring of additional accounting staff. The elements of our remediation plan can only be accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects.

Plan of Remediation

As we work towards remediating these material weaknesses, we will design and implement controls to properly identify transactions for which a valuation of our common stock is required and to review assumptions used in the valuation models to ensure our equity-based transactions are accounted for in accordance with U.S. generally accepted accounting principles. Additionally, we will design and implement controls to properly calculate basic and diluted weighted-average shares outstanding. Lastly, we will design, document, and consistently perform control activities in the identified areas which are currently lacking. To assist us in the remediation and performance of remediated controls we recently hired a Corporate Controller, and we will continue to utilize an accounting and financial reporting advisory firm with significant experience with publicly held companies to assist our management in evaluating transactions requiring the valuation of our common stock, in retaining and reviewing the work of valuation experts necessary to complete those valuations, and performing the calculation of basic and diluted weighted-average shares outstanding.

We may identify future material weaknesses in our internal controls over financial reporting or fail to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes-Oxley, and we may be unable to accurately report our financial results, or report them within the timeframes required by law or stock exchange regulations. We cannot assure that our existing material weakness will be remediated or that additional material weaknesses will not exist or otherwise be discovered, any of which could adversely affect our reputation, financial condition and results of operations.

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 the final prospectus for our initial public offering dated July 27, 2022 under the heading "*Risk Factors"* and filed with the SEC on July 29, 2022. 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, there have been no material changes to the risk factors disclosed in our final prospectus, other than as set forth below.

We identified material weaknesses in our internal control over financial reporting, and we may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If we fail to remediate any material weaknesses or if we otherwise fail to establish and maintain effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected.

Upon becoming a public company, we are required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which will require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our controls over financial reporting. Although are required to disclose changes made in our internal controls and procedures on a quarterly basis, we will not be required to make our first annual assessment of our internal controls over financial reporting pursuant to Section 404 until the later of (i) the year following our first annual report required to be filed with the SEC or (ii) the date we are no longer an emerging growth company. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting, as well as a statement that our independent registered public accounting firm has issued an opinion on the effectiveness of our internal control over financial reporting, provided that our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until our first annual report required to be filed with the Securities and Exchange Commission, or SEC, following the later of the date we are deemed to be an "accelerated filer" or a "large accelerated filer," each as defined in the Exchange Act, or the date we are no longer an emerging growth company, as defined in the JOBS Act. We could be an emerging growth company for up to five years.

We identified deficiencies in our internal control that we consider to be material weaknesses in our internal control over financial reporting which existed as of December 31, 2021. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis.

The Company did not maintain an effective control environment as there was an insufficient complement of personnel within the finance and accounting function with appropriate degree of knowledge, experience and training in the application of U.S. generally accepted accounting principles ("U.S. GAAP). In addition, the Company did not have an effective risk assessment process that defined clear financial reporting objectives and elevated risks, including fraud risks, at a sufficient level of detail to identify all relevant risks of material misstatement including the risks associated with the use of outsourced consultants in the preparation of schedules supporting balances

within the consolidated financial statements. These factors contributed to the following additional material weaknesses.
We failed to design, implement and maintain effective controls regarding:

1. the accounting for stock-based compensation and other stock-based financial instruments in accordance with U.S. GAAP. Specifically, we did not design and maintain controls to timely identify transactions requiring a valuation of our common stock and to review in sufficient detail, the valuation model assumptions used in determining the fair value of our common stock which is used as an input in accounting for stock-based compensation provided to employees and other stock-based financial instruments;
2. the calculation of earnings per share in accordance with U.S. GAAP; and
3. the reconciliation and review of significant account balances, authorization over cash disbursements, stock-based compensation calculations and related valuation models including inputs, period end financial reporting, risks associated with segregation of duties, and certain other entity level controls.

In addition, in connection with SEC pronouncements related to Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 480, Distinguishing Liabilities from Equity ("ASC 480"), we re-evaluated our accounting for the issuance of ratchet shares to certain private investors that purchased shares of our common stock prior to our initial public offering (the "IPO") and warrants issued to the underwriters in connection with its initial public offering (the "Underwriter Warrants"). As a result, we determined that the ratchet shares that were issued had improperly been treated as a deemed dividend instead of operating expense and the Underwriter Warrants were improperly classified as equity instead of a liability.

On February 3, 2023, the audit committee ("Audit Committee") of our board of directors concluded, after discussion with our management, that it was appropriate to restate our previously issued unaudited condensed consolidated balance sheet as of September 30, 2022, the unaudited condensed consolidated statements of operations, unaudited condensed consolidated statements of comprehensive loss and unaudited condensed consolidated statements of stockholders' equity for the three and nine months ended September 30, 2022, and the unaudited condensed consolidated statement of cash flows for the nine months ended September 30, 2022 included in our previously filed Quarterly Report on Form 10-Q with the Securities and Exchange Commission (the "Form 10-Q" and, the financial statements included in the Form 10-Q, the "Non-Reliance Financial Statements"). The Audit Committee concluded that the Non-Reliance Financial Statements should no longer be relied upon, and that we would amend the Form 10-Q to include restatements of the Non-Reliance Financial Statements. The changes do not impact our cash position.

Our management also concluded that in light of the errors described above, a material weakness exists in our internal control over financial reporting and that our disclosure controls and procedures were not effective.
As we work towards remediating these material weaknesses, we will design and implement controls to properly identify transactions for which a valuation of our common stock is required and to review assumptions used in the valuation models to ensure our equity-based transactions are accounted for in accordance with U.S. generally accepted accounting principles. Additionally, we will design and implement controls to properly calculate basic and diluted weighted-average shares outstanding. Lastly, we will design, document, and consistently perform control activities in the identified areas which are currently lacking. To assist us in the remediation and performance of remediated controls we recently hired a Corporate Controller, and we will continue to utilize an accounting and financial reporting advisory firm with significant experience with publicly held companies to assist our management in evaluating transactions requiring the valuation of our common stock, in retaining and reviewing the work of valuation experts necessary to complete those valuations, and performing the calculation of basic and diluted weighted-average shares outstanding.

We may identify future material weaknesses in our internal controls over financial reporting or fail to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes-Oxley, and we may be unable to accurately report our financial results, or report them within the timeframes required by law or stock exchange regulations. We cannot assure that our existing material weakness will be remediated or that additional material weaknesses will not exist or otherwise be discovered, any of which could adversely affect our reputation, financial condition and results of operations.

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

Recent sales of unregistered securities

None.

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.

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/A for the quarter ended September 30, 2022 (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.
4.1[(1)]	Form of Representative's Warrant (included in Exhibit 10.1).
10.1[(1)]	Underwriting Agreement by and between the Company and the Representative dated July 27, 2022.
10.2[(1)]	Form of Indemnification Agreement between the Company and each of its directors and executive officers.
10.3[(2)]	Employment Agreement, dated as of September 16, 2022, between the Company and Vlad Vitoc.
10.4[(2]	Employment Agreement, dated as of September 16, 2022, between the Company and Mihail Obrocea.
10.5[(2)]	Employment Agreement, dated as of September 16, 2022, between the Company and Sergei Gryaznov.
10.6[(2)]	Employment Agreement, dated as of September 16, 2022, between the Company and Joseph McGuire.
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 21, 2022.

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.

Company Name

Date: February 6, 2023

By: /s/ Vlad Vitoc

Vlad Vitoc
Chief Executive Officer

Date: February 6, 2023

By: /s/ Joseph McGuire

Joseph McGuire
Chief 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/A 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: February 6, 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/A 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: February 6, 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/A for the period ended September 30, 2022 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: February 6, 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/A for the period ended September 30, 2022 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: February 6, 2023

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