UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

OR

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

For the transition period from _____to _____

Commission File Number: 001-41210

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

Delaware	**84-2642541**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1200 Route 22 East, Suite 2000, Bridgewater, NJ	**08807**
(Address of principal executive offices)	(Zip Code)

(908) 955-3140
(Registrant's telephone number, including area code)

Not applicable
(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.0001 par value	THAR	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period 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, a 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 ☒

Number of common shares outstanding as of November 6, 2023 was 17,511,839.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Quarterly Report on Form 10-Q contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements may be identified by such forward-looking terminology as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. Our forward-looking statements are based on a series of expectations, assumptions, estimates and projections about our company, are not guarantees of future results or performance and involve substantial risks and uncertainty. We may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements. Our business and our forward-looking statements involve substantial known and unknown risks and uncertainties, including the risks and uncertainties inherent in our statements regarding:

- our projected financial position and estimated cash burn rate;
- our estimates regarding expenses, future revenues and capital requirements;
- our ability to continue as a going concern;
- our need to raise substantial additional capital to fund our operation;
- the success, cost and timing of our clinical trials;
- our dependence on third parties in the conduct of our clinical trials;
- our ability to obtain the necessary regulatory approvals to market and commercialize our product candidates;
- the impact of a health epidemic, on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole;
- the potential that results of pre-clinical and clinical trials indicate our current product candidates or any future product candidates we may seek to develop are unsafe or ineffective;
- the results of market research conducted by us or others;
- our ability to obtain and maintain intellectual property protection for our current and future product candidates;
- our ability to protect our intellectual property rights and the potential for us to incur substantial costs from lawsuits to enforce or protect our intellectual property rights;
- the possibility that a third party may claim we or our third-party licensors have infringed, misappropriated or otherwise violated their intellectual property rights and that we may incur substantial costs and be required to devote substantial time defending against claims against us;
- our reliance on third-party suppliers and manufacturers;
- the success of competing therapies and products that are or become available;
- our ability to expand our organization to accommodate potential growth and our ability to retain and attract key personnel;
- the potential for us to incur substantial costs resulting from product liability lawsuits against us and the potential for these product liability lawsuits to cause us to limit our commercialization of our product candidates;
- market acceptance of our product candidates, the size and growth of the potential markets for our current product candidates and any future product candidates we may seek to develop, and our ability to serve those markets; and
- the successful development of our commercialization capabilities, including sales and marketing capabilities.

All of our forward-looking statements are as of the date of this Quarterly Report on Form 10-Q only. In each case, actual results may differ materially from such forward-looking information. We can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of, or any material adverse change in, one or more of the risk factors or risks and uncertainties referred to in this Quarterly Report on Form 10-Q or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the U.S. Securities and Exchange Commission (the "SEC") could materially and adversely affect our business, prospects, financial condition and results of operations. Except as required by law, we do not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions, estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Quarterly Report on Form 10-Q, even if such results, changes or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by us following this Quarterly Report on Form 10-Q that modify or impact any of the forward-looking statements contained in this Quarterly Report on Form 10-Q will be deemed to modify or supersede such statements in this Quarterly Report on Form 10-Q.

This Quarterly Report on Form 10-Q may include market data and certain industry data and forecasts, which we may obtain from internal company surveys, market research, consultant surveys, publicly available information, reports of governmental agencies and industry publications, articles and surveys. Industry surveys, publications, consultant surveys and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable, but the accuracy and completeness of such information is not guaranteed. While we believe that such studies and publications are reliable, we have not independently verified market and industry data from third-party sources.

ITEM 1. FINANCIAL STATEMENTS

THARIMMUNE, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current assets		
Cash	$ 2,689,061	$ 6,510,534
Prepaid expenses and other current assets	412,890	178,094
Deferred offering costs	65,000	-
Total current assets	3,166,951	6,688,628
Total assets	$ 3,166,951	$ 6,688,628
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,138,695	$ 954,505
Accrued expenses	190,293	190,468
Insurance premium financing liability	81,040	-
Total current liabilities	1,410,028	1,144,973
Total liabilities	1,410,028	1,144,973
Commitments and contingencies (see Note 8)		
Stockholders' equity		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding as of September 30, 2023 and December 31, 2022	-	-
Common stock, $0.0001 par value, 250,000,000 shares authorized, 17,602,665 shares and 11,604,970 shares issued and 17,511,839 shares and 11,514,144 shares outstanding as of September 30, 2023 and December 31, 2022, respectively	1,760	1,160
Additional paid-in capital	24,054,877	20,996,892
Accumulated deficit	(22,229,749)	(15,384,432)
Treasury stock, at cost, 90,826 shares held in treasury as of September 30, 2023 and December 31, 2022	(69,965)	(69,965)
Total stockholders' equity	1,756,923	5,543,655
Total liabilities and stockholders' equity	$ 3,166,951	$ 6,688,628

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

THARIMMUNE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses				
Research and development	$ 488,177	$ 831,844	$ 2,566,910	$ 1,595,219
General and administrative	1,356,893	1,295,642	4,357,154	3,520,281

Total operating expenses	1,845,070	2,127,486	6,924,064	5,115,500
Loss from operations	(1,845,070)	(2,127,486)	(6,924,064)	(5,115,500)
Other income (expense)				
Interest expense	(3,496)	-	(16,151)	(1,591,244)
Interest income	28,451	-	94,898	-
Total other income (expense), net	24,955	-	78,747	(1,591,244)
Net loss	$ (1,820,115)	$ (2,127,486)	$ (6,845,317)	$ (6,706,744)
Net loss per share:				
Basic and diluted	$ (0.11)	$ (0.18)	$ (0.47)	$ (0.60)
Weighted average number of common shares outstanding:				
Basic and diluted	17,294,113	11,531,899	14,607,394	11,248,041

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

THARIMMUNE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2023 AND 2022
(UNAUDITED)

	Common Stock		Additional Paid-in	Accumulated	Treasury Stock		
	Shares	Amount	Capital	Deficit	Shares	Amount	Total
For the three months ended September 30, 2022:							
Balance, June 30, 2022	11,604,970	$ 1,160	$20,554,128	$(11,490,508)	30,000	$ (24,703)	$ 9,040,077
Net loss	-	-	-	(2,127,486)	-	-	(2,127,486)
Stock based compensation	-	-	240,762	-	-	-	240,762
Purchase of treasury stock at cost	-	-	-	-	45,109	(37,444)	(37,444)
Balance, September 30, 2022	11,604,970	$ 1,160	$20,794,890	$(13,617,994)	75,109	$ (62,147)	$ 7,115,909
For the nine months ended September 30, 2022:							
Balance, December 31, 2021	6,357,314	$ 636	$ 2,225,712	$ (6,911,250)	-	$ -	$ (4,684,902)
Net loss	-	-	-	(6,706,744)	-	-	(6,706,744)
Exercise of stock options	240,526	24	24,365	-	-	-	24,389
Stock based compensation	-	-	598,694	-	-	-	598,694
Stock issuance pursuant to services agreement	31,746	3	99,997	-	-	-	100,000
Initial public offering, net of issuance costs of $2,054,918	3,750,000	375	12,944,707	-	-	-	12,945,082
Conversion of related-party convertible notes	1,225,384	122	4,901,415	-	-	-	4,901,537
Purchase of treasury stock at cost	-	-	-	-	75,109	(62,147)	(62,147)
Balance, September 30, 2022	11,604,970	$ 1,160	$20,794,890	$(13,617,994)	75,109	$ (62,147)	$ 7,115,909
For the three months ended September 30, 2023:							
Balance, June 30, 2023	16,904,970	$ 1,690	$23,546,987	$(20,409,634)	90,826	$ (69,965)	$ 3,069,078
Stock issuance pursuant to service agreements	697,695	70	349,930	-	-	-	350,000
Net loss	-	-	-	(1,820,115)	-	-	(1,820,115)
Stock based compensation	-	-	157,960	-	-	-	157,960
Balance, September 30, 2023	17,602,665	$ 1,760	$24,054,877	$(22,229,749)	90,826	$ (69,965)	$ 1,756,923
For the nine months ended September 30, 2023:							
Balance, December 31, 2022	11,604,970	$ 1,160	$20,996,892	$(15,384,432)	90,826	$ (69,965)	$ 5,543,655

Public offering, net of issuance costs of $602,834	5,300,000	530	2,046,636	-	-	-	2,047,166
Stock issuance pursuant to service agreements	697,695	70	349,930	-	-	-	350,000
Net loss	-	-	-	(6,845,317)	-	-	(6,845,317)
Stock based compensation	-	-	661,419	-	-	-	661,419
Balance, September 30, 2023	17,602,665	$ 1,760	$24,054,877	$(22,229,749)	90,826	$ (69,965)	$ 1,756,923

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

THARIMMUNE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	For the Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (6,845,317)	$ (6,706,744)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of debt discount	-	1,569,003
Stock based compensation	661,419	598,694
Stock issuance pursuant to services agreement	250,000	100,000
Interest and original issuance discount on promissory notes	-	14,645
Increase in operating assets:		
Prepaid expenses and other current assets	(134,796)	(350,920)
Increase (decrease) in operating liabilities:		
Accounts payable	184,190	(558,837)
Accrued interest	-	7,237
Due to founder	-	(200,000)
Accrued expenses	(175)	(138,352)
Net cash used in operating activities	(5,884,679)	(5,665,274)
Net cash provided by (used in) investing activities	-	-
Cash flows from financing activities:		
Exercise of stock options	-	24,389
Purchase of treasury stock at cost	-	(62,147)
Proceeds from issuance of common stock upon initial public offering, net of underwriting discounts and issuance costs	-	13,645,643
Proceeds from issuance of common stock upon public offering, net of underwriting discounts and issuance costs	2,263,826	-
Payment of deferred offering costs	(281,660)	(521,294)
Proceeds from insurance premium financing liability	716,775	917,472
Repayment of insurance premium financing liability	(635,735)	(731,833)
Proceeds from promissory notes	-	125,000
Repayments on promissory notes	-	(139,645)
Net cash provided by financing activities	2,063,206	13,257,585
Net increase (decrease) in cash	(3,821,473)	7,592,311
Cash, beginning of period	6,510,534	4,356
Cash, end of period	$ 2,689,061	$ 7,596,667
Supplemental disclosure of non-cash financing activities:		
Issuance of common stock for:		
Prepaid marketing and investor related consulting services	$ 100,000	$ -
Research and development service licensing agreement Intangible license asset	$ 250,000	$ -
Conversion of related party convertible notes:		
Related party convertible notes principal converted to common stock upon initial public offering	$ -	$ 3,734,446
Related party convertible notes accrued interest converted to common stock upon initial public offering	$ -	$ 186,858
Redemption liability converted to common stock upon initial public offering	$ -	$ 980,233

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

THARIMMUNE, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

Note 1 – Description of Business and Liquidity

Nature of Operations

Tharimmune, Inc. (formerly, Hillstream BioPharma, Inc.) ("Tharimmune" or the "Company") was incorporated on March 28, 2017, as a Delaware C-corporation. At September 30, 2023, Tharimmune had one wholly-owned subsidiary, HB Pharma Corp. ("HB").

Tharimmune is a clinical-stage biotechnology company developing therapeutic candidates in rare, inflammatory and oncologic conditions with high unmet need. On November 3, 2023, the Company entered into a patent license agreement (the "Avior Patent License Agreement") with Avior Inc. d/b/a Avior Bio, LLC ("Avior") pursuant to which it received an exclusive sublicensable right and license to Licensed Patent Rights (as defined in the Avior Patent License Agreement) and Licensed Technology (as defined in the Avior Patent License Agreement) to, among other things, Develop (as defined in the Avior Patent License Agreement), have Developed, make, have made, use, sell, import, export and commercialize AV104 (to be renamed TH104 and hereinafter referred to as TH104) and AV103 (to be renamed TH103 and hereinafter referred to as TH103) and to practice the Licensed Technology in connection with the foregoing, throughout the world. In February 2023, the U.S. Food and Drug Administration ("FDA") approved an investigational new drug ("IND") application for TH104. TH104 has a dual mechanism of action by affecting multiple receptors, known to suppress chronic, debilitating pruritis or "uncontrollable itching". With respect to TH104, the Company intends to first seek approval for the treatment of moderate to severe chronic pruritis in patients with primary biliary cholangitis ("PBC"), an orphan rare form of liver disease with no known cure in which more than 70% of patients suffer from debilitating chronic pruritis, and with respect to TH103, it intends to develop the product candidate and potentially file an IND.

The Company is also developing an early-stage pipeline of novel therapeutic candidates targeting validated high value immuno-oncology ("IO") targets including human epidermal growth factor ("EGF") receptor 2 ("HER2"), human EGF receptor 3 ("HER3") and programmed cell death protein 1 ("PD-1"). The Company is developing antibodies including bispecific antibodies, antibody drug conjugates ("ADCs") and small molecular weight bovine-derived Picobodies™ or antibody "knob" domains which have the potential to target and bind more tightly to "undruggable" epitopes better than full sized antibodies. The Company is advancing TH3215, a bispecific against both HER2 and HER3 antibody which targets a novel "bridging epitope" encompassing multiple domains of the HER2 extracellular domain ("ECD") as well as ligand-dependent and independent blocking of the ECD of HER3 into IND-enabling studies in 2024. In addition, the Company anticipates that TH0059, a HER2/HER3 bispecific ADC ("bsADC"), and TH1940, a PD-1 Picobody, will progress to enter IND-enabling studies in 2024.

The Company has deprioritized its previous preclinical candidate, HSB-1216, due to a strategic reprioritization of its vision to focus on therapeutics in high unmet need cancers focused on novel epitopes of certain antitumor drug targets.

Name Change

On September 21, 2023, Hillstream BioPharma, Inc. filed a Certificate of Amendment (the "Amendment") to its Certificate of Incorporation, as amended (the "Certificate of Incorporation"), with the Secretary of State of the State of Delaware pursuant to which it changed its name to Tharimmune, Inc. effective as of September 25, 2023. The name change became effective with The Nasdaq Capital Market on September 25, 2023 and the Company's common stock has since traded on The Nasdaq Capital Market under the new name and new ticker symbol, "THAR."

Liquidity and Going Concern

The accompanying condensed consolidated financial statements have been prepared on the basis that the Company is a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. For the nine months ended September 30, 2023, the Company incurred operating losses in the amount of approximately $6.9 million, expended approximately $5.9 million in cash used in operating activities, and had an accumulated deficit of approximately $22.2 million as of September 30, 2023. The Company financed its working capital requirements through September 30, 2023 primarily through the issuance of common stock in its initial public offering ("IPO") on January 14, 2022. Net proceeds to the Company from the IPO were approximately $13.0 million. See Note 5 to the condensed consolidated financial statements for details regarding the IPO. Additionally, the Company closed a public offering (the "May Offering") of its common stock on May 2, 2023. Net proceeds to the Company from the offering were approximately $2.0 million. Also see Note 5 to the condensed consolidated financial statements for details regarding the May Offering. The shares of the Company's common stock began trading on The Nasdaq Capital Market on January 12, 2022 under the ticker symbol "HILS" and, effective as of September 25, 2023, are traded under the ticker symbol "THAR."

Based on the Company's limited operating history, recurring negative cash flows from operations, current plans and available resources, the Company will need substantial additional funding to support future operating activities. The Company has concluded that the prevailing conditions and ongoing liquidity risks faced raise substantial doubt about the Company's ability to continue as a going concern for at least one year following the date these condensed consolidated financial statements are issued. The accompanying condensed consolidated financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

The Company may seek to raise additional funding through the sale of additional equity or debt securities, enter into strategic partnerships, grants, or other arrangements or a combination of the foregoing to support its future operations, however, there can be no assurance that the Company will be able to obtain additional capital on terms acceptable to the Company, on a timely basis or at all. The failure to obtain sufficient additional funding could adversely affect the Company's ability to achieve its business objectives and product development timelines and may result in the Company delaying or terminating clinical trial activities which could have a material adverse effect on the Company's results of operations.

Other Risks and Uncertainties

There can be no assurance that the Company's products, if approved, will be accepted in the marketplace, nor can there be any assurance that any future products can be developed or manufactured at an acceptable cost and with appropriate performance characteristics, or that such products will be successfully marketed, if at all. The Company is subject to risks common to biopharmaceutical companies including, but not limited to, the development of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, product liability, uncertainty of market acceptance of products and the need to obtain additional financing. The Company is dependent on third party suppliers. The Company's products require approval or clearance from the FDA prior to commencing commercial sales in the United States. Approvals or clearances are also required in foreign jurisdictions in which the Company may license or sell its products. There can be no assurance that the Company's products will receive all of the required approvals or clearances.

Note 2 – Summary of Significant Accounting Policies

Basis of Presentation

These accompanying unaudited condensed consolidated interim financial statements have been prepared by the Company pursuant to the rules and

regulations of the Securities and Exchange Commission ("SEC") for interim financial reporting. These financial statements are unaudited and, in the opinion of management, include all adjustments (consisting of normal recurring adjustments and accruals) necessary for a fair statement of the balance sheet, operating results, and cash flows for the periods presented in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Operating results for the nine months ended September 30, 2023 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2023 or any other future period. Certain information and footnote disclosure normally included in the annual financial statements prepared in accordance with U.S. GAAP have been omitted in accordance with the SEC's rules and regulations for interim reporting. The Company's financial position, results of operations, and cash flows are presented in U.S. Dollars. These financial statements and related notes should be read in conjunction with the audited financial statements and related notes thereto for the year ended December 31, 2022 included in the Company's amended Annual Report on Form 10-K/A filed with the SEC on May 22, 2023. The Company operates in one segment.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of Tharimmune and its wholly-owned subsidiaries, HB and Farrington Therapeutics LLC. All significant intercompany balances and transactions have been eliminated in consolidation. On February 27, 2023, the Company filed a Certificate of Cancellation with the Delaware Secretary of State with respect to Farrington Therapeutics LLC.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Management bases its estimates on historical experience and on assumptions believed to be reasonable under the circumstances. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Estimates are used in the following areas, among others: research and development expense recognition, valuation of common shares and stock options, allowances of deferred tax assets, valuation of debt related instruments, and cash flow assumptions regarding going concern considerations. Although management believes the estimates that have been used are reasonable, actual results could vary from the estimates that were used.

Concentration of Credit Risk

The Company maintains cash balances with various financial institutions. Account balances at these institutions are insured by the Federal Deposit Insurance Corporation up to $250,000 per depositor. At various times during the year, bank account balances may have been in excess of federally insured limits. The Company has not experienced losses in such accounts. The Company believes that it is not subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. Cash equivalents, if any, are stated at cost and consist primarily of money market accounts.

Research and Development

Research and development costs are expensed as incurred. Research and development expenses include personnel costs associated with research and development activities, including third party contractors to perform research, conduct clinical trials, and manufacture drug supplies and materials. The Company accrues for costs incurred by external service providers, including contract research organizations and clinical investigators, based on its estimates of service performed and costs incurred. These estimates include the level of services performed by third parties, patient enrollment in clinical trials, administrative costs incurred by third parties, and other indicators of the services completed. Approximately $61,000 of prepaid expenses at December 31, 2022 relate to a manufacturing services agreement.

Stock Based Compensation

The Company recognizes compensation costs resulting from the issuance of stock-based awards to employees, non-employees, and directors as an expense in the condensed consolidated statements of operations over the requisite service period based on a measurement of fair value for each stock-based award. The fair value of each option grant to employees, non-employees and directors is estimated as of the date of grant using the Black-Scholes option-pricing model, net of actual forfeitures. The fair value is amortized as compensation cost on the straight-line basis over the requisite service period of the awards, which is generally the vesting period.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. Prior to January 12, 2022, the Company was a private company and the Company's common stock has only been publicly traded since that date. As a result, the Company has lacked company-specific historical and implied volatility information. Therefore, it has estimated its expected stock volatility based on the historical data regarding the volatility of a publicly traded set of peer companies. The expected term of stock options granted was between five and seven years. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award.

Common Stock Valuations

Prior to the IPO, the Company was required to periodically estimate the fair value of common stock with the assistance of an independent third-party valuation expert when issuing stock options and computing its estimated stock-based compensation expense and value of shares issued in acquiring product candidates. The assumptions underlying these valuations represented management's best estimates, which involved inherent uncertainties and the application of significant levels of management judgment. In order to determine the fair value, the Company considered, among other things, contemporaneous valuations of the Company's common stock; the Company's business, financial condition and results of operations, including related industry trends affecting its operations; the likelihood of achieving various liquidity events; the lack of marketability of the Company's common stock; the market performance of comparable publicly traded companies; and U.S. and global economic and capital market conditions. Since the closing of the Company's IPO on January 14, 2022, the fair value of common stock has been determined by using the closing price of the Company's common stock on The Nasdaq Capital Market.

Treasury Stock

The Company's board of directors authorized the repurchase of up to $ 1 million of shares of the Company's common stock, from time to time, until December 31, 2022, in the open market or through privately-negotiated transactions, at such times and at such prices as the Company's management may decide. Treasury stock purchases are accounted for under the cost method whereby the entire cost of the acquired common stock is recorded as treasury stock.

Debt Discount and Derivative Instruments

The initial fair value of the redemption feature relating to the convertible debt instruments was treated as a debt discount and was amortized over the term of the related debt using the straight-line method, which approximates the interest method. Amortization of debt discount was recorded as a component of interest expense. If a loan is paid in full, any unamortized debt discounts will be removed from the related accounts and charged to operations. As the convertible debt was converted into common stock at the date of the IPO, the unamortized debt discount was charged to interest expense.

The Company accounts for derivative instruments in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 815, *Derivative and Hedging*, which establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other financial instruments or contracts and requires recognition of all derivatives on the balance sheet at fair value. The Company's derivative financial instrument consisted of an embedded feature contained in the Company's convertible debt that was bifurcated and accounted for separately. See Note 3 to the condensed consolidated financial statements for further details.

Fair Value Measurements

The Company applies FASB ASC Topic 820, *Fair Value Measurement* ("ASC Topic 820"), which establishes a framework for measuring fair value and clarifies the definition of fair value within that framework. ASC Topic 820 defines fair value as an exit price, which is the price that would be received for an asset or paid to transfer a liability in the Company's principal or most advantageous market in an orderly transaction between market participants on the measurement date. The fair value hierarchy established in ASC Topic 820 generally requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Observable inputs reflect the assumptions that market participants would use in pricing the asset or liability and are developed based on market data obtained from sources independent of the reporting entity. Unobservable inputs reflect the entity's own assumptions based on market data and the entity's judgments about the assumptions that market participants would use in pricing the asset or liability and are to be developed based on the best information available in the circumstances.

The carrying value of the Company's cash, prepaid expenses, accounts payable, and accrued expenses approximate fair value because of the short-term maturity of these financial instruments. The redemption feature of the debt instruments is recorded at fair value. See Note 4 to the condensed consolidated financial statements for further details.

The valuation hierarchy is composed of three levels. The classification within the valuation hierarchy is based on the lowest level of input that is significant to the fair value measurement. The levels within the valuation hierarchy are described below:

Level 1 Inputs: Observable inputs such as quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2 Inputs: Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for assets or liabilities recently traded in active markets, with similar underlying terms, as well as direct or indirect observable inputs, such as interest rates and yield curves that are observable at commonly quoted intervals, as well as quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3 Inputs: Unobservable inputs, such as estimates, assumptions, and valuation techniques when little or no market data exists for the assets or liabilities, that reflect the reporting entity's own assumptions.

Deferred Offering Costs

Deferred offering costs prior to the IPO consisted of legal, accounting, printing, and filing fees that the Company capitalized which were offset against the proceeds from the IPO. Deferred offering costs prior to the additional public offering of the Company's common stock which closed on May 2, 2023 consisted of professional services incurred for filing of the Company's Registration Statement on Form S-3 using a "shelf" registration process for additional securities offerings. These deferred offering costs were offset against the proceeds from the public offering of the Company's common stock. See Note 5 to the condensed consolidated financial statements. Deferred offering costs of $65,000 at September 30, 2023 consist of professional services incurred for the filing of the Company's Registration Statement on Form S-1 for an additional public offering of securities. See Note 9 to the condensed consolidated financial statements.

Insurance Premium Financing Liability

Relating to the directors' and officers' insurance premium with an effective date of January 2022, the Company entered into an insurance premium financing agreement for $1,207,200, with a term of 10 months and an annual interest rate of 3.5%. The Company made a down payment of $ 289,728 and was required to make monthly principal and interest payments of $93,225 over the term of the agreement, which was repaid in full in November 2022.

Relating to the directors' and officers' insurance premium with an effective date of January 2023, the Company entered into an insurance premium financing agreement for $955,700, with a term of nine months and an annual interest rate of 5.25%. The Company made a down payment of $ 238,925 and is required to make monthly principal and interest payments of $81,394 over the term of the agreement, which comes due in October 2023. Related prepaid insurance at September 30, 2023 of $238,922 is included in prepaid expenses and other current assets on the accompanying condensed consolidated balance sheet.

Retirement Plan

The Company has a 401(k) defined contribution plan which covers all employees that meet the plan's eligibility requirements. Eligible employees may contribute a percentage of their salary subject to certain limitations. The Company makes a discretionary match which is currently up to 3% of employee contributions. Total Company contributions to the plan were $3,602 and $7,498 for the three and nine months ended September 30, 2023, respectively, and $3,694 and $7,835 for the three and nine months ended September 30, 2022, respectively.

Income Taxes

The Company accounts for income taxes using the asset-and-liability method in accordance with FASB ASC Topic 740, *Income Taxes* ("ASC Topic 740"). Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards.

Deferred income taxes are recognized for the tax effect of temporary differences between the financial statement carrying amount of assets and liabilities and the amounts used for income tax purposes and for certain changes in valuation allowances. Valuation allowances are recorded to reduce certain deferred tax assets when, in management's estimation, it is more-likely-than-not that a tax benefit will not be realized. A valuation allowance has been recognized for all periods since it is more-likely-than-not that some portion or all of the deferred tax assets will not be realized in future periods.

The Company follows the guidance in FASB ASC Subtopic 740-10 in assessing uncertain tax positions. The standard applies to all tax positions and clarifies the recognition of tax benefits in the financial statements by providing for a two-step approach of recognition and measurement. The first step involves assessing whether the tax position is more-likely-than-not to be sustained upon examination based upon its technical merits. The second step involves measurement of the amount to be recognized. Tax positions that meet the more-likely-than-not threshold are measured at the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate finalization with the taxing authority. The Company recognizes the impact of an uncertain income tax position in the financial statements if it believes that the position is more-likely-than-not to be sustained by the relevant taxing authority. The Company will recognize interest and penalties related to tax positions in income tax expense. At September 30, 2023 and December 31, 2022, the Company had no unrecognized uncertain income tax positions, and therefore no amounts have been recognized in the condensed consolidated financial statements.

Net Loss per Share

The Company reports loss per share in accordance with FASB ASC Subtopic 260-10, *Earnings Per Share*, which provides for calculation of basic and diluted earnings per share. Basic earnings per share includes no dilution and is computed by dividing net income or loss available to common stockholders by the weighted average common shares outstanding for the period. Diluted earnings per share reflect the potential dilution of securities that could share in the earnings of an entity. The calculation of diluted net earnings (loss) per share gives effect to common stock equivalents; however, potential common shares are excluded if their effect is anti-dilutive.

Potentially dilutive securities not included in the computation of loss per share for the three and nine months ended September 30, 2023 and 2022 included options to purchase 2,143,940 and 1,628,813 shares of common stock, respectively. Other potentially dilutive securities also not included in the computation of loss per share for the three and nine months ended September 30, 2023 and 2022 included warrants to purchase 187,500 shares of the Company's common stock related to the IPO and for the three and nine months ended September 30, 2023, an additional 159,000 shares of the Company's common stock related to the public offering which closed on May 2, 2023.

Reclassifications

Certain items have been reclassified on the September 30, 2022 condensed consolidated statement of cash flows for comparison purposes with the December 31, 2022 consolidated statement of cash flows, which is not presented herein, but should be referenced in conjunction with the condensed consolidated figures for September 30, 2022. Interest and the original issuance discount on promissory notes was added to the net cash used in operating activities and proceeds from promissory notes and repayments of promissory notes were added to net cash provided by (used in) financing activities.

Recently Adopted Accounting Pronouncements

The Company has evaluated all recent accounting pronouncements that were required to be adopted and believes that none of them will have a material effect on the Company's financial position, results of operations, or cash flows.

Recent Accounting Pronouncements Not Yet Adopted

Debt with Conversion and Other Options and Derivatives and Hedging

The FASB issued Accounting Standards Update ("ASU") 2020-06, *Debt - Debt with Conversion and Other Options* (Subtopic 470- 20) and *Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"), to reduce complexity in applying U.S. GAAP to certain financial instruments with characteristics of liabilities and equity. The guidance in ASU 2020-06 simplifies the accounting for convertible debt instruments and convertible preferred stock by removing the existing guidance that requires entities to account for beneficial conversion features and cash conversion features in equity, separately from the host convertible debt or preferred stock. The guidance in FASB ASC Subtopic 470-20 applies to convertible instruments for which the embedded conversion features are not required to be bifurcated from the host contract and accounted for as derivatives. In addition, the amendments revise the scope exception from derivative accounting in FASB ASC Subtopic 815-40 for freestanding financial instruments and embedded features that are both indexed to the issuer's own stock and classified in stockholders' equity, by removing certain criteria required for equity classification. These amendments are expected to result in more freestanding financial instruments qualifying for equity classification (and, therefore, not accounted for as derivatives), as well as fewer embedded features requiring separate accounting from the host contract. The amendments in ASU 2020-06 further revise the guidance in FASB ASC Topic 260, *Earnings Per Share*, to require entities to calculate diluted earnings per share ("EPS") for convertible instruments by using the if-converted method. In addition, entities must presume share settlement for purposes of calculating diluted EPS when an instrument may be settled in cash or shares. The amendments in ASU 2020-06 are effective for public entities that meet the definition of an SEC filer, excluding smaller reporting companies (as defined by the SEC) for fiscal years beginning after December 15, 2021. For all other entities, including the Company, the amendments are effective for fiscal years beginning after December 15, 2023. Early adoption is permitted. The Company is currently evaluating the impact this standard will have on its condensed consolidated financial statements.

Note 3 – Convertible Notes - Related Parties

Commencing in May 2017, the Company entered into Subordinated Convertible Promissory Note Agreements (the "Agreements") with certain lenders (together, the "Holders" or individually, the "Holder"), pursuant to which the Company issued Subordinated Convertible Promissory Notes (individually the "Note" or together, the "Notes") to the Holders, principally all to the Chief Executive Officer ("CEO") and founder of the Company, a member of the Company's board of directors and third parties that are family members of the founder and CEO. Interest on the unpaid principal balance accrued at a rate of 5% per annum, computed on the basis of the actual number of days elapsed and a year of 365 days. Unless earlier converted into shares of the Company's common stock or preferred stock (collectively, the "Equity Securities"), the principal and accrued interest was to be due and payable by the Company on demand by the Holders at any time after the earlier of (i) the Maturity Date (as defined in each Agreement) and (ii) the closing of the Next Equity Financing. "Next Equity Financing" means the next sale, or series of related sales, by the Company of its Equity Securities pursuant to which the Company received gross proceeds of not less than $5.0 million for Notes issued in 2017 and through November 2020 and $ 7.5 million for Notes issued after November 2020 (including the aggregate amount of debt securities converted into Equity Securities upon conversion or cancellation of the Notes). The Company's IPO qualified as a Next Equity Financing.

In general, the stated maturity date was two years from the date of issuance, except for the Notes issued in December 2020 and thereafter (in the aggregate principal amount of approximately $2.1 million) which had a stated maturity date of three years. For Notes issued in 2017 and through September 2018, the default interest rate of 20% was added to the Notes for the period after the stated maturity date.

The Notes were to automatically convert into the type of Equity Securities issued in the Next Equity Financing upon closing. The number of shares of such Equity Securities to be issued was equal to the quotient obtained by dividing the outstanding principal and unpaid accrued interest due on the Note

on the date of conversion by the lesser of (i) 80% of the price paid per share for Equity Securities by the investors in the Next Equity Financing, or (ii) an equity valuation of $25 million ($50 million for Notes issued after December 2020) . On January 14, 2022, all outstanding Notes and accrued interest were converted into an aggregate of 1,225,384 shares of the Company's common stock as the IPO qualified as a Next Equity Financing.

Certain embedded features contained in the Notes in the aggregate were embedded derivative instruments, which were recorded as a debt discount and derivative liability at the issuance date at their estimated fair value for all Notes of approximately $2.4 million. Amortization of debt discount for the Notes recorded as interest expense was approximately $1.6 million for the nine months ended September 30, 2022. This amount contains amortization charged to interest expense of approximately $34,000 up to the date of the IPO and the full amount of the unamortized debt discount of approximately $ 1.5 million charged to interest expense on the date of the IPO.

Accrued interest expense associated with the Notes at the date of the IPO was approximately $ 187,000 and was converted into common stock as the IPO qualified as a Next Equity Financing. Total interest expense, including accrued interest and amortization of the debt discount, amounted to approximately $1.6 million for the nine months ended September 30, 2022.

Note 4 – Redemption Liability

The fair value of the redemption liability is calculated under Level 3 of the fair value hierarchy, determined based upon a probability-weighted expected returns method ("PWERM"). This PWERM was determined to be the most appropriate method of estimating the value of possible redemption or conversion outcomes over time, since the Company had not entered into a priced equity round through December 31, 2021. The significant assumptions utilized in these calculations are the possible exit scenarios (either a conversion of the principal and accrued interest of the Notes in the event of a Next Equity Financing (see Note 3 to the condensed consolidated financial statements), a repayment of the Notes and accrued interest in the event of a corporate transaction (as defined in the Notes) or a repayment of the Notes and accrued interest at maturity), the pre-money valuation of the Company's common stock, the probabilities of such exit events occurring, and discounts/premiums available to the Holders at such measurement dates. The calculation of the redemption liability prior to the IPO was based upon the actual incremental value derived by the Holders at the IPO date. The balance of approximately $980,000 as of the date of the IPO was converted into common stock in connection with the related-party convertible debt to which it related.

Note 5 – Common Stock

Pursuant to an amendment to the Company's Certificate of Incorporation filed in April 2019, the Company increased the number of authorized shares of common stock to 250,000,000 shares. On September 16, 2021, the Company effectuated a reverse split of shares of its common stock at a ratio of 1-for-26.4 pursuant to an amendment to the Company's Certificate of Incorporation filed with the Delaware Secretary of State and approved by the Company's board of directors and stockholders. The par value of the Company's common stock was not adjusted as a result of the reverse split.

On January 14, 2022, the Company closed the IPO pursuant to which it issued 3,750,000 shares of its common stock at a public offering price of $ 4.00 per share. The gross proceeds to the Company from the IPO were $15.0 million, prior to deducting underwriting discounts of approximately $ 1.1 million and commissions and other offering expenses of approximately $1.0 million. Other offering expenses include deferred offering costs of approximately $547,000 that were capitalized and additional costs incurred prior to the date of the IPO. The net proceeds to the Company from the IPO were approximately $13.0 million. The Company granted the underwriters a 45-day option to purchase up to an additional 562,500 shares of common stock at the public offering price less discounts and commissions, to cover over-allotments; however, this option expired unexercised. Additionally, and as a result of the completion of the IPO, all of the Company's convertible debt and accrued interest was converted into an aggregate of 1,225,384 shares of the Company's common stock pursuant to the terms of the Notes. Outstanding principal of approximately $3.7 million, accrued interest of approximately $187,000, and a redemption liability of approximately $ 980,000 were converted to common stock as the IPO qualified as a Next Equity Financing. In addition, the Company issued warrants in connection with the IPO. See Note 6 to the condensed consolidated financial statements for a discussion of the warrants issued.

On February 16, 2022, the Company entered into an agreement for marketing and investor related consulting services. Pursuant to the agreement, compensation includes a monthly fee and an upfront issuance of shares of the Company's common stock. On the effective date of February 16, 2022, the Company issued 31,746 shares of its common stock with a per share value of $ 3.15 and a total value of $ 100,000 as compensation expense. The agreement automatically renews annually and upon renewal, a payment of $100,000 of shares of the Company's common stock is to be issued. On February 16, 2023, the agreement was renewed and on the effective date of August 22, 2023, an additional 70,028 shares of the Company's common stock were issued with a per share value of $1.428 (as calculated based on the trailing 10-day average closing value of the Company's common stock prior to the renewal date) and a total value of $100,000 as compensation expense. The amount is recorded as a prepaid expense upon issuance and expensed over the term of the agreement, which is 12 months. At September 30, 2023, $37,500 remains in prepaid expenses.

On June 9, 2022, the Company's Board of Directors authorized the repurchase of up to $ 1,000,000 shares of the Company's common stock until December 31, 2022. On June 10, 2022, the Company entered into a Repurchase Agreement (the "Repurchase Agreement") with a financial institution pursuant to which such financial institution was able to purchase shares of the Company's common stock upon the terms and conditions set forth in such agreement, including in accordance with the guidelines specified in Rules 10b5-1 and 10b-8 under the Securities Exchange Act of 1934, as amended. Shares of the Company's common stock were able to be repurchased in open market or through privately-negotiated transactions. Pursuant to the Repurchase Agreement, the financial institution was to cease purchasing shares of the Company's common stock upon the earlier of (i) the close of trading on December 31, 2022, (ii) the completion of repurchases up to the approved amount and (iii) the date upon which the Company gave notice of termination of the Repurchase Agreement to the financial institution. The Company determined the timing and amount of any repurchases based upon its evaluation of market conditions, applicable SEC guidelines and regulations, and other factors.

During the three and nine months ended September 30, 2022, the Company purchased 45,109 and 75,109 shares of its common stock, respectively, for a total purchase cost of approximately $37,000 and $62,000, respectively.

On March 17, 2023, the Company filed a Registration Statement on Form S-3 with the SEC using a "shelf" registration process pursuant to which, the Company may sell, from time to time in one or more offerings, shares of common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or as units comprised of a combination of one or more of the other securities in one or more offerings up to a total dollar amount of $75 million.

On May 2, 2023, the Company closed a public offering pursuant to which it issued 5,300,000 shares of its common stock at a public offering price of $0.50 per share. The gross proceeds to the Company from the public offering were approximately $ 2.7 million, prior to deducting underwriting discounts and commissions of approximately $186,000 and other offering expenses of approximately $ 417,000. Other offering expenses include deferred offering costs of approximately $217,000 that were capitalized and additional costs incurred prior to the date of the public offering. The net proceeds to the Company from the public offering were approximately $2.1 million. The Company granted the underwriters a 45-day option to purchase up to an additional 795,000 shares of common stock at the public offering price less discounts and commissions, to cover over-allotments; however, this option expired unexercised.

On June 27, 2023, pursuant to the research and development collaboration and license agreement with Applied Biomedical Science Institute ("ABSI") as discussed in Note 8 to the condensed consolidated financial statements, on the effective date of the agreement, the Company issued $250,000 of its common stock to ABSI. On the effective date of July 26, 2023, the Company issued 627,667 shares of its common stock with a per share value of $ 0.398 (as calculated based on the trailing 10-day average closing value of the Company's common stock prior to the agreement date) and a total value of $250,000 as compensation expense.

Note 6 – Stock Based Compensation

Incentive Plans and Options

Under the Company's 2017 Stock Incentive Plan (the "2017 Stock Incentive Plan") the Company may grant incentive stock options, non-statutory stock options, rights to purchase common stock, stock appreciation rights, restricted stock, performance shares, and performance units to employees, directors, and consultants of the Company and its affiliates. Up to 94,696 shares of the Company's common stock may be issued pursuant to the 2017 Stock Incentive Plan.

The Company has granted options to acquire 92,801 shares of common stock at $ 13.20 per share under the 2017 Stock Incentive Plan, and 1,895 shares remain available for issuance. At both September 30, 2023 and December 31, 2022, there were options outstanding to acquire 92,801 shares of common stock. As of both September 30, 2023 and December 31, 2022, all such options were fully vested, and the weighted average remaining contractual life for such options was approximately 4.4 and 5.2 years, respectively.

In July 2019, the Company authorized a new plan (the "2019 Stock Incentive Plan"). The Company initially reserved 284,090 shares of its common stock for issuance pursuant to the 2019 Stock Incentive Plan in the form of incentive stock options, non-statutory stock options, rights to purchase common stock, stock appreciation rights, restricted stock, performance shares, and performance units to employees, directors, and consultants of the Company and its affiliates. On August 30, 2019, the Company approved an increase in the number of shares authorized for issuance under the 2019 Stock Incentive Plan by 2,575,757 shares. In January 2021, the Company approved an increase in the number of shares reserved for issuance under the 2019 Stock Incentive Plan by 574,494 shares. On May 31, 2021, the Company approved an increase in the number of shares reserved for issuance under the 2019 Stock Incentive Plan by 467,171 shares. At both September 30, 2023 and December 31, 2022, a total of 3,901,512 shares were authorized for issuance under the 2019 Stock Incentive Plan.

The Company has granted options to acquire 3,901,512 and 3,386,385 shares of common stock under the 2019 Stock Incentive Plan, and 0 and 515,127 shares of common stock remain available for issuance under the 2019 Stock Incentive Plan at September 30, 2023 and December 31, 2022, respectively. There are stock options outstanding to acquire 2,051,139 and 1,536,012 shares of common stock with weighted average exercise prices of $ 2.95 and $3.80 and weighted average contractual terms of 8.1 years and 8.4 years at September 30, 2023 and December 31, 2022, respectively.

The following table summarizes stock-based activities under the 2017 Stock Incentive Plan and 2019 Stock Incentive Plans:

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Contractual Terms
Outstanding at December 31, 2022	1,628,813	$ 4.34	8.2 years
Granted	515,127	$ 0.39	
Outstanding at September 30, 2023	2,143,940	$ 3.39	7.9 years
Exercisable options at September 30, 2023	1,704,356	$ 3.23	7.8 years
Vested and expected to vest at September 30, 2023	2,143,940	$ 3.39	7.9 years

The fair value of stock option awards is estimated at the date of grant using the Black-Scholes option-pricing model. The estimated fair value of each stock option is then expensed over the requisite service period, which is generally the vesting period (ranging between immediate vesting and four years). The determination of fair value using the Black-Scholes model is affected by the Company's share price as well as assumptions regarding a number of complex and subjective variables, including expected price volatility, expected life, risk-free interest rate and forfeitures.

Stock options granted during the three and nine months ended September 30, 2023 and 2022 were valued using the Black-Scholes option-pricing model with the following weighted average assumptions:

	For the three months ended		For the nine months ended	
	September 30, 2023*	September 30, 2022	September 30, 2023	September 30, 2022
Expected volatility	N/A	104.0%	95.1%	94.5% - 104.0%
Risk-free interest rate	N/A	3.39%	3.99%	1.69% - 3.39%
Expected dividend yield	N/A	0%	0%	0%
Expected life of options in years	N/A	5.0	5.0	5.0 – 7.0
Estimated fair value of options granted	N/A	$ 0.78	$ 0.29	$0.78 - $3.20

* No stock options were granted during the three months ended September 30, 2023.

The weighted average grant date fair value of stock options granted during the three months ended September 30, 2022 was approximately $ 0.78. The weighted average grant date fair value of stock options granted during the nine months ended September 30, 2023 and 2022 was approximately $0.29 and $2.70, respectively. The weighted average fair value of stock options vested during the three and nine months ended September 30, 2023 was approximately $2.84 and $0.92, respectively, and during the three and nine months ended September 30, 2022 was approximately $ 1.60 and $1.10, respectively.

Included in the above table are stock options granted in 2019 to purchase 231,058 shares of the Company's common stock at an exercise price of $ 0.08 per share, which vested upon a specified performance condition. These stock options vested at the date of the Company's IPO, which was the specified performance condition.

Total stock based compensation expense included in the accompanying condensed consolidated statements of operations was as follows:

	For the three months ended		For the nine months ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Research and development	$ 82,066	$ 87,829	$ 325,675	$ 253,561
General and administrative	75,894	152,933	335,744	345,133
Total stock based compensation	$ 157,960	$ 240,762	$ 661,419	$ 598,694

At September 30, 2023, the total unrecognized compensation expense related to non-vested options was approximately $ 1.4 million and is expected to be recognized over the remaining weighted average service period of approximately 2.3 years.

Warrants

In connection with the IPO, the Company issued warrants to purchase such number of shares of the Company's common stock equal to 5% of the total shares of common stock issued in the IPO. The warrants are exercisable at $5.00 per share, were not exercisable within the first six months after issuance, and may, under certain circumstances, be exercised on a cashless basis. The exercise price of the warrants is subject to standard antidilutive provision adjustments for stock splits, stock combinations, or similar events affecting the Company's common stock. The Company has determined that these warrants should be classified as equity instruments since they do not require the Company to repurchase the underlying common stock and do not require the Company to issue a variable amount of common stock. In addition, these warrants are indexed to common stock and do not have any unusual antidilution rights.

In connection with the May 2, 2023 public offering as described in Note 5 to the condensed consolidated financial statements, the Company issued warrants to designees of the underwriter (the "Representative's Warrants") to purchase 159,000 shares of the Company's common stock (which is equal to 3% of the number of shares sold in the public offering) at an initial exercise price of $ 0.625 per share, subject to adjustment. The Representative's Warrants are exercisable at any time and from time to time, in whole or in part, during the four and one half year period commencing 180 days from the commencement of sales of the shares of common stock in the public offering.

Terms of the warrants outstanding at September 30, 2023 are as follows:

Issuance Date	Initial Exercise Date	Expiration Date	Exercise Price	Warrants Issued	Warrants Exercised	Warrants Outstanding
January 14, 2022	July 10, 2022	January 11, 2027	$ 5.00	187,500	-	187,500
May 2, 2023	November 2, 2023	May 2, 2028	$ 0.625	159,000	-	159,000

Note 7 – Related-party Transactions

As described in Note 3 to the condensed consolidated financial statements, the Company entered into the Notes with the Holders commencing in May 2017. The Holders of substantially all of the Notes were the Company's founder and CEO, a member of the Company's board of directors, and third parties that are family members of the founder and CEO. The Notes were converted into shares of the Company's common stock on January 14, 2022 in connection with the closing of the IPO.

On January 4, 2022 and January 6, 2022, the Company issued unsecured promissory notes in the aggregate principal amount of approximately $ 139,000 (including an original issuance discount of an aggregate of approximately $14,000) to three related-party investors. The notes were to accrue interest at a rate of 12% per annum and mature upon the earlier of (i) June 30, 2022 and (ii) the closing of a subsequent equity financing. "Subsequent equity financing" means the next sale (or series of related sales) by the Company of its equity securities following the date of the notes pursuant to which the Company receives gross proceeds of not less than $5.0 million. The notes were repaid in full on January 21, 2022 following the Company's IPO on January 14, 2022 as the IPO was considered a subsequent Equity Financing.

Note 8 – Commitments and Contingencies

Small Molecule Analogues

On December 30, 2019, the Company acquired a series of small molecule analogues pursuant to an Asset Purchase Agreement ("APA"). Pursuant to the APA, the Company is required to make a payment of $50,000 upon raising of at least $2.0 million in funding, and up to approximately $1.75 million based upon successfully meeting clinical and sales milestones. As of September 30, 2023 and December 31, 2022, such fund-raising requirement was not met and no payments were made pursuant to the APA. The Company included, in accounts payable at both September 30, 2023 and December 31, 2022, the $50,000 required initial payment. Milestone based payments, if any, will be expensed as incurred.

Research Collaboration and Product License Agreement with Minotaur Therapeutics, Inc. ("Minotaur") and Commercial License Agreement with Taurus Biosciences, LLC ("Taurus")

The Company has entered into a research collaboration and product license agreement with Minotaur (as amended, the "Minotaur Agreement") and a commercial license agreement with Taurus (the "Taurus Agreement") for use of certain technology, including OmniAb antibodies, to advance Picobodies against novel, unreachable, and undruggable epitopes in high-value validated targets starting with PD-1. The Minotaur Agreement and Taurus Agreement are for the development of proprietary targeted biologics, including TH 1940, against PD-1. It is anticipated that the Company will collaborate with Minotaur under the license from Taurus to discover, develop, and advance biotherapeutics against high-value validated IO targets starting with PD-1.

The Minotaur Agreement included an up-front payment of $ 150,000, which was paid in January 2023. In addition, the Company shall fund the discovery and characterization study performed by Minotaur as set forth in the Minotaur Agreement. Pursuant to the Minotaur Agreement, the Company shall pay Minotaur a milestone payment of $1,000,000 for each first Product (as defined in the Minotaur Agreement) directed against a target and first regulatory approval in the U.S. In addition, the Company shall pay a low single digit royalty on net sales until the later of (i) ten years after the First Commercial Sale (as defined in the Minotaur Agreement) of such Product in such country and (ii) the expiration of the last-to-expire Valid Claim (as defined in the Minotaur Agreement) of a Collaboration Patent (as defined in the Minotaur Agreement) or MINT Patent (as defined in the Minotaur Agreement) covering the manufacture, use, or sale of such Product. The Taurus Agreement contains single digit payments on net product sales and certain development milestone payments tied to the advancement through clinical trials and final regulatory approval.

Research and Development Collaboration and License Agreement with Applied Biomedical Science Institute

On July 5, 2023 (the "ABSI Effective Date"), the Company entered into a Research and Development Collaboration and License Agreement (the "ABSI Agreement") with ABSI pursuant to which ABSI granted the Company an exclusive royalty-bearing, sublicensable license to the ABSI Patents (as defined in the ABSI Agreement) and a non-exclusive, royalty-bearing, sublicensable license to the ABSI Know-How (as defined in the ABSI Agreement) to Exploit (as defined in the ABSI Agreement) the ABSI Products (as defined in the ABSI Agreement) for the treatment, diagnosis, prediction, detection or prevention of disease in humans and animals worldwide (the "Territory").

Pursuant to the ABSI Agreement, the parties shall form a committee to manage the preclinical, investigational new drug enabling studies and such other activities as shall lead to the initiation of a Phase 1 clinical trial of the ABSI Product. The parties will collaborate on a Target-by-Target basis to identify and evaluate ABSI Products directed against such Target (as defined below) with a view to identifying or generating suitable Products (as defined in the ABSI Agreement) for the Company to Exploit. "Target" means ErB2 (Her2) and ErbB3. Upon completion of the Discovery Timeline (as defined in the ABSI Agreement) for a Target, subject to the terms and conditions of ABSI Agreement, the Company shall exclusively own any ABSI Products against such Target. In the event the committee determines that the discovery activities are unsuccessful with respect to a Target, the Company may propose an additional target, which, upon approval by ABSI, shall replace a failed Target.

Pursuant to the ABSI Agreement: (i) the Company issued ABSI 627,667 shares of its common stock which is equal to $ 250,000 based on the ten day trailing volume weighted-average price of the Company's common stock prior to the date of issuance (see Note 5 to the condensed consolidated financial statements for details of the July 27, 2023 issuance of the Company's common stock to ABSI); (ii) in the event the Company closes a financing pursuant to which it receives more than $10 million in Net Proceeds (as defined in the ABSI Agreement), the Company shall pay ABSI a mid six digit amount; (iii) upon the achievement of certain milestones as set forth in the ABSI Agreement, the Company shall pay ABSI up to an aggregate of $ 8,250,000; (iv) after the second anniversary of the ABSI Effective Date, the Company shall pay ABSI a low five digit amount for the first year and a mid five digit amount thereafter during the Royalty Term (as defined in the ABSI Agreement); and (v) during the Royalty Term for each Product, the Company shall pay ABSI a quarterly royalty on the Net Sales (as defined in the ABSI Agreement) with royalties at percentages which range from the low to mid single digits, with high Net Sales being subject to lower royalty rates, subject to adjustment as set forth in the ABSI Agreement. In addition, in the event the Company transfers all or substantially all of its rights to a Product to a third party, the Company shall pay to ABSI the percentage of Net Proceeds attributable to the transfer of the Product. Specifically, the Company shall pay ABSI amounts at percentages which range from the mid single digit to low double digits depending on the Company Expenses (as defined in the ABSI Agreement), with higher Company Expenses being subject to lower rates.

On a Product by Product basis, upon the expiration of the last Royalty Term of such Product in the Territory, licenses granted to the Company with respect to such Product shall be deemed non-exclusive, fully paid, royalty-free, perpetual and irrevocable. The ABSI Agreement shall expire upon the expiration of the last Royalty Term of the last Product, unless such agreement is terminated earlier pursuant to its terms. The ABSI Agreement may also be terminated (i) by either the Company or ABSI for (A) a material breach of the ABSI Agreement or (B) bankruptcy, (ii) ABSI may terminate the ABSI Agreement upon the commencement of a Challenge Proceeding (as defined in the ABSI Agreement) or (iii) the Company may terminate the ABSI Agreement at any time upon 90 days prior written notice to ABSI. Upon termination or expiration of the ABSI Agreement other than as a result of a bankruptcy or Challenge Proceeding, all licenses granted to the Company pursuant to such agreement will terminate and all rights under such licenses shall revert to ABSI.

Employment Agreements

In January 2019, the Company entered into a three-year employment agreement with its CEO which provided a specified base salary and bonus. The employment agreement also provided the CEO with certain benefits while employed and if employment ceases. The Company accrued $200,000 in 2019 related to the CEO's base salary as per the employment agreement, which was paid in full on April 1, 2022. No bonus was approved by the board of directors of the Company for any period through September 30, 2023.

In January 2020, the Company amended the employment agreement pursuant to which, in lieu of a cash base salary, the CEO was to be compensated with stock options to purchase 7,575 shares of the Company's common stock per month (at an exercise price based upon the Company's most recent 409A valuation at the date of the grant) effective January 1, 2020 until the Company received a minimum of $3.0 million of gross proceeds from the sale of its securities, after which time, cash compensation, pursuant to the employment agreement, would be paid.

Effective January 1, 2021, the Company amended the employment agreement with its CEO to provide a revised base salary pre-funding (as defined in the employment agreement). In lieu of cash base salary, the CEO was to be compensated with stock options to purchase 18,939 shares of the Company's common stock per month at an exercise price of $7.82 per share effective January 1, 2021 until funding met or exceeded $ 5.0 million, after which time, cash compensation, pursuant to his employment agreement, would be paid. Under this agreement, the CEO was granted stock options to purchase 113,634 shares of the Company's common stock.

The amended employment agreement also provided for a future base salary for the CEO after the Company received funding greater than $ 5.0 million or completed an initial public offering or similar transaction as set forth in the employment agreement. In addition, if the CEO acted as the "finder" of an investor who purchased more than $5.0 million of the Company's equity, he would receive a grant of stock options to acquire 757,575 shares of common stock of the Company at an exercise price equal to the most recent fair value of the Company's common stock at the time of grant. On the date of the Company's IPO, the CEO was granted stock options to purchase 757,575 shares of the Company's common stock.

On June 1, 2021, the Company entered into an Amended and Restated Employment Agreement, as amended on September 24, 2021 (the "Amended and Restated Employment Agreement") with the Company's CEO. The term of the Amended and Restated Employment Agreement commenced upon the closing of the Company's IPO and continues for a period of five years and automatically renews for successive one-year periods at the end of each term unless either party provides written notice of their intent not to renew at least 60 days prior to the expiration of the then effective term. Pursuant to the Amended and Restated Employment Agreement, the CEO will receive an annual base salary of $485,000, which may be increased from time to time, and shall be eligible to receive an annual cash bonus equal to 55% of his then base salary based upon the achievement of Company and individual performance targets established by the Company's board of directors. In addition, in the first year in which the Company's market capitalization (as defined in the Amended and Restated Employment Agreement) equals or exceeds (i) $250 million, the CEO shall receive a cash payment of $150,000; (ii) $500 million, the CEO shall receive a cash payment of $350,000; and (iii) $1.0 billion, the CEO shall receive a cash payment of $750,000. Furthermore, following the date of the Company's IPO, the CEO was issued an option to purchase 757,575 shares of the Company's common stock at an exercise price of $4.00 per share, which options shall vest over a 48-month period commencing 12 months after the date of grant. This shall be in addition to any additional equity-based compensation awards the Company may grant the CEO from time to time.

On January 1, 2023, in lieu of half of his 2023 salary, the CEO was issued options to purchase up to 515,127 shares of the Company's common stock at an exercise price of $0.39 per share, which options vested immediately on the date of grant.

On July 6, 2023, the Company entered into an amended and restated employment agreement (the "CEO Employment Agreement") with the CEO. The

Employment Agreement has the same terms as the COO Employment Agreement (as defined below) except, the CEO shall (i) receive a base salary of $500,000 per year, which may be increased by the Board; and (ii) be eligible to receive an annual bonus equal to 60% of his then base salary based upon the achievement of Company and individual targets to be established by the Board, in its sole discretion. In addition, in the event the CEO's employment is terminated by the Company other than as a result of his death or Disability (as defined in the CEO Employment Agreement) and other than for Cause (as defined in the CEO Employment Agreement), or if the CEO terminates his employment for Good Reason (as defined in the CEO Employment Agreement), then, in addition to the Accrued Compensation, the Company shall continue to pay the CEO's base salary and provide health benefits for a period of 18 months following the termination date and all Restricted Shares and Stock Options that have not vested as of the date of termination shall be forfeited and outstanding unvested time-based equity awards shall be accelerated in accordance with the applicable vesting schedule as if the CEO had been in service for an additional 12 months as of the termination date.

In connection with the appointment of the Company's Chief Operating Officer, on July 11, 2023 (the "Effective Date"), the Company entered into an employment agreement (the "COO Employment Agreement") with the COO. The COO Employment Agreement shall continue for a period of five years and, thereafter, shall automatically renew for successive one year terms unless either party provides the other party with written notice of non-renewal at least 60 days prior to the last day of the then current term. Pursuant to the COO Employment Agreement, the COO shall: (i) receive a base salary of $400,000 per year, which may be increased by the Board; (ii) be eligible to receive an annual bonus equal to 50% of his then base salary based upon the achievement of Company and individual targets to be established by the Board, in its sole discretion; (iii) shall be eligible to receive equity-based compensation awards as determined by the Company; (iv) receive reimbursement of reasonable business expenses; and (v) receive such other benefits that the Company may make available to its senior executives from time to time along with vacation, sick and holiday pay in accordance with the Company's policies established and in effect from time to time.

Note 9 – Subsequent Events

Except as noted below, there were no material subsequent events that required recognition or additional disclosure in these condensed consolidated financial statements.

Avior Patent License Agreement

On November 3, 2023 (the "Avior Effective Date"), the Company entered into the Avior Patent License Agreement with Avior pursuant to which the Company received an exclusive sublicensable right and license to Licensed Patent Rights and Licensed Technology to, among other things, Develop, have Developed, make, have made, use, sell, import, export and commercialize TH104 and TH103 and to practice the Licensed Technology in connection with the foregoing, throughout the world. Pursuant to the Avior Patent License Agreement, the Company shall pay Avior a mid six digit up front license fee within ten days of the Avior Effective Date and an additional mid six digit license fee which shall be paid in four equal installments within ten days of the end of each fiscal quarter following the Avior Effective Date. In addition, the Company shall pay Avior a high single digit percentage of any upfront payments received by it as a result of the grant of any sublicenses with respect to TH104. The Company shall also pay Avior milestone payments in the aggregate amount of $24,250,000 upon the occurrence of various development milestones (the "Development Milestone Payments"). Furthermore, the Company shall pay Avior certain fees based upon sales milestones. The payments for such sales milestones range from the low seven digits to the low eight digits with higher sales being subject to higher fees. Finally, the Company shall pay Avior royalties based on net sales. Such royalties range from low single digit percentages to mid single digit percentages with higher sales being subject to lower percentages. The Avior Patent License Agreement shall expire upon the expiration of the final payment obligation due to Avior as set forth in such agreement. Upon the expiration of the Avior Patent License Agreement, the Company shall have a fully paid, irrevocable, freely transferable and sublicensable worldwide license to the Licensed Patent Rights and Licensed Technology to Develop, have Developed, make, have made, use, have used sell, offer for sale, have sold, import, have imported, export, have exported, commercialize or have commercialized any and all Licensed Products and to practice the Licensed Technology worldwide. Pursuant to the Avior Patent License Agreement, the Company may terminate the agreement at any time without cause, upon 30 days' prior written notice to Avior along with payment of the next unpaid Development Milestone Payment, if any. Furthermore, either the Company or Avior may terminate the Avior Patent License Agreement (i) on written notice to the other party if the other party materially breaches any provision of the Avior Patent License Agreement and fails to cure such breach within 30 days after the breaching party receives written notice thereof or (ii) on written notice in the event that either party (A) becomes insolvent or admits its inability to pay its debts generally as they become due; (B) becomes subject, voluntarily or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency law, which is not fully dismissed or vacated within 60 days; (C) is dissolved or liquidated or takes any corporate action for such purpose; (D) makes a general assignment for the benefit of creditors; or (E) has a receiver, trustee, custodian or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business. Upon termination of the Avior Patent License Agreement, the license granted pursuant to such agreement shall terminate and all rights in the Licensed Patent Rights and Licensed Products shall revert back to Avior.

2023 Omnibus Equity Incentive Plan

On August 17, 2023, the Board of Directors adopted the Tharimmune, Inc. 2023 Omnibus Equity Incentive Plan (the "2023 Plan"), which became effective upon approval by the stockholders on October 23, 2023. Under the Company's 2023 Plan, the Company may grant incentive stock options, non-statutory stock options, rights to purchase common stock, stock appreciation rights, restricted stock, performance shares, and performance units to employees, directors, and consultants of the Company and its affiliates. Up to 2,600,000 shares of the Company's common stock may initially be issued pursuant to the 2023 Plan.

Both of the 2017 Stock Incentive Plan and 2019 Stock Incentive Plan (together, the "Prior Plans") are currently maintained and the 2023 Plan is intended to succeed the Prior Plans with the intention that no further awards shall be issued under the Prior Plans. All outstanding awards under the Prior Plans will continue to be governed by the terms, conditions, and procedures set forth in the Prior Plans and any applicable award agreement.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited interim condensed consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included in our Annual Report on Form 10-K/A for the fiscal year ended December 31, 2022, as may be amended, supplemented or superseded from time to time by other reports we file with the SEC. All amounts in this report are in U.S. dollars, unless otherwise noted.

Throughout this Quarterly Report on Form 10-Q, references to "we," "our," "us," the "Company," or "Tharimmune," refer to Tharimmune, Inc. (formerly, Hillstream BioPharma, Inc.), individually, or as the context requires, collectively with its subsidiaries.

Overview

Tharimmune is a clinical-stage biotechnology company developing therapeutic candidates in rare, inflammatory and oncologic conditions with high unmet need. On November 3, 2023, we entered into a patent license agreement (the "Avior Patent License Agreement") with Avior Inc. d/b/a Avior Bio, LLC ("Avior") pursuant to which we received an exclusive sublicensable right and license to Licensed Patent Rights (as defined in the Avior Patent License Agreement) and Licensed Technology (as defined in the Avior Patent License Agreement) to, among other things, Develop (as defined in the Avior Patent License Agreement), have Developed, make, have made, use, sell, import, export and commercialize AV104 (to be renamed TH104 and hereinafter referred to as TH104) and AV103 (to be renamed TH103 and hereinafter referred to as TH103) and to practice the Licensed Technology in connection with the foregoing, throughout the world. See "Recent Developments" below for additional information. In February 2023, the U.S. Food and Drug Administration ("FDA") approved an investigational new drug ("IND") application for TH104. TH104 has a dual mechanism of action by affecting multiple receptors, known to suppress chronic, debilitating pruritis or "uncontrollable itching". With respect to TH104, we intend to first seek approval for the treatment of moderate to severe chronic pruritis in patients with primary biliary cholangitis ("PBC"), an orphan rare form of liver disease with no known cure in which more than 70% of patients suffer from debilitating chronic pruritis, and with respect to TH103, we intend to develop the product candidate and potentially file an IND.

We are also developing an early-stage pipeline of novel therapeutic candidates targeting validated high value immuno-oncology ("IO") targets including human epidermal growth factor ("EGF") receptor 2 ("HER2"), human EGF receptor 3 (" HER3") and programmed cell death protein 1 ("PD-1"). We are developing antibodies including bispecific antibodies, antibody drug conjugates ("ADCs") and small molecular weight bovine-derived Picobodies™ or antibody "knob" domains which have the potential to target and bind more tightly to "undruggable" epitopes better than full sized antibodies. We are advancing TH3215, a bispecific against both HER2 and HER3 antibody which targets a novel "bridging epitope" encompassing multiple domains of the HER2 extracellular domain ("ECD") as well as ligand-dependent and independent blocking of the ECD of HER3 into IND-enabling studies in 2024. In addition, we anticipate that TH0059, a HER2/HER3 bispecific ADC ("bsADC"), and TH1940, a PD-1 Picobody, will progress to enter IND-enabling studies in 2024.

We have deprioritized our previous preclinical candidate, HSB-1216, due to a strategic reprioritization of our vision to focus on therapeutics in high unmet need cancers focused on novel epitopes of certain antitumor drug targets.

Minotaur Research and Collaboration Agreement and Taurus License Agreement

On November 21, 2022, we entered into a research collaboration and product license agreement with Minotaur Therapeutics, Inc. ("Minotaur") and a commercial license agreement with Taurus Biosciences, LLC ("Taurus") for use of certain technology, including OmniAb antibodies, to advance Picobodies against novel, unreachable, and undruggable epitopes in high-value validated targets starting with PD-1. The research and collaboration agreement and product license agreement are for the development of proprietary targeted biologics including TH 1940, against PD-1. It is anticipated that we will collaborate with Minotaur under the license from Taurus to discover, develop and advance biotherapeutics against high-value validated IO targets starting with PD-1. We extended this agreement in July of 2023 with an additional target (HER3) and an oncology target.

Applied Biomedical Research Institute Research and Development Collaboration and License Agreement

On July 5, 2023 (the "ABSI Effective Date"), we entered into a Research and Development Collaboration and License Agreement (the "ABSI Agreement") with Applied Biomedical Science Institute ("ABSI") pursuant to which ABSI granted us an exclusive royalty-bearing, sublicensable license to the ABSI Patents (as defined in the ABSI Agreement) and a non-exclusive, royalty-bearing, sublicensable license to the ABSI Know-How (as defined in the ABSI Agreement) to Exploit (as defined in the ABSI Agreement) the ABSI Products (as defined in the ABSI Agreement) for the treatment, diagnosis, prediction, detection or prevention of disease in humans and animals worldwide (the "Territory"). Pursuant to the ABSI Agreement, the parties shall form a committee to manage the preclinical, investigational new drug enabling studies and such other activities as shall lead to the initiation of a Phase 1 clinical trial of the ABSI Product. The parties will collaborate on a Target-by-Target basis to identify and evaluate ABSI Products directed against such Target with a view to identifying or generating suitable Products (as defined in the ABSI Agreement) for our Company to Exploit. "Target" means ErB2 (Her2) and ErbB3. Upon completion of the Discovery Timeline (as defined in the ABSI Agreement) for a Target, subject to the terms and conditions of ABSI Agreement, we shall exclusively own any ABSI Products against such Target. In the event the committee determines that the discovery activities are unsuccessful with respect to a Target, we may propose an additional target, which, upon approval by ABSI, shall replace a failed Target.

As part of the ABSI Agreement, on the effective date of the agreement, we issued $250,000 of our common stock to ABSI. On the effective date of July 26, 2023, we issued 627,667 shares of our common stock with a per share value of $0.398 and a total value of $250,000 as compensation expense.

Recent Developments

On November 3, 2023 (the "Avior Effective Date"), we entered into the Avior Patent License Agreement with Avior pursuant to which we received an exclusive sublicensable right and license to Licensed Patent Rights and Licensed Technology to, among other things, Develop, have Developed, make, have made, use, sell, import, export and commercialize TH104 and TH103 and to practice the Licensed Technology in connection with the foregoing, throughout the world. Pursuant to the Avior Patent License Agreement, we shall pay Avior a mid six digit up front license fee within ten days of the Avior Effective Date and an additional mid six digit license fee which shall be paid in four equal installments within ten days of the end of each fiscal quarter following the Avior Effective Date. In addition, we shall pay Avior a high single digit percentage of any upfront payments received by us as a result of the grant of any sublicenses with respect to TH104. We shall also pay Avior milestone payments in the aggregate amount of $24,250,000 upon the occurrence of various development milestones (the "Development Milestone Payments"). Furthermore, we shall pay Avior certain fees based upon sales milestones. The payments for such sales milestones range from the low seven digits to the low eight digits with higher sales being subject to higher fees. Finally, we shall pay Avior royalties based on net sales. Such royalties range from low single digit percentages to mid single digit percentages with higher sales being subject to lower percentages. The Avior Patent License Agreement shall expire upon the expiration of the final payment obligation due to Avior as set forth in such agreement. Upon the expiration of the Avior Patent License Agreement, we shall have a fully paid-up, irrevocable, freely transferable and sublicensable worldwide license to the Licensed Patent Rights and Licensed Technology to Develop, have Developed, make, have made, use, have used sell, offer for sale, have sold, import, have imported, export, have exported, commercialize or have commercialized any and all Licensed Products and to practice the Licensed Technology worldwide. Pursuant to the Avior Patent License Agreement, we may terminate the agreement at any time without cause, upon 30 days' prior written notice to Avior along with payment of the next unpaid Development Milestone Payment, if any. Furthermore, either we or Avior may terminate the Avior Patent License Agreement (i) on written notice to the other party if the other party materially breaches any provision of the Avior Patent License Agreement and fails to cure such breach within 30 days after the breaching party receives written notice thereof or (ii) on written notice in the event that either party (A) becomes insolvent or admits its inability to pay its debts generally as they become due; (B) becomes subject, voluntarily or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency law, which is not fully dismissed or vacated within 60 days; (C) is dissolved or liquidated or takes any corporate action for such purpose; (D) makes a general assignment for the benefit of creditors; or (E) has a receiver, trustee, custodian or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business. Upon termination of the Avior Patent License Agreement, the license granted pursuant to such agreement shall terminate and all rights in the Licensed Patent Rights and Licensed Products shall revert back to Avior.

Components of Results of Operations

Revenue

We did not recognize revenues for the three and nine months ended September 30, 2023 and 2022.

Research and Development Expenses

Research and development expenses include personnel costs associated with research and development activities, including third-party contractors to perform research, conduct clinical trials, and manufacture drug supplies and materials as well as stock-based compensation. Research and development expenses are charged to operations as incurred.

We accrue costs incurred by external service providers, including contract research organizations and clinical investigators, based on estimates of service performed and costs incurred. These estimates include the level of services performed by third parties, patient enrollment in clinical trials, administrative costs incurred by third parties, and other indicators of the services completed. Based on the timing of amounts invoiced by service providers, we may also record payments made to those providers as prepaid expenses that will be recognized as expense in future periods as the related services are rendered.

We have incurred research and development expenses related to the development of HSB-1216, which has been deprioritized. We expect that our research and development expenses will increase as we plan for and commence our clinical trials of TH3215 and TH1940.

We cannot determine with certainty the duration and costs of future clinical trials of our product candidates, TH3215 and TH1940, or any other product candidates we may develop or if, when or to what extent we will generate revenue from the commercialization and sale of any of our product candidates for which we obtain marketing approval. We may never succeed in obtaining marketing approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our current and future product candidates will depend on a variety of factors, including:

- the scope, rate of progress, expense and results of clinical trials of our current product candidates, as well as of any future clinical trials of our future product candidates and other research and development activities that we may conduct;

- uncertainties in clinical trial design and patient enrollment rates;
- the actual probability of success for our product candidates, including their safety and efficacy, early clinical data, competition, manufacturing capability and commercial viability;
- significant and changing government regulations and regulatory guidance; and
- the timing and receipt of any marketing approvals.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to slower than expected patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation and consulting related expenses, including stock-based compensation. General and administrative expenses also include professional fees and other corporate expenses, including legal fees relating to corporate matters; professional fees for accounting, auditing, tax, and consulting services; insurance costs; travel expenses and other operating costs that are not specifically attributable to research activities.

We expect that our general and administrative expenses will increase in the future as we increase our personnel headcount to support our continued research activities and development of our product candidates. We also incur expenses associated with being a public company, including expenses related to compliance with the rules and regulations of the SEC and Nasdaq, director and officer insurance expenses, corporate governance expenses, investor relations activities and other administrative and professional services.

Interest Income

Interest income consists of interest income from funds held in our cash accounts.

Results of Operations

Three Months Ended September 30, 2023 Compared to the Three Months Ended September 30, 2022

	Three Months Ended September 30,		
	2023	**2022**	**Change**
Condensed Consolidated Statements of Operations Data:			
Operating expenses:			
Research and development	$ 488,177	$ 831,844	$ (343,667)
General and administrative	1,356,893	1,295,642	61,251
Total operating expenses	1,845,070	2,127,486	(282,416)
Other expense:			
Interest expense	(3,496)	-	(3,496)
Interest income	28,451	-	28,451
Total other income (expense)	24,955	-	24,955
Net loss	$ (1,820,115)	$ (2,127,486)	$ 307,371

Research and Development Expenses

Research and development expenses decreased by $343,667, or 41.3%, to $488,177 for the three months ended September 30, 2023 from $831,844 for the three months ended September 30, 2022. The decrease was the result of a decrease in expenses for pre-clinical activities of $198,484 and consulting expenses of $139,420 related to research and development team members as well as a decrease in stock based compensation expense of $5,763. The decrease for the three months ended September 30, 2023 was primarily the result of placing our now deprioritized product candidate, HSB-1216, on hold during the quarter.

General and Administrative Expenses

General and administrative expenses increased by $61,251, or 4.7%, to $1,356,893 for the three months ended September 30, 2023 from $1,295,642 for the three months ended September 30, 2022. The change in general and administrative expenses was primarily due to an increase of $176,572 in investor relations expenses and $108,011 in legal expenses. These increases were offset by a decrease of $248,132 in financial consulting expenses. The overall increase in general and administrative expenses during the three months ended September 30, 2023 was due to increased licensing agreements, increased investor relations costs, and increased salaries related to individuals that took a pay reduction in 2022.

Interest Expense

Interest expense increased by $3,496, or 100.0%, to $3,496 for the three months ended September 30, 2023 from $0 for the three months ended September 30, 2022. The increase in interest expense was primarily related to insurance premium financing liability.

Interest Income

Interest income increased by $28,451, or 100.0%, to $28,451 for the three months ended September 30, 2023 from $0 for the three months ended September 30, 2022. The increase in interest income was primarily from the funds held in our cash accounts.

Net Loss

Net loss decreased by $307,371, or 14.4%, to $1,820,115 for the three months ended September 30, 2023 from $2,127,486 for the three months ended September 30, 2022. The change in net loss was primarily related to the decrease in research and development expenses described above.

Nine Months Ended September 30, 2023 Compared to the Nine Months Ended September 30, 2022

	Nine Months Ended September 30,		
	2023	**2022**	**Change**
Condensed Consolidated Statements of Operations Data:			
Operating expenses:			
Research and development	$ 2,566,910	$ 1,595,219	$ 971,691
General and administrative	4,357,154	3,520,281	836,873
Total operating expenses	6,924,064	5,115,500	1,808,564
Other expense:			
Interest expense	(16,151)	(1,591,244)	1,575,093
Interest income	94,898	-	94,898
Total other income (expense)	78,747	(1,591,244)	1,669,991
Net loss	$ (6,845,317)	$ (6,706,744)	$ (138,573)

Research and Development Expenses

Research and development expenses increased by $971,691, or 60.9%, to $2,566,910 for the nine months ended September 30, 2023 from $1,595,219 for the nine months ended September 30, 2022. The increase was primarily the result of an increase in expenses for pre-clinical activities of $903,561 and stock based compensation expense of $72,114 related to research and development team members. The increase during the nine months ended September 30, 2023 was due to pre-clinical costs, which includes regulatory review of our now deprioritized product candidate, HSB-1216, associated subject studies, scale-up manufacturing costs, and costs under research and development collaboration agreements.

General and Administrative Expenses

General and administrative expenses increased by $836,873, or 23.8%, to $4,357,154 for the nine months ended September 30, 2023 from $3,520,281 for the nine months ended September 30, 2022. The increase in general and administrative expenses was primarily due to an increase of $958,988 in investor relations expenses, $191,960 in legal expenses, $87,920 in accounting expenses, and $80,226 in corporate taxes. These increases were offset by decreases of $193,201 in insurance expense, $87,660 in remuneration paid to our directors, and $204,450 in financial consulting expenses. The overall increase in general and administrative expenses during the nine months ended September 30, 2023 was due to increased licensing agreements, increased investor relations costs, and increased accounting fees.

Interest Expense

Interest expense decreased by $1,575,093, or 99.0%, to $16,151 for the nine months ended September 30, 2023 from $1,591,244 for the nine months ended September 30, 2022. The decrease in interest expense was primarily related to the unamortized debt discount charged to interest expense on the date of the closing of our IPO. See Note 3 to the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Interest Income

Interest income increased by $94,898, or 100.0%, to $94,898 for the nine months ended September 30, 2023 from $0 for the nine months ended September 30, 2022. The increase in interest income was primarily from the funds held in our cash accounts.

Net Loss

Net loss increased by $138,573, or 2.1%, to $6,845,317 for the nine months ended September 30, 2023 from $6,706,744 for the nine months ended September 30, 2022. The change in net loss was primarily related to the increases in research and development and general and administrative expenses as described above.

Liquidity and Capital Resources

The accompanying condensed consolidated financial statements have been prepared on the basis that we are a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. For the nine months ended September 30, 2023, we incurred operating losses in the amount of approximately $6.9 million, expended approximately $5.9 million in cash in operating activities, and had an accumulated deficit of approximately $22.2 million as of September 30, 2023. We financed our working capital requirements through September 30, 2023 primarily through the issuance of common stock in our IPO which closed on January 14, 2022. Net proceeds to us from the IPO were approximately $13.0 million. In addition, we closed a public offering of shares of our common stock on May 2, 2023. Net proceeds to us from such offering were approximately $2.1 million.

Based on our limited operating history, recurring negative cash flows from operations, current plans and available resources, we will need substantial additional funding to support future operating activities. We have concluded that the prevailing conditions and ongoing liquidity risks faced by us raise substantial doubt about our ability to continue as a going concern for at least one year following the date the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q are issued. The accompanying condensed consolidated financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern.

We may seek to raise additional funding through the sale of additional equity or debt securities, enter into strategic partnerships, grants or other arrangements or a combination of the foregoing to support our future operations; however, there can be no assurance that we will be able to obtain additional capital on terms acceptable to us, on a timely basis, or at all. The failure to obtain sufficient additional funding could adversely affect our ability to achieve our business objectives and product development timelines and may result in delaying or terminating clinical trial activities which could have a material adverse effect on our results of operations.

Cash Flow Activities for the Nine Months Ended September 30, 2023 and 2022

The following table sets forth a summary of our cash flows for the periods presented.

	Nine Months Ended September 30,	
	2023	2022
Net cash used in operating activities	$ (5,884,679)	$ (5,665,274)
Net cash provided by financing activities	2,063,206	13,257,585
Net increase (decrease) in cash	$ (3,821,473)	$ 7,592,311

Cash Flows from Operating Activities

Cash used in operating activities for the nine months ended September 30, 2023 was $5,884,679 which consisted of net loss of $6,845,317, partially offset by $911,419 in non-cash charges and other adjustments to reconcile net loss to net cash used in operating activities and a $49,219 in net increase in operating accounts. The non-cash charges consist of stock based compensation of $661,419 and $250,000 of stock issuance pursuant to a services agreement. The net increase in operating activities was primarily due to an increase of $134,796 in prepaid expenses and other current assets offset by an increase of $184,190 in accounts payable.

Cash used in operating activities for the nine months ended September 30, 2022 was $5,665,274 which consisted of net loss of $6,706,744, partially offset by $2,282,342 in non-cash charges and other adjustments to reconcile net loss to net cash used in operating activities and $1,240,872 in net decrease in operating accounts. The non-cash charges consist of amortization of debt discount of $1,569,003, stock issuance pursuant to services agreement of $100,000, stock based compensation of $598,694, and interest and original issuance discount on promissory notes of $14,645. The net decrease in operating activities was primarily due to a decrease of $558,837 in accounts payable, a decrease in due to founder of $200,000, a decrease in accrued expenses of $138,352, an increase of $350,920 in prepaid expenses and other current assets offset by an increase of $7,237 in accrued interest.

Cash Flows from Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2023 was $2,063,206. The net increase in financing activities was from net cash proceeds of $2,263,826 from the issuance of our common stock in connection with a public offering and $716,775 in proceeds received from insurance premium financing liability offset by deferred offering costs of $281,660 and $635,735 in repayments of insurance premium financing liability.

Cash provided by financing activities for the nine months ended September 30, 2022 was $13,257,585. The net increase in financing activities was from net cash proceeds of $13,645,643 from the issuance of our common stock in connection with our IPO, $917,472 in proceeds received from insurance premium financing liability, $125,000 from issuance of promissory notes, and $24,389 from exercise of stock options offset by deferred offering costs of $521,294, $731,833 in repayments of insurance premium financing liability, $139,645 repayments on promissory notes, and purchases of treasury stock at cost of $62,147.

Critical Accounting Policies and Use of Estimates

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Management bases its estimates on historical experience and on assumptions believed to be reasonable under the circumstances. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Estimates are used in the following areas, among others: research and development expense recognition, valuation of common shares and stock options, allowances of deferred tax assets, valuation of debt related instruments, and cash flow assumptions regarding going concern considerations. Although management believes the estimates that have been used are reasonable, actual results could vary from the estimates that were used.

Critical Accounting Policies

Research and development

Research and development costs are expensed as incurred. Research and development expenses include personnel costs associated with research and development activities, including third party contractors to perform research, conduct clinical trials and manufacture drug supplies and materials. We accrue for costs incurred by external service providers, including contract research organizations and clinical investigators, based on our estimates of

service performed and costs incurred. These estimates include the level of services performed by third parties, patient enrollment in clinical trials, administrative costs incurred by third parties, and other indicators of the services completed.

Stock based compensation

Stock based compensation represents the cost related to stock based awards granted to our employees, directors and consultants, and our affiliates. We measure stock based compensation costs at the grant date, based on the estimated fair value of the award and recognize the cost over the requisite service period.

We recognize compensation costs resulting from the issuance of stock based awards to employees, non-employees and directors as an expense in the condensed consolidated statements of operations over the requisite service period based on a measurement of fair value for each stock based award. The fair value of each option grant to employees, non-employees and directors is estimated as of the date of grant using the Black-Scholes option-pricing model, net of actual forfeitures. The fair value is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. Prior to January 12, 2022, we were a private company and our common stock has only been publicly traded since that date. As a result, we lacked company-specific historical and implied volatility information. Therefore, we have estimated our expected stock volatility based on the historical data regarding the volatility of a publicly traded set of peer companies. The expected term of stock options granted was between five and seven years. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award.

Recently Issued and Adopted Accounting Standards

See Note 2 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act (the "JOBS Act") was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We have chosen to take advantage of the extended transition periods available to emerging growth companies under the JOBS Act for complying with new or revised accounting standards until those standards would otherwise apply to private companies provided under the JOBS Act. As a result, our financial statements may not be comparable to those of companies that comply with public company effective dates for complying with new or revised accounting standards.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including, without limitation, (i) providing an auditor's attestation report on our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended, and (ii) complying with the requirement adopted by the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on financial statements. We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our IPO; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

The Company is not required to provide the information required by this Item as it is a "smaller reporting company," as defined in Rule 12b-2 of the Exchange Act.

ITEM 4. CONTROLS AND PROCEDURES.

Our principal executive officer and principal financial officer evaluated the effectiveness of our "disclosure controls and procedures" as of September 30, 2023, the end of the period covered by this Quarterly Report on Form 10-Q. The term "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. 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 under the Exchange Act is accumulated and communicated to a company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Based on the evaluation of our disclosure controls and procedures as of September 30, 2023, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were not effective. The material weaknesses that have been identified relate to (i) the design and implementation of appropriate segregation of duties to separate the roles of authorizing, initiating, and recording transactions or reviewing transactions for the completeness and accuracy of contracts with financial reporting implications and (ii) the Company lacking sufficient appropriate accounting and reporting knowledge to effectively perform review controls surrounding technical accounting matters. Effective internal control contemplates an appropriate level of review to ensure timely preparation and completeness and accuracy of the financial statements and disclosures.

Remediation Plans

We continue to work to strengthen internal control over financial reporting and management is committed to ensuring that such controls are designed and operating effectively. We are implementing processing and control improvements to address the above material weaknesses as follows:

- we have initiated a procedure to remediate the material weakness by reviewing the material contracts on a quarterly basis with the accounting department and supporting staff; and
- we will use third party experts to review the accounting treatment for significant transactions and provide management with guidance on the treatment of the transactions.

Changes in Internal Control

Except as set forth above, there were no changes in our internal control over financial reporting that occurred during the three months ended September

30, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

From time to time, we may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. Litigation is subject to inherent uncertainties and an adverse result in these or other matters may arise from time to time that may harm our business. We are currently not aware of any such legal proceedings or claims that will have, individually or in the aggregate, a material adverse effect on our business, financial condition or operating results.

ITEM 1A. RISK FACTORS.

Risk factors that affect our business and financial results are discussed in Part I, Item 1A "Risk Factors," in our Annual Report on Form 10-K/A for the year ended December 31, 2022 as filed with the SEC on May 22, 2023 ("Annual Report"), as supplemented by our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 as filed with the SEC on August 11, 2023 (the "Quarterly Report" and together with the Annual Report, the "Periodic Reports"). There have been no material changes in our risk factors from those previously disclosed in our Periodic Reports. You should carefully consider the risks described in our Periodic Reports, which could materially affect our business, financial condition or future results. The risks described in our Periodic Reports are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, and/or operating results. If any of the risks actually occur, our business, financial condition, and/or results of operations could be negatively affected.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

In July 2023, we issued 627,667 shares of our common stock pursuant to a license agreement.

In August 2023, we issued 70,028 shares of our common stock for services.

The foregoing issuances were exempt from registration under Section 4(a)(2) of the Securities Act.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

Exhibit No.	Description
3.1	Certificate of Amendment to Certificate of Incorporation dated September 21, 2023 (Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on September 25, 2023)
10.1#	Research and Development Collaboration and License Agreement by and between the Company and Applied Biomedical Science Institute dated July 5, 2023 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 11, 2023)
10.2+	Employment Agreement by and between the Company and Sireesh Appajosyula dated July 11, 2023 (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on July 11, 2023)
10.3+	Amended and Restated Employment Agreement by and between the Company and Randy Milby dated July 6, 2023 (Incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the SEC on July 11, 2023)
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
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 - the cover page from the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 is formatted in Inline XBRL included in the Exhibit 101 Inline XBRL Document Set

* Filed herewith.
** Furnished herewith.

Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit were omitted by means of marking such portions with an asterisk because such information is both not material and is the type that the Company treats as private or confidential.

+ Indicates a management contract or any compensatory plan, contract or arrangement.

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.

THARIMMUNE, INC.

Date: November 7, 2023

By: */s/ Randy Milby*
Randy Milby
Chief Executive Officer
(Principal Executive Officer)

Date: November 7, 2023

By: */s/ Thomas Hess*
Thomas Hess
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

Certification of Chief Executive Officer of Tharimmune, Inc.
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Randy Milby, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Tharimmune, 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: November 7, 2023

/s/ Randy Milby
Randy Milby
Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

Certification of Chief Financial Officer of Tharimmune, Inc.
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Thomas Hess, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Tharimmune, 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: November 7, 2023

/s/ Thomas Hess
Thomas Hess
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

Certification of Chief Executive Officer
Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned, Randy Milby, Chief Executive Officer of Tharimmune, Inc. (the "Company"), hereby certifies that based on the undersigned's knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2023 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 2023

/s/ Randy Milby
Randy Milby
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

Certification of Chief Financial Officer
Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned, Thomas Hess, Chief Financial Officer of Tharimmune, Inc. (the "Company"), hereby certifies that based on the undersigned's knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2023 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 2023

/s/ Thomas Hess
Thomas Hess
Chief Financial Officer
(Principal Financial and Accounting Officer)