

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: 001-41109



Intensity Therapeutics, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	46-1488089
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1 Enterprise Drive, Suite 430 Shelton, CT	06484-4779
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (203) 221-7381

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	INTS	The Nasdaq Stock Market

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

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

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

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

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

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

As of November 13, 2023, the registrant had 13,709,377 shares of common stock outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Financial Statements (Unaudited).

INTENSITY THERAPEUTICS, INC.
Condensed Balance Sheets

	September 30, 2023 (unaudited)	December 31, 2022 (audited)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 6,693,825	\$ 1,311,877
Marketable debt securities	8,955,316	-
Prepaid expenses	971,239	62,924
Other current assets	14,366	75,535
Total current assets	<u>16,634,746</u>	<u>1,450,336</u>
Right-of-use asset, net	152,605	139,089
Other assets	28,438	167,738
Total assets	<u>\$ 16,815,789</u>	<u>\$ 1,757,163</u>
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
Current liabilities:		
Accounts payable	\$ 358,404	\$ 603,176
Accrued expenses	355,006	1,723,400
Current lease liability	10,556	143,221
Convertible note and accrued interest	-	4,348,548
Total current liabilities	<u>723,966</u>	<u>6,818,345</u>
Long-term lease liability	144,891	-
Related party deposit	36,000	36,000
Total liabilities	<u>904,857</u>	<u>6,854,345</u>
Series A redeemable convertible preferred stock, par value \$.0001. Authorized, issued, and outstanding shares of none and 5,000,000 as of September 30, 2023 and December 31, 2022, respectively.	-	10,000,000
STOCKHOLDERS' EQUITY (DEFICIENCY)		
Authorized preferred stock is 15,000,000 shares as of September 30, 2023. None issued or outstanding as of September 30, 2023.		
Series B convertible preferred stock, par value \$.0001. Authorized, issued, and outstanding shares of none and 1,449,113 as of September 30, 2023 and December 31, 2022, respectively.	-	145
Series C convertible preferred stock, par value \$.0001. Authorized, issued, and outstanding shares of none and 1,800,606 as of September 30, 2023 and December 31, 2022, respectively.	-	180
Common stock, par value \$.0001. Authorized shares of 135,000,000 and 50,000,000 as of September 30, 2023 and December 31, 2022, respectively. Issued and outstanding shares of 13,709,377 and 3,410,103 as of September 30, 2023 and December 31, 2022, respectively.	1,371	341
Additional paid-in capital	63,252,862	23,555,160
Accumulated deficit	(47,343,301)	(38,653,008)
Total stockholders' equity (deficiency)	<u>15,910,932</u>	<u>(15,097,182)</u>
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficiency)	<u>\$ 16,815,789</u>	<u>\$ 1,757,163</u>

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

INTENSITY THERAPEUTICS, INC.
Condensed Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development costs	\$ 1,351,766	\$ 1,160,737	\$ 2,984,752	\$ 4,241,203
General and administrative costs	1,138,748	607,113	1,981,594	1,834,966
Total operating expenses	<u>2,490,514</u>	<u>1,767,850</u>	<u>4,966,346</u>	<u>6,076,169</u>
Loss from operations	(2,490,514)	(1,767,850)	(4,966,346)	(6,076,169)
Other income (expense):				
Interest income	147,539	988	148,026	1,844
Interest expense	-	(15,123)	(305,161)	(44,877)
Loss on debt extinguishment	-	-	(2,261,581)	-
Other	13,230	7,118	18,304	47,646
Net loss	<u>\$ (2,329,745)</u>	<u>\$ (1,774,867)</u>	<u>\$ (7,366,758)</u>	<u>\$ (6,071,556)</u>
Preferred stock deemed dividend	-	-	(1,323,535)	-
Net loss attributable to common stockholders	<u>\$ (2,329,745)</u>	<u>\$ (1,774,867)</u>	<u>\$ (8,690,293)</u>	<u>\$ (6,071,556)</u>
Loss per share, basic and diluted	\$ (0.17)	\$ (0.52)	\$ (1.26)	\$ (1.78)
Weighted average number of shares of common stock, basic and diluted.	13,660,627	3,410,103	6,899,984	3,410,103

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

Intensity Therapeutics Inc.
Condensed Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Equity
(Deficiency)
Nine Months and Three Months Ended September 30, 2023 and 2022
(unaudited)

	Series A Redeemable Convertible Preferred Stock		Series B Convertible Preferred		Series C Convertible Preferred		Common Stock		Additional Paid in Capital	Accumulated Deficit	Stockholders' Equity (Deficiency)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balances at December 31, 2022	5,000,000	\$ 10,000,000	1,449,113	\$ 145	1,800,606	\$ 180	3,410,103	\$ 341	\$23,555,160	\$ (38,653,008)	\$ (15,097,182)
Stock-based compensation expense									975,422		975,422
Warrants issued to convertible note holders									159,262		159,262
Warrants issued to underwriters in connection with public offering and overallotment									1,169,719		1,169,719
Issuance of common stock in public offering for cash, net of \$3,031,484 issuance costs							3,900,000	390	16,468,126		16,468,516
Issuance of common stock in overallotment for cash, net of \$371,583 issuance costs							585,000	59	2,553,358		2,553,417
Conversion of preferred stock into common stock	(5,000,000)	(10,000,000)	(1,449,113)	(145)	(1,800,606)	(180)	4,124,851	413	9,999,868		9,999,956
Conversion of convertible notes into common stock							1,399,716	140	6,998,440		6,998,580
Exercise of options and warrants							25,000	2	49,998		50,000
Deemed dividend							264,707	26	1,323,509	(1,323,535)	-
Net loss										(7,366,758)	(7,366,758)
Balances at September 30, 2023	-	\$ -	-	\$ -	-	\$ -	13,709,377	\$ 1,371	\$63,252,862	\$ (47,343,301)	\$ 15,910,932
Balances at June 30, 2023	-	\$ -	-	\$ -	-	\$ -	13,099,377	\$ 1,310	\$60,145,764	\$ (45,013,556)	\$ 15,133,518
Stock-based compensation expense									351,169		351,169
Warrants issued to underwriters in connection with public offering and overallotment									152,573		152,573
Issuance of common stock in connection with overallotment, net of \$371,583 issuance costs							585,000	59	2,553,358		2,553,417
Exercise of options and warrants							25,000	2	49,998		50,000
Net loss										(2,329,745)	(2,329,745)
Balances at September 30, 2023	-	\$ -	-	\$ 0	-	\$ 0	13,709,377	\$ 1,371	\$63,252,862	\$ (47,343,301)	\$ 15,910,932
Balances at December 31, 2021	5,000,000	10,000,000	1,449,113	\$ 145	1,800,606	\$ 180	3,410,103	\$ 341	\$22,386,341	\$ (31,071,111)	\$ (8,684,104)
Stock-based compensation expense									541,333		541,333
Net loss										(6,071,556)	(6,071,556)

Balances at September 30, 2022	5,000,000	\$ 10,000,000	1,449,113	\$ 145	1,800,606	\$ 180	3,410,103	\$ 341	\$22,927,674	\$ (37,142,667)	\$ (14,214,327)
Balances at June 30, 2022	5,000,000	10,000,000	1,449,113	145	1,800,606	180	3,410,103	341	\$22,886,963	\$ (35,367,800)	\$ (12,480,171)
Stock-based compensation expense									40,711		40,711
Net loss										(1,774,867)	(1,774,867)
Balances at September 30, 2022	5,000,000	\$ 10,000,000	1,449,113	\$ 145	1,800,606	\$ 180	3,410,103	\$ 341	\$22,927,674	\$ (37,142,667)	\$ (14,214,327)

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

INTENSITY THERAPEUTICS, INC.
Condensed Statements of Cash Flows
(Unaudited)

	Nine Months Ended	
	September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (7,366,758)	\$ (6,071,556)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of discount on convertible notes	159,262	-
Change in carrying value of right-of-use asset	141,108	133,605
Stock-based compensation expense	975,422	541,333
Loss on debt extinguishment	2,261,581	-
Changes in operating assets and liabilities, net:		
Accrued interest on marketable debt securities	(110,937)	-
Prepaid expenses	(908,315)	32,384
Other current assets	61,169	2,353
Other assets	139,300	-
Accounts payable	(244,772)	623,797
Accrued expenses	(1,368,394)	986,189
Accrued interest on convertible note	145,899	44,877
Change in lease liabilities	(142,398)	(135,645)
Net cash used in operating activities	<u>(6,257,833)</u>	<u>(3,842,663)</u>
Cash flows from investing activities:		
Purchase of marketable debt securities	(8,844,379)	-
Net cash used in investing activities	<u>(8,844,379)</u>	<u>-</u>
Cash flows from financing activities:		
Proceeds from issuance of convertible note	242,552	-
Payout of fractional shares on reverse split	(44)	-
Proceeds from Initial Public Offering	19,500,000	-
Proceeds from overallotment shares	2,925,000	-
Issuance costs related to initial public offering and overallotment	(2,233,348)	-
Proceeds from exercise of options and warrants	50,000	-
Net cash provided by financing activities	<u>20,484,160</u>	<u>-</u>
Net increase (decrease) in cash and cash equivalents	5,381,948	(3,842,663)
Cash and cash equivalents at beginning of period	1,311,877	4,539,229
Cash and cash equivalents at end of period	\$ 6,693,825	\$ 696,566
Supplemental disclosure of non-cash financing activities:		
Right-of-use lease asset and operating lease liability	\$ 154,624	-
Conversion of convertible notes and accrued interest into common stock	\$ 4,736,999	-
Warrants issued in relation to issuance of convertible notes	\$ 159,262	-
Warrants issued to underwriter in connection with stock issuance	\$ 1,169,719	-
Preferred stock deemed dividend	\$ 1,323,535	-

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

INTENSITY THERAPEUTICS, INC.
Notes to Unaudited Condensed
Financial Statements
September 30, 2023

Note A — Nature of Business

Intensity Therapeutics, Inc. (“the Company”) is Connecticut-based and incorporated in Delaware in December 2012. The Company is a biotechnology company whose treatment approach addresses both the regional and systemic nature of a patient’s cancer. The Company’s DfuseRxSM technology platform has identified a lead drug, INT230-6.

As a result of its initial public offering (“IPO”) that priced on June 29, 2023, the Company began trading on the Nasdaq Capital Market under the symbol “INTS” on June 30, 2023. The IPO closed on July 5, 2023, at which time the Company issued 3,900,000 shares of our common stock and received gross proceeds of \$19,500,000 less some of the issuance costs for a cash transfer of \$17,765,000. There were additional issuance costs on the IPO of approximately \$264,000. The IPO shares were issued on July 5, 2023, the closing date, at the time that the net proceeds were transferred to the Company. On July 7, 2023, the Company sold the full overallocation shares of the IPO. The overallocation resulted in the issuance of 585,000 shares of our common stock, and the Company received \$2,691,000 in net cash proceeds. The Company has begun to use and will continue to use the net proceeds from the IPO and overallocation to complete pre-clinical and clinical studies, conduct manufacturing suitable for phase 3 studies, submit regulatory filings to the United States Food & Drug Administration (“FDA”) and for general and corporate purposes.

On April 27, 2023, the Company effected a two-for-one reverse stock split (the “Reverse Stock Split”). All owners of record as of April 27, 2023 received one issued and outstanding share of the Company’s common stock in exchange for two outstanding shares of the Company’s common stock. All fractional shares created by the two-for-one exchange were paid in cash. The conversion price of Series A redeemable convertible preferred stock, Series B convertible preferred stock, and Series C convertible preferred stock were adjusted to reflect the Reverse Stock Split by doubling the original conversion price. The Reverse Stock Split has no impact on the par value per share of the Company’s common stock, Series A redeemable convertible preferred stock, Series B convertible preferred stock, and Series C convertible preferred stock, all of which remain at \$.0001. All holders of options and warrants had the exercise price doubled and the number of shares issuable upon exercise reduced by half. All current and prior period amounts related to shares, share prices and loss per share, presented in the Company’s financial statements and the accompanying notes have been restated for the Reverse Stock Split. All preferred stock and convertible notes that were issued during the pre-IPO period were converted into common stock.

Note B — Liquidity and Plan of Operation

The accompanying unaudited condensed financial statements have been prepared in conformity with generally accepted accounting principles, which contemplate the continuation of the Company as a going concern.

The Company is a research and development company and has not generated any revenue from its product candidates. The Company, therefore, has experienced net losses and negative cash flows from operations each year since its inception. Through September 30, 2023, the Company has an accumulated deficit of approximately \$47.3 million. The Company’s operations have been financed primarily through the sale of equity securities and convertible notes. The Company’s net loss for the nine months ended September 30, 2023 was approximately \$7.4 million.

To date, the Company has not obtained regulatory approval for any of its product candidates. The Company expects to incur significant expenses to complete development of its product candidates. The Company may never be able to obtain regulatory approval for the marketing of any of its product candidates in the United States or internationally and there can be no assurance that the Company will generate revenues or ever achieve profitability. The Company does not expect to receive significant product revenue in the near term. The Company, therefore, expects to continue to incur substantial losses for the foreseeable future.

INTENSITY THERAPEUTICS, INC.
Notes to Unaudited Condensed
Financial Statements
September 30, 2023

Note B — Liquidity and Plan of Operation (continued)

Cash and cash equivalents at September 30, 2023 totaled approximately \$6.7 million. The Company's investment in marketable debt securities totaled approximately \$9.0 million at September 30, 2023. These two accounts total approximately \$15.7 million. Until such time, if ever, as the Company can generate substantial product revenue, the Company expects to finance its operational needs through a combination of equity offerings and convertible debt financings. The Company does not have any committed external source of funds. To the extent that the Company can raise additional capital through the sale of equity or convertible debt securities, the ownership interest of the Company stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of the common stockholders. If the Company is unable to raise additional funds through equity or debt financings when needed, the Company may be required to delay, limit, reduce or terminate its research and product development.

Based on the cash, cash equivalents, and investment in marketable debt securities as of September 30, 2023, the Company expects its cash and cash equivalents to be sufficient to fund operations for a period of at least 12 months from the date that these financial statements are issued.

Note C — Summary of Significant Accounting Policies and Accounts

[1] Basis of presentation:

The accompanying condensed financial statements include the accounts of Intensity Therapeutics, Inc. These condensed financial statements have been prepared in accordance with the instructions to Form 10-Q and therefore do not include all information and footnotes necessary for a fair presentation of financial position, results of operations and cash flows in conformity with generally accepted accounting principles in the United States of America ("GAAP"); however, such information reflects all adjustments consisting solely of normal recurring adjustments, which are, in the opinion of management, necessary for a fair presentation of the results for the interim periods.

The condensed financial statements should be read in conjunction with the audited financial statements and notes included in the Company's prospectus, dated June 29, 2023 and filed with the Securities and Exchange Commission on June 30, 2023.

[2] Use of estimates:

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Certain accounting principles require subjective and complex judgments to be used in the preparation of financial statements. Accordingly, a different financial presentation could result depending on the judgments, estimates, or assumptions that are used.

The Company utilizes significant estimates and assumptions in valuing its stock-based awards. An additional significant estimate is that these financial statements are based on the assumption of the Company continuing as a going concern. See Note B with regard to the Company's ability to continue as a going concern.

INTENSITY THERAPEUTICS, INC.
Notes to Unaudited Condensed
Financial Statements
September 30, 2023

Note C — Summary of Significant Accounting Policies and Accounts (continued)

[3] Concentration of credit risk:

The Company's financial instruments that are exposed to concentrations of credit risk consist entirely of cash and investments in U.S. Treasury bills. These financial instruments are held at two U.S. financial institutions. The cash accounts are insured by the Federal Deposit Insurance Corporation ("FDIC") up to regulatory limits. During the nine months ended September 30, 2023 and 2022, the Company's cash balances exceeded the FDIC insurance limit. The investments in U.S. Treasury bills are not FDIC insured but are backed by the U.S. government. U.S. Treasury bills are subject to market risk if they are sold prior to maturity. The Company has not experienced any losses in such accounts. Although the Company believes that the financial institutions with whom the Company does business will be able to fulfill their commitments to the Company, there is no assurance that those institutions will be able to continue to do so beyond amounts guaranteed by the FDIC.

[4] Cash and cash equivalents:

The Company considers all liquid investments with an original maturity of three months or less to be cash equivalents.

[5] Marketable debt securities:

Investments in U.S. Treasury bills purchased with an original maturity over three months are classified separately from cash and cash equivalents in current assets. Investments in U.S. Treasury bills are classified as available for sale. Under the classification of available for sale, securities are reported at fair value. Unrealized gains or losses would be included in accumulated other comprehensive income within the equity section of the Balance Sheet. At September 30, 2023, there were no unrealized gains or losses and all accrued interest was recognized as Interest income in the Statement of Operations.

[6] Fair value measurement:

The Company reports its investments at fair value. Fair value is an estimate of the exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants (i.e., the exit price at the measurement date). Fair value measurements are not adjusted for transaction costs. A fair value hierarchy provides for prioritizing inputs to valuation techniques used to measure fair value into three levels:

Level 1 Unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 Inputs other than quoted market prices that are observable, either directly or indirectly, and reasonably available. Observable inputs reflect the assumptions market participants would use in pricing the asset or liability and are developed based on market data obtained from sources independent of the Company.

Level 3 Unobservable inputs. Unobservable inputs reflect the assumptions that the Company develops based on available information about what market participants would use in valuing the asset or liability.

An asset's or liability's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. Availability of observable inputs can vary and is affected by a variety of factors. The Company uses judgment in determining fair value of assets and liabilities and Level 3 assets and liabilities involve greater judgment than Level 1 or Level 2 assets or liabilities.

INTENSITY THERAPEUTICS, INC.
Notes to Unaudited Condensed
Financial Statements
September 30, 2023

Note C — Summary of Significant Accounting Policies and Accounts (continued)

[6] Fair value measurement: (continued)

At September 30, 2023, the Company has a total of approximately \$9.0 million invested in U.S. Treasury Bills: none is included in cash and cash equivalents and \$9.0 million is included in marketable debt securities. U.S. Treasury bills are valued at market price. U.S. Treasury Bills are categorized in Level 1 of their fair value hierarchy. At December 31, 2022, there were no investments in U.S. Treasury Bills.

The Company's financial instruments, including cash equivalents and current liabilities are carried at cost, which approximates fair value due to the short-term nature of these instruments.

[7] Stock-based compensation:

The Company accounts for stock-based compensation to employees and non-employees, which consists of stock option grants, through the Statements of Operations based on their fair values at the date of grant.

The Company calculates the fair value of option grants utilizing the Black-Scholes pricing model. The resulting stock-based compensation expense for both employee and non-employee awards is generally recognized on a straight-line basis over the requisite service period of the award. Forfeitures are recognized as they occur.

[8] Research and development and patent costs:

Research and development costs are charged to operations as they are incurred. Legal fees and other direct costs incurred in obtaining and protecting patents are also expensed as incurred, due to the uncertainty with respect to future cash flows resulting from the patents and are included as part of general and administrative expenses in the Company's Statements of Operations.

[9] Income taxes:

The Company accounts for income taxes through the use of the asset-and-liability method whereby deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company utilizes a valuation allowance to reduce deferred tax assets to their estimated realizable value.

The Company accounts for uncertain tax positions. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized.

The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. At September 30, 2023, the Company does not have any significant uncertain tax positions.

INTENSITY THERAPEUTICS, INC.
Notes to Unaudited Condensed
Financial Statements
September 30, 2023

Note C — Summary of Significant Accounting Policies and Accounts (continued)

[9] Income taxes: (continued)

There are no estimated interest costs and penalties provided for in the Company's financial statements for the nine months ended September 30, 2023. If at any time the Company should record interest and penalties in connection with income taxes, the interest and penalties will be expensed within the income tax line.

The Company's income tax returns are subject to Federal, state and local income tax examination by the authorities for the last three tax years.

[10] Leases:

The Company determines if an arrangement contains a lease at contract inception. With the exception of short-term leases (leases with terms less than 12 months), all leases with contractual fixed costs are recorded on the balance sheet on the commencement date as a right-of-use (ROU) asset and a lease liability. Lease liabilities to be paid over the next twelve months are classified as current lease liability and all other lease obligations are classified as long-term lease liability. Lease liabilities are initially measured at the present value of the future minimum lease payments and subsequently increased to reflect the interest accrued and reduced by the lease payments made. The Company's building leases require a pro-rata share of operating expenses and real estate taxes, which are variable in nature and excluded from the measurement of lease liabilities. ROU assets are initially measured at the present value of the future minimum lease payments adjusted for any prior lease pre-payments, lease incentives and initial direct costs. Certain leases contain escalation, renewal and/or termination options that are factored into the ROU asset as appropriate. Operating leases result in a straight-line rent expense over the expected lease term.

The Company uses its estimated incremental borrowing rate, which is derived from information available at the lease commencement date, in determining the present value of future lease payments, if the rate implicit in the lease is not readily determinable. Consideration is given to publicly available data for instruments with similar characteristics when calculating incremental borrowing rates. This incremental borrowing rate estimate is based on a synthetic credit rating derived from the market capitalization of similar companies, the treasury yield curve, and corporate yield spreads.

[11] Basic and dilutive loss per share:

Basic net loss per share is determined using the weighted average number of shares of common stock outstanding during each period. Dilutive net loss per share includes the effect, if any, from the potential exercise or conversion of securities, such as convertible preferred stock, stock options, and stock warrants, which would result in the issuance of incremental shares of common stock. The computation of diluted net loss per share does not include the conversion of securities that would have an anti-dilutive effect. Potential shares of common stock issuable upon conversion of preferred stock, exercise of stock options, and exercise of warrants that are excluded from the computation of diluted weighted average shares outstanding listed in the table below because they are anti-dilutive. The basic and diluted computation of net loss per share for the Company are the same because the effects of the Company's convertible securities would be anti-dilutive. All common and preferred stock participate equally in dividends and the distribution of earnings if and when declared by the Board of Directors, on the Company's common stock for the three and nine months ended September 30, 2022. For purposes of computing earnings per share, all series of preferred stock are considered participating securities. Therefore, the Company must calculate basic and diluted earnings per share using the two-class method. Under the two-class method, net income for the period is allocated between common stockholders and participating securities according to dividends declared and participation rights in undistributed earnings. As the preferred stockholders have no obligation to fund losses no portion of net loss was allocated to the participating securities for the three months or nine months ended September 30, 2022. There were no preferred shares outstanding at September 30, 2023.

At September 30, 2023 and 2022, the following shares of common stock underlying preferred stock, options, and warrants were excluded from the computation of diluted weighted average shares outstanding. In accordance with the Reverse Stock Split on April 27, 2023 (see Note A), the number of shares of common stock underlying the preferred stock, options and warrants are now half, and the below information gives effect to this Reverse Stock Split:

	<u>September 30, 2023</u>	<u>September 30, 2022</u>
Preferred stock Series A outstanding	-	2,499,999
Preferred stock Series B outstanding	-	724,552
Preferred stock Series C outstanding	-	900,300
Options outstanding	1,081,750	851,250
Warrants outstanding	689,200	323,250
	<u>1,770,950</u>	<u>5,299,351</u>

As of September 30, 2022 the shares that would be issued from the convertible notes outstanding are also excluded from diluted weighted average shares outstanding, since the conversion rate is dependent upon qualified liquidity events. All convertible notes were converted into shares of common stock on June 29, 2023.

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Note C — Summary of Significant Accounting Policies and Accounts (continued)

[12] Stock issuance costs:

The Company incurred costs related to the sale of its common stock in its IPO and the subsequent sale of common stock in the overallotment. These costs included underwriter commissions and fees, legal fees, accounting fees, and printing costs. These costs were recorded as a deduction to Additional Paid in Capital.

[13] Recently issued pronouncements:

The Company does not believe that any recently issued, but not yet effective, accounting pronouncements, if currently adopted, would have a material impact on its financial statements.

[14] Reclassifications:

Certain prior year amounts have been reclassified to conform to current year presentation.

Note D — Marketable Debt Securities

Marketable debt securities consist of U.S. Treasury bills purchased with original maturities of at least three months, but less than twelve months. Securities with a maturity value of \$9,030,000 were purchased for \$8,844,400. At September 30, 2023, these securities were recorded at a market value of \$8,955,300.

Note E — Prepaid Expenses

Prepaid expenses at September 30, 2023 and December 31, 2022 include:

	September 30, 2023	December 31, 2022
Prepaid insurance	\$ 917,807	\$ 29,359
Prepaid rent	-	16,200
Prepaid other	53,432	17,365
	<u>\$ 971,239</u>	<u>\$ 62,924</u>

Note F — Other Current Assets

Other current assets at September 30, 2023 and December 31, 2022 include:

	September 30, 2023	December 31, 2022
Tax credit receivable	\$ 8,785	\$ 15,903
Receivable with related party	-	46,401
State income tax receivable	5,581	13,231
	<u>\$ 14,366</u>	<u>\$ 75,535</u>

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Note G — Other Assets

Other assets at September 30, 2023 and December 31, 2022 include:

	September 30, 2023	December 31, 2022
Deposit with vendor	\$ -	\$ 150,000
Deposits with landlords	28,438	17,738
	<u>\$ 28,438</u>	<u>\$ 167,738</u>

Note H — Accrued Expenses

Accrued expenses at September 30, 2023 and December 31, 2022 include:

	September 30, 2023	December 31, 2022
Accrued vacation, wages, and related payroll taxes	\$ -	\$ 328,527
Patient costs incurred but not yet invoiced	340,639	1,392,604
Accrued other	14,367	2,269
	<u>\$ 355,006</u>	<u>\$ 1,723,400</u>

Note I — Convertible Notes

Prior to the June 29, 2023 IPO, the Company entered into a series of interest bearing convertible notes described below. On June 29, 2023, all notes converted to shares following the pricing of the IPO.

On September 20, 2021, the Company entered into a convertible debt agreement (the “2021 Convertible Note”) with a shareholder for aggregate principal of \$2,000,000 due October 1, 2025, as amended on November 29, 2022, with the following conversion terms. The outstanding principal balance together with the unpaid and accrued interest of the note would be automatically converted upon the earlier of (i) an IPO in excess of \$7,000,000 gross proceeds, (ii) a sale event of all or substantially all of the company’s assets or a majority of its equity securities, (iii) Non-IPO financing by selling preferred stock in an equity offering other than an IPO or (iv) maturity date of October 1, 2025. If an IPO, sale event or Non-IPO financing occurred between September 20, 2021 through September 19, 2022 a conversion price discount of 25% would be assessed, if between September 20, 2022 through March 19, 2023 a conversion price discount of 30% would be assessed, if between March 20, 2023 through October 1, 2025 a conversion price discount of 35% would be assessed. Otherwise at the maturity date a conversion price of \$11.50 per share would be assessed. The 2021 Convertible Note accrues interest at 3% per annum, convertible to shares as previously described herein. On November 29, 2022 this agreement was amended so that the interest rate changes to 6% per annum after October 1, 2023. The occurrence of any of the following would constitute an event of default: a) failure to pay when due any principal payment; b) voluntary bankruptcy or insolvency proceedings; c) involuntary bankruptcy or insolvency proceedings; d) judgements in excess of \$500,000; or e) defaults under other indebtedness. Under these occurrences, the holder may declare all outstanding principal and interest payable to be immediately due and payable.

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Note 1 — Convertible Notes (continued)

On November 21, 2022, the Company entered into two convertible debt agreements (the “November 21, 2022 Convertible Notes”) with shareholders for \$250,000 and \$500,000. The outstanding principal balance together with the unpaid and accrued interest of the note would be automatically converted upon the earlier of (i) an IPO of no less than \$7,000,000 gross proceeds, as amended (ii) a sale event of all or substantially all of the company’s assets or a majority of its equity securities, (iii) Non-IPO financing by selling preferred stock in an equity offering other than an IPO or (iv) maturity date of November 21, 2024. If an IPO, sale event or Non-IPO financing occurred prior to November 21, 2024 a conversion price discount of 30% would be assessed. Otherwise at the maturity date a conversion price of \$11.50 per share would be assessed. The November 21, 2022 Convertible Notes accrue interest at 10% per annum, convertible to shares as previously described herein. The occurrence of any of the following would constitute an event of default: a) failure to pay when due any principal payment; b) voluntary bankruptcy or insolvency proceedings; c) involuntary bankruptcy or insolvency proceedings; d) judgements in excess of \$500,000; or e) defaults under other indebtedness. Under these occurrences, the holders may declare all outstanding principal and interest payable to be immediately due and payable.

On November 29, 2022, the Company entered into a convertible debt agreement (the “November 29, 2022 Convertible Note”) for \$1,500,000 with a holder. The outstanding principal balance together with the unpaid and accrued interest of the note would be automatically converted upon the earlier of (i) an IPO of no less than \$7,000,000 gross proceeds, as amended (ii) a sale event of all or substantially all of the company’s assets or a majority of its equity securities, (iii) Non-IPO financing by selling preferred stock in an equity offering other than an IPO or (iv) maturity date of October 1, 2025. If an IPO, sale event or Non-IPO financing occurred prior to October 1, 2025 a conversion price discount of 30% would be assessed. Otherwise at the maturity date a conversion price of \$11.50 per share would be assessed. The November 29, 2022 Convertible Note accrues interest at 10% per annum, convertible to shares as previously described herein. The occurrence of any of the following would constitute an event of default: a) failure to pay when due any principal payment; b) voluntary bankruptcy or insolvency proceedings; c) involuntary bankruptcy or insolvency proceedings; d) judgements in excess of \$500,000; or e) defaults under other indebtedness. Under these occurrences, the holder may declare all outstanding principal and interest payable to be immediately due and payable.

On March 16, 2023, the Company entered into a convertible debt agreement (the “March 16, 2023 Convertible Note”) for \$50,000 with a holder. On March 30, 2023 the Company entered into a convertible note debt agreement (the “March 30, 2023 Convertible Note”) for \$155,000 with a holder. The outstanding principal balances together with the unpaid and accrued interest of these notes would be automatically converted upon the earlier of (i) an IPO of no less than \$7,000,000 gross proceeds (ii) a sale event of all or substantially all of the company’s assets or a majority of its equity securities, (iii) Non-IPO financing by selling preferred stock in an equity offering other than an IPO or (iv) maturity date of March 16, 2026 for the March 16, 2023 Convertible Note and March 30, 2026 for the March 30, 2023 Convertible Note. If an IPO, sale event or Non-IPO financing occurred prior to March 16, 2026 for the March 16, 2023 Convertible Note or prior to March 30, 2026 for the March 30, 2023 Convertible Note, a conversion price discount of 30% would be assessed. Otherwise at the maturity date a conversion price of \$11.50 per share would be assessed. These notes accrue interest at 10% per annum, convertible to shares as previously described herein. The occurrence of any of the following would constitute an event of default: a) failure to pay when due any principal payment; b) voluntary bankruptcy or insolvency proceedings; c) involuntary bankruptcy or insolvency proceedings; d) judgements in excess of \$500,000; or e) defaults under other indebtedness. Under these occurrences, the holder may declare all outstanding principal and interest payable to be immediately due and payable.

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Note 1 — Convertible Notes (continued)

On April 1, 2023, the Company entered into a convertible debt agreement (the “April 1, 2023 Convertible Note”) for \$12,552 with our landlord in exchange for services. The outstanding principal balances together with the unpaid and accrued interest of these notes would be automatically converted upon the earlier of (i) an IPO of no less than \$7,000,000 gross proceeds (ii) a sale event of all or substantially all of the company’s assets or a majority of its equity securities, (iii) Non- IPO financing by selling preferred stock in an equity offering other than an IPO or (iv) maturity date of April 1, 2026. If an IPO, sale event or Non-IPO financing occurred prior to April 1, 2026, a conversion price discount of 30% would be assessed. Otherwise at the maturity date a conversion price of \$11.50 per share would be assessed. This note accrues interest at 10% per annum, convertible to shares as previously described herein. The occurrence of any of the following would constitute an event of default: a) failure to pay when due any principal payment; b) voluntary bankruptcy or insolvency proceedings; c) involuntary bankruptcy or insolvency proceedings; d) judgements in excess of \$500,000; or e) defaults under other indebtedness. Under these occurrences, the holder may declare all outstanding principal and interest payable to be immediately due and payable.

On May 11, 2023, the Company entered into a convertible debt agreement (the “May 11, 2023 Convertible Note”) for \$25,000 with a holder. The outstanding principal balances together with the unpaid and accrued interest of these notes would be automatically converted upon the earlier of (i) an IPO of no less than \$7,000,000 gross proceeds (ii) a sale event of all or substantially all of the company’s assets or a majority of its equity securities, (iii) Non- IPO financing by selling preferred stock in an equity offering other than an IPO or (iv) maturity date of May 11, 2026. If an IPO, sale event or Non-IPO financing occurred prior to May 11, 2026, a conversion price discount of 30% would be assessed. Otherwise at the maturity date a conversion price of \$11.50 per share would be assessed. These note accrues interest at 10% per annum, convertible to shares as previously described herein. The occurrence of any of the following would constitute an event of default: a) failure to pay when due any principal payment; b) voluntary bankruptcy or insolvency proceedings; c) involuntary bankruptcy or insolvency proceedings; d) judgements in excess of \$500,000; or e) defaults under other indebtedness. Under these occurrences, the holder may declare all outstanding principal and interest payable to be immediately due and payable.

A loss was recorded to account for the discount given to convertible noteholders as provided by their convertible note agreements. Upon the settlement of the notes, a loss of \$2,261,581 was recorded on the Statement of Operations for the nine months ended September 30, 2023 for the discount given to the convertible debt holders.

The balance at December 31, 2022 consists of:

	Principal	Accrued Interest	Total
Convertible note dated September 20, 2021	\$ 2,000,000	\$ 76,767	\$ 2,076,767
Convertible notes dated November 21, 2022	750,000	8,219	758,219
Convertible note dated November 29, 2022	1,500,000	13,562	1,513,562
	<u>\$ 4,250,000</u>	<u>\$ 98,548</u>	<u>\$ 4,348,548</u>

There was no balance in Convertible notes as of September 30, 2023 since all principal and accrued interest of \$4,492,552 and \$244,447, respectively was converted into 1,399,716 shares of common stock on June 29, 2023.

At December 31, 2022, the Company classified the convertible notes as a current liability since the Company anticipated that these notes will automatically convert into shares of common stock within one year of the balance sheet date. The unamortized discount was amortized over the life of the convertible notes. The unamortized balance at the time of the conversion into shares of common stock of approximately \$117,700 is included in interest expense in the Statement of Operations.

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Note J — Stockholders' Equity

On June 29, 2023, as described in Note A, the Company priced its IPO, issuing 3,900,000 shares of common stock. Pursuant to the IPO, all of the Company's preferred stock was converted into common stock at conversion prices that reflected the Reverse Stock Split effective June 29, 2023. All convertible notes and related accrued interest were converted into 1,399,716 shares of common stock, as described in Note I and the Company recorded a non-operating loss on debt extinguishment on the Statement of Operations for \$2,261,581 which is equal to the discount on the IPO price that was specified in the convertible note agreements. As the IPO price was less than the original issue price per share of the Series B and Series C preferred stock, each of these series received a conversion price adjustment pursuant to their original terms. Upon conversion of the preferred stock, the Company issued an additional 100,189 shares of common stock pursuant to Series B conversion price adjustment and an additional 164,518 shares of common stock pursuant to the Series C conversion price adjustment. The additional shares have been recorded as a deemed dividend on the Statement of Operations and Statement of Changes in Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficiency).

On July 7, 2023, the Company sold the full over allotment of the IPO shares and issued 585,000 shares of common stock at the IPO price of \$5.00 per share.

The sixth amended and restated Certificate of Incorporation, which was approved by the Company's stockholders on November 23, 2021, increased the number of authorized shares from 50,000,000 to 135,000,000 upon the completion of the IPO.

Note K — Common Stock Warrants

The following table summarizes information about common stock warrants at September 30, 2023 and 2022:

	Number of Shares Underlying Warrants	Weighted Average Exercise Price
Outstanding January 1, 2022	323,250	\$ 6.01
Issued	-	-
Exercised	-	-
Forfeited	-	-
Outstanding March 31, 2022	323,250	6.01
Issued	-	
Exercised	-	
Forfeited	-	
Outstanding June 30, 2022	323,250	6.01
Issued	-	
Exercised	-	
Forfeited	-	
Outstanding September 30, 2022	323,250	\$ 6.01
Outstanding January 1, 2023	357,750	\$ 6.00
Issued	30,000	12.50
Exercised	-	
Forfeited	-	
Outstanding March 31, 2023	387,750	6.51
Issued	273,000	6.00
Exercised	-	
Forfeited	-	
Outstanding June 30, 2023	660,750	6.30
Issued	40,950	6.00
Exercised	(12,500)	2.00
Forfeited	-	
Outstanding September 30, 2023	689,200	\$ 6.36
Exercisable September 30, 2023	659,450	\$ 6.21

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Note K — Common Stock Warrants (continued)

The following table summarizes the assumptions used to estimate the fair value of 30,000 stock warrants granted on January 1, 2023 at the date of grant:

Stock price	\$	4.50
Exercise price	\$	6.25
Expected volatility		103.85%
Risk free interest rates		3.59%
Term		3 years

30,000 warrants were granted on January 1, 2023 to two holders of convertible notes. These warrants were exercisable upon issuance and expire in three years. The value of the warrants is \$159,262. The value of the warrants is recorded as a discount to the convertible notes and was being amortized over the life of the convertible notes. The amortization appears on the Statement of Operations as interest expense.

The following table summarizes the assumptions used to estimate the fair value of stock warrants committed by the Company on June 29 and July 7, 2023 as part of the IPO and sale of the IPO over allotment:

Stock price	\$	5.00
Exercise price	\$	6.00
Expected volatility		101.46%
Risk free interest rates		3.97%
Term		5 years

273,000 warrants were granted to the underwriters of the IPO for the sale of the IPO base shares. The value of these warrants is approximately \$1,017,000. 40,950 warrants were granted to the underwriters for the sale of the over allotment shares. The value of these warrants is approximately \$153,000. All of these warrants are recorded as both an increase and decrease to Additional Paid in Capital on the Balance Sheet since they are costs related to the issuance of the shares of common stock. These warrants are exercisable beginning on January 5, 2024 and expire January 5, 2029. There was no stock compensation expense recorded on these warrants.

The Company recognized stock-based compensation expense related to warrants in its condensed Statements of Operations as follows (approximately):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2023	2022	2023	2022
Research and Development	\$ 67,000	\$ 4,000	\$ 203,000	\$ 11,000
General and Administrative	4,000	-	11,000	100,000
Total	\$ 71,000	\$ 4,000	\$ 214,000	\$ 111,000

At September 30, 2023, total unrecognized compensation cost related to warrants was approximately \$164,000 and is expected to be recognized over the remaining weighted average service period of 1.9 years.

The aggregate intrinsic value of outstanding warrants is calculated as the difference between the exercise price of the stock warrants and the fair value of the Company's common stock for those stock warrants that had exercise prices lower than the fair value of the Company's common stock. The aggregate intrinsic value of outstanding warrants was approximately \$67,000 at September 30, 2023.

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Note L — Stock Based Compensation

The Company had a stock option plan, the 2013 Plan, which is administered by our Compensation Committee. Under the 2013 Plan, stock options to purchase a total of 4,500,000 shares of common stock could be granted to eligible employees, officers, directors and consultants of the Company.

In 2020, the Company amended its 2013 Stock Option Plan (the “2013 Plan”) to increase the number of authorized shares available under the 2013 Plan from 1,800,000 to 4,500,000. On November 12, 2021, the Company adopted the 2021 Stock Incentive Plan (the “2021 Plan”) authorizing the granting of equity awards for the issuance of up to 3,000,000 shares of common stock. Prior to the adoption of the 2021 Plan, there were 2,677,500 shares available under the 2013 Plan. However, upon adoption of the 2021 Plan, no more shares would be issued under the 2013 Plan. Starting on January 1, 2022, the shares authorized under the 2021 Plan shall have an annual increase of the lesser of (a) 3.5% of the aggregate number of shares of Common Stock outstanding on the final day of the preceding calendar year, or (b) such smaller amount as determined by the Board. On January 1, 2023, an additional 238,700 shares were authorized under the 2021 Plan.

The following table summarizes information about common stock options at September 30, 2023 and 2022:

	Number of Shares Underlying Options	Weighted Average Exercise Price
Outstanding at January 1, 2022	911,250	\$ 8.57
Issued	-	
Exercised	-	
Forfeited	-	
Outstanding March 31, 2022	<u>911,250</u>	8.57
Issued	-	
Exercised	-	
Forfeited	-	
Outstanding June 30, 2022	<u>911,250</u>	8.57
Issued	-	
Exercised	-	
Forfeited	(60,000)	11.50
Outstanding September 30, 2022	<u><u>851,250</u></u>	\$ 8.36
Outstanding January 1, 2023	1,044,250	\$ 8.48
Issued	-	
Exercised	-	
Forfeited	-	
Outstanding March 31, 2023	<u>1,044,250</u>	8.48
Issued	-	
Exercised	-	
Forfeited	-	
Outstanding June 30, 2023	<u>1,044,250</u>	8.48
Issued	50,000	6.43
Exercised	(12,500)	2.00
Forfeited	-	
Outstanding September 30, 2023	<u><u>1,081,750</u></u>	\$ 8.46
Exercisable September 30, 2023	801,750	\$ 8.10

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Note L — Stock Based Compensation (continued)

The aggregate intrinsic value of outstanding options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The aggregate intrinsic value of options outstanding was approximately \$85,000 at September 30, 2023.

Employee option vesting is based on the employee's continued service with the Company.

The 2013 Plan and the 2021 Plan provide an immediate vesting of outstanding options in the event of a change of control, such as an acquisition, notwithstanding any other provision of the 2013 Plan or 2021 Plan.

The following table summarizes the assumptions used to estimate the fair value of stock options issued on July 19, 2023:

Stock price	\$	6.43
Exercise price	\$	6.43
Expected volatility		99.74%
Risk free interest rates		3.87%
Expected term		3 years

At September 30, 2023, total unrecognized compensation cost related to options was approximately \$1,466,000 and is expected to be recognized over the remaining weighted average service period of 1.6 years.

The Company recorded stock-based compensation related to stock options in its condensed Statements of Operations as follows (approximately):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2023	2022	2023	2022
Research and Development	\$ 119,000	\$ (21,000)	\$ 448,000	\$ 286,000
General and Administrative	161,000	58,000	313,000	144,000
Total	\$ 280,000	\$ 37,000	\$ 761,000	\$ 430,000

All options expire ten years from date of grant. Options outstanding begin to expire in August 2024. Options that were granted to employees and consultants have vesting periods that vary by award to recipient and range from immediate vesting to a period of up to 4 years.

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Note M — Leases

In January 2017, the Company entered into a lease for 2,534 square feet of office space in Westport, Connecticut, the “Westport Lease”). The lease commenced in May 2017. The initial lease term was two years. In November 2018, the Company exercised the option to extend the lease for an additional three years.

In July 2020, the Company amended the Westport Lease to increase office space by an additional 1,653 square feet in the same building. The amended lease that includes the space included in the original lease had monthly rent as follows:

Year 1 (October 2020 through September 2021)	\$15,502 per month	(\$44.43 per square foot)
Year 2 (October 2021 through September 2022)	\$15,851 per month	(\$45.43 per square foot)
Year 3 (October 2022 through September 2023)	\$16,200 per month	(\$46.43 per square foot)

The Company had an option to extend this amended lease for an additional 3 years at the following amounts:

Year 4: (October 2023 through September 2024)	\$16,338 per month	(\$46.83 per square foot)
Year 5: (October 2024 through September 2025)	\$16,476 per month	(\$47.22 per square foot)
Year 6: (October 2025 through September 2026)	\$16,825 per month	(\$48.22 per square foot)

The Company had until March 31, 2023 to exercise this option to extend. On February 27, 2023, the Company informed the landlord that it will not exercise its option to extend the amended lease. On March 27, 2023, the Company modified the lease to reduce the office space as of April 30, 2023 and to further reduce the office space as of May 31, 2023. These two modifications reduced the operating lease asset and liability. The amended lease was set to expire on September 30, 2023. On April 17, 2023 another modification was made to the lease that terminated the lease as of June 30, 2023.

The Company also paid a pro-rata share of operating expenses and real estate taxes. For the Westport Lease, the following variables were used to determine the right-of-use asset and the operating lease liabilities as of commencement date: Weighted average remaining lease term 1.00 years and Weighted average operating lease discount rate 3.92%.

On July 7, 2023 the Company signed a 5.5 year lease for 2,686 square feet of office space in Shelton, Connecticut, (the “Shelton Lease”.) The initial monthly base rent payments are zero for the first six months, \$2,910 for each of the next six months, and gradually increase to \$3,275 per month for the last twelve months. The lease commencement date was September 1, 2023. The Company also pays a pro-rata share of common area maintenance, real estate taxes, and insurances which are treated as non-lease components and recorded as variable facilities costs on a monthly basis. The Company has a one-time option to cancel the Shelton Lease after 36 months if it provides written notice before the end of month 30. An additional \$46,679 would be due at the end of month 36 if the Company exercises this option. This option is not reasonably certain to occur.

The Shelton Lease uses a discount rate of 6.39% and a weighted average remaining term of 5 years 5 months as of September 30, 2023. Rent expense for the nine months ended September 30, 2023 was \$54,547 of which \$2,842 pertains to the Shelton Lease for the month of September 2023.

The following table summarizes the balance sheet classification of the operating lease asset and related lease liabilities at September 30, 2023 for the Shelton Lease and at December 31, 2022 for the Westport Lease:

	September 30, 2023	December 31, 2022
Operating lease right-of-use assets	\$ 152,605	\$ 139,089
Current portion of operating lease liabilities	\$ 10,556	\$ 143,221
Long-term operating lease liabilities	144,891	-
	<u>\$ 155,447</u>	<u>\$ 143,221</u>

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Note N — Other Uncertainties

The Company holds one of its patents in Russia. The payment for this patent is paid until September 15, 2024. If subsequent payments to Russia are restricted, the Company may lose this patent in Russia. The Company has no other significant business activities in Belarus, Russia or the Ukraine. The Company also holds a patent in Israel which is currently involved in military action.

Note O — Related Parties

The liabilities section of the September 30, 2023 and December 31, 2022 balance sheet shows a \$36,000 deposit related to a Provider Service Agreement (“PSA”) with a minority stockholder. This account is entitled “Related party deposit” on the balance sheet. This deposit will be returned to the minority stockholder at the end of the PSA once all charges have been settled. At September 30, 2023 and December 31, 2022, the Company had a receivable of approximately none and \$46,400, respectively, related to this agreement. This receivable is included in “Other current assets” on the balance sheet.

In February 2022, a minority stockholder became a consultant to the Company. Services provided include acting as the Company’s Chief Medical Officer. The Company has accrued approximately none and \$95,900 at September 30, 2023 and December 31, 2022, respectively. This liability is included in accounts payable. Expenses related to this consulting agreement were approximately \$6,200 and \$80,900 for the nine months ended September 30, 2023 and 2022, respectively and approximately \$2,200 and \$15,000 for the three months ended September 30, 2023 and 2022, respectively.

Sublease income from the related party was approximately \$23,000 and \$50,600 for the nine months ended September 30, 2023 and 2022 and none and approximately \$16,900 for the three months ended September 30, 2023 and 2022. April 2023 was the last month for the sublease income. Sublease income is recorded as a reduction of general and administrative expenses in the Statement of Operations.

Note P — Income Taxes

The Company recorded Federal research and development credits, of approximately \$18,300 and \$47,700 for the nine months ended September 30, 2023 and 2022, respectively. These amounts are included in Other Income in the Statements of Operations. Other current assets include a tax credit that is the Federal refundable research and development tax credit.

At September 30, 2023, the Company generated Connecticut and Federal net operating loss carryforwards of approximately \$30.3 million. For the Federal net operating loss carryforwards, approximately \$7.0 million expire at various dates beginning in 2033. Under the Tax Cuts and Job Act passed on December 22, 2017, corporate net operating losses generated beginning in 2018 cannot be carried back but are carried forward indefinitely. The Internal Revenue Code (the “IRC”) contains limitations on the use of net operating loss carryforwards after the occurrence of substantial ownership changes as defined by IRC Section 382. Utilization of such operating loss carryforwards may be limited if such capital raises are determined to be a change in ownership under IRC Section 382.

At September 30, 2023, aside from the Federal research and development tax credits used to offset Social Security taxes, the Company had Federal General Business Credit carryforwards of approximately \$439,400 which are available to offset future taxable income expiring at various times beginning in 2033.

At September 30, 2023, the Company has Connecticut research and development tax credit carryforwards of approximately \$196,600 which are available to offset future Connecticut taxable income.

Note Q — Retirement Plan – Defined Contribution

The Company maintains a defined contribution plan for all employees age 21 and older who have completed one month of service. This 401K plan began for payrolls after July 1, 2017. The Company makes a matching contribution equal to 100% of an employee’s contribution, up to 3% of an employee’s eligible earnings. The Company match is vested after one year of service. Retirement expense for this plan was approximately \$14,700 and \$29,300 for the nine months ended September 30, 2023 and 2022, respectively and approximately \$4,800 and \$6,000 for the three months ended September 30, 2023 and 2022, respectively.

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

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements generally relate to future events or our future financial or operating performance and may include statements concerning, among other things, our business strategy (including anticipated trends and developments in, and management plans for, our business and the markets in which we operate), financial results, operations, and the markets and communities in which we, our clients, and partners operate, results of operations, revenues, operating expenses, and capital expenditures, sales and marketing initiatives and competition. In some cases, you can identify forward-looking statements because they contain words such as “may,” “might,” “will,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “target,” “projects,” “contemplates,” “believes,” “estimates,” “predicts,” “suggests,” “potential” or “continue” or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans or intentions. These statements are not guarantees of future performance; they reflect our current views with respect to future events and are based on assumptions and are subject to known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from expectations or results projected or implied by forward-looking statements.

We discuss many of these risks in our Final Prospectus on Form 424(b)(4) dated June 29, 2023, in greater detail under the heading “Risk Factors” and in other filings we make from time to time with the Securities and Exchange Commission (“SEC”). Also, these forward-looking statements represent our estimates and assumptions only as of the date of this Quarterly Report on Form 10-Q, which are inherently subject to change and involve risks and uncertainties. Unless required by federal securities laws, we assume no obligation to update any of these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated, to reflect circumstances or events that occur after the statements are made. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Our actual results could differ materially from the results contemplated by these forward-looking statements due to a number of factors. Such factors include, but are not limited to, the following:

- the initiation, timing, progress and results of future preclinical studies and clinical trials, and our research and development programs;
- our need to raise additional funding before we can expect to generate any revenues from product sales;
- our plans to develop and commercialize our product candidates;
- the timing or likelihood of regulatory filings and approvals;
- the ability of our research to generate and advance additional product candidates;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the rate and degree of market acceptance and clinical utility of our system;
- our competitive position;
- our intellectual property position;
- developments and projections relating to our competitors and our industry;
- our ability to maintain and establish collaborations or obtain additional funding; and
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this report and have filed with the SEC, including our Final Prospectus on Form 424(b)(4) dated June 29, 2023, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

References to “Notes” are notes included in our unaudited Financial Statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Unless otherwise indicated, the terms “Intensity,” “Company,” “we,” “us,” or “our” refer to Intensity Therapeutics, Inc.

Overview

Intensity Therapeutics, Inc. is a clinical-stage biotechnology company committed to applying scientific leadership in the field of localized cancer reduction leading to anti-cancer immune activation. Our approach involves the direct injection into tumors of a unique product created from our DfuseRxSM discovery platform.

The concept of intratumoral treatment (IT) has been an objective of clinicians since the first discovery of chemotherapeutic agents. Keeping the drug in the tumor and sparing the body of toxicity. The challenge with IT treatment approaches is that a tumor's lipophilic, high fat and pressurized microenvironment is incompatible with and does not absorb water-based products. We believe that intratumoral drug delivery is a chemistry challenge and that prior or current IT treatments have formulated their product without consideration of the incompatibility of water and tumors. Another issue with IT or local delivery has been that metastatic cancer is a whole body disease. Local treatments need a systemic component to be effective for a survival benefit. Accordingly, there remains a continued unmet need for the development of direct IT therapies for solid tumors that provide high local killing efficacy coupled with nontoxic systemic anti-cancer effects. We believe we have created such a product candidate with the necessary chemistry to overcome this local delivery challenge and a mechanism of action that induces a systemic effect. Clinical and nonclinical evidence shows that our drug candidate's mechanism of tumor killing also leads to immune activation in certain cancers.

Our platform creates patented anti-cancer product candidates comprising active anti-cancer agents and amphiphilic molecules. Amphiphilic molecules have two distinct components: one part is soluble in water and the other is soluble in fat or oils. When certain amphiphilic compounds are mixed with therapeutic agents, such as chemotherapies, the agents can also become soluble in both fat and water. Our product candidates include novel formulations consisting of potent anti-cancer drugs mixed together with these amphiphilic agents.

Our lead product candidate, INT230-6, consists of two proven anti-cancer cytotoxic agents, cisplatin and vinblastine sulfate, mixed with the amphiphilic molecule (SHAO) — all in one vial. The anti-cancer agents, cisplatin and vinblastine sulfate, used in our product candidate are both generic and are available to purchase in bulk supply commercially. In 2017, we initiated a Phase 1/2 dose escalation study using INT230-6 in the United States under an investigational new drug application (“IND”) authorized by the FDA and in Canada following receipt of a no objection letter from Health Canada. The study, IT-01, explored the safety and efficacy of INT230-6 in patients with refractory or metastatic cancers. We completed enrollment of study IT-01 in June 2022 and locked the IT-01 database in February 2023 and finalized the clinical study report in September 2023.

The IT-01 trial dosed 110 patients. This clinical trial used our lead product candidate INT230-6 alone; in combination with Merck's Keytruda® (pembrolizumab) for patients with advanced solid malignancies including pancreatic, bile duct, squamous cell, and non-MSI high colon cancers; and in combination with Bristol Myers Squibb's Yervoy® (ipilimumab) for patients with breast cancer, liver cancer, and advanced sarcoma. In the third quarter of 2023 we completed the clinical study reports (CSR) for the IT-01 trial. We expect to deliver the reports and other information to our partners in the fourth quarter of 2023.

Our second clinical trial (the INVINCIBLE Study or IT-02) tested INT230-6 in early stage breast cancer for patients not suitable for presurgical chemotherapy. The study enrolled 91 subjects; enrollment is now complete. This clinical trial was a Phase 2 randomized, window of opportunity for patients who were ineligible or chose not to have presurgical chemotherapy. The key endpoint was whether INT230-6 could reduce patient's cancer by 50% to 100% defined as a major pathological response compared to no treatment (the current standard of care) or a saline injection and stimulate a systemic anti-cancer immune response prior to surgery. Substantial reduction of cancer presurgically in aggressive forms of cancer has been shown to correlate with delaying disease recurrence. Other endpoints of the INVINCIBLE study were to understand the percentage of necrosis that can be achieved in tumors especially tumors larger than 2 cm in longest diameter and whether either a local or whole body anti-cancer immune response could be induced. In the third quarter of 2023 we finalized the statistical analysis plan and the design of the tables listings and figures.

On September 7, 2023, the Company announced that the FDA's Office of Orphan Products Development has granted orphan-drug designation for the treatment of soft tissue sarcoma to the three active moieties comprising INT230-6, cisplatin, vinblastine sulfate, and the diffusion enhancer SHAO-FA ((2-hydroxybenzoyl) amino) octanoate). The Orphan Drug Designation qualifies the Company for incentives including tax credits for qualified clinical trials, exemption from user fees and potentially seven years of marketing exclusivity for products containing these three key components should the Company gain approval of INT230-6 for treatment of soft tissue sarcoma.

Phase 3 Sarcoma Study

The Company intends to test INT230-6 as a treatment in advance soft tissue sarcoma with an endpoint of overall survival. In the third quarter of 2023, the Company continued to work on the protocol for Study IT-03 which treats soft tissue sarcoma. To achieve this objective immediately following the close of the IPO we reserved a slot with our drug product manufacturing vendor to produce a new batch of INT230-6 in the fourth quarter of 2023 that would be suitable for phase 3 clinical use. For phase 3 development and validation of new assays for determining vinblastine and SHAO concentrations in our drug product was required. The assay for cisplatin was already phase 3 ready. The new assays have been developed. we anticipate validation of the methods to begin and complete in the fourth quarter. In our meeting with FDA held in October of 2021, the Agency requested we schedule a Chemical Manufacturing and Controls (CMC) meeting to discuss the issues needed for phase 3 and product registration. We submitted our CMC questions in Q3 to the Agency. The FDA granted us a meeting that is scheduled to occur in the fourth quarter of 2023. In the third quarter of 2023 we drafted several of the required documents necessary for commencing the soft tissue sarcoma phase 3 study. Our intent is to submit an IND to FDA with the phase 3 protocol in the fourth quarter of 2023.

Phase 2/3 Program in Presurgical Breast Cancer

Based on the data generated and presented to date, we are working to develop a phase 2/3 study protocol in presurgical (neoadjuvant) breast cancer. The study will test INT230-6 in combination with the standard of care (SOC) treatment (chemotherapy/immunotherapy) compared to SOC alone in women with triple negative breast cancer. The clinical materials being manufactured in the fourth quarter of 2023 for the sarcoma study will also be used in the breast cancer study. The endpoint for the phase 2 portion of the trial will a change in pathological complete response rate for the combination compared to the SOC alone. That data will allow for sizing of the phase 3 program.

Since our inception in 2012, our operations have included business planning, hiring personnel, raising capital, building our intellectual property portfolio, and performing both research and development on our product candidates. We have incurred net losses since inception and expect to incur net losses in the future as we continue our research and development activities. To date, we have funded our operations primarily through approximately \$54.5 million in cash received from the net proceeds of sales of our common stock, preferred stock and convertible notes. As of September 30, 2023, we had approximately \$6.7 million of cash and cash equivalents plus approximately \$9.0 million in investments in U.S. Treasury bills. Since our inception, we have incurred significant operating losses. We incurred net losses of \$2.3 million and \$1.8 million for the three months ended September 30, 2023 and 2022, respectively, and losses of \$7.4 million and \$6.1 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, we had an accumulated deficit of approximately \$47.3 million. We expect to incur significant expenses and operating losses for the next several years. See "Funding Requirements" below.

We expect our expenses to increase as we continue to:

- Initiate Phase 3 programs in sarcoma and/or breast cancer;
- Complete our current Phase 2 programs;
- Advance our preclinical research and bring new product candidates into clinical development;
- Incur manufacturing costs for additional GMP batches of our product candidates and enhancer molecules;
- Seek regulatory approvals for any of our product candidates that successfully complete clinical trials;
- Hire additional personnel;
- Expand our operational, financial, and management systems;
- Invest in measures to protect our existing and new intellectual property; and
- Establish a sales, marketing, medical affairs, and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize.

Our ability to ultimately generate revenue to achieve profitability will depend heavily on the development, approval, and subsequent commercialization of our product candidates. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financing, or other capital sources, which may include collaborations with other companies or other strategic transactions. We may not be able to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we would have to significantly delay, reduce, or eliminate the development and commercialization of one or more of our product candidates.

Components of Results of Operations

Revenue

To date, we have not generated any revenue from product sales and we do not expect any revenue from the sale of product in the foreseeable future. We have not generated any revenue from licensing of our technology or product candidates yet either. If our development efforts for any of our product candidates are successful and result in regulatory approval, then we may generate revenue in the future from product sales or licensing. We cannot predict if, when, or to what extent we will generate revenue from the commercialization, licensing or sale of any of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates.

Research and Development Costs

Salaries and Payroll Taxes

Salaries and payroll taxes include Company employees involved in our pre-clinical research and clinical trials. This includes medical officers, project management, manufacturing staff and research scientists. The payroll taxes include all government required payments such as social security and unemployment taxes.

Benefits

We offer a partially funded health insurance and dental insurance plan. We maintain a defined contribution plan for all employees age 21 and older who have completed one year of service. This 401K plan makes a matching contribution equal to 100% of an employee's contribution, up to 3% of an employee's eligible earnings.

Clinical Trial and Other Costs

Research costs include:

- Pre-clinical research
- Manufacture of new enhancer compounds,
- Manufacture and labelling of GMP product candidate
- Product candidate stability testing of GMP batches
- Costs due to clinical trials for patient care
- Other clinical trial costs such as shipping, storage, and analytical testing
- Scientific consulting costs related to non-employees involved in research. This category includes: statistical analysis, clinical trial operations, development of product manufacturing techniques, and internet research related to oncology and chemistry issues that may impact our preclinical or clinical research.

Stock-Based Compensation

Stock-based compensation is the expense related to stock options granted to our employees and board members and warrants granted to our independent consultants who work in the research aspects.

General and Administrative Costs

Salaries and Payroll Taxes

Salaries and payroll taxes include Company employees who are involved in fund raising, management, and our financial administration. The payroll taxes include all government required payments such as social security and unemployment taxes.

Benefits

We offer a partially funded health insurance and dental insurance plan. We maintain a defined contribution plan for all employees age 21 and older who have completed one year of service. This 401K plan makes a matching contribution equal to 100% of an employee's contribution, up to 3% of an employee's eligible earnings.

Legal

Legal costs relate primarily to our corporate administration. All legal costs relate to expenses for outside law firms.

Patent and Trademark

Patent and Trademark are the legal costs and filing costs to establish and maintain patents in 38 countries.

Insurance

Insurance includes: directors and officers insurance, workers compensation insurance, product liability insurance, business insurance, employee and cyber liability insurance.

Facilities and Rent

Facilities and rent through June 30, 2023 is the cost of maintaining our office facility in Westport, Connecticut. The three months ended September 30, 2023 includes some minor costs related to temporary storage of furniture and equipment as we transitioned into our new office space.

In July 2023, we signed a lease to move into 2,686 square feet of office space at 1 Enterprise Drive, Suite 430, Shelton, Connecticut to improve recruiting of staff and to reduce costs. The three months ended September 30, 2023 includes the cost of renting and maintaining this office space.

The commencement date of the Shelton Lease is September 1, 2023 and rent for September 2023 was \$2,842. The initial payments for base rent is zero for the first six months, \$2,910 for each of the next six months, and gradually increase to \$3,275 per month for the final months of the lease. The Company has an option to cancel this lease after 36 months.

Investor Relations

Investor relations are costs paid to outside consultants to develop the materials to present to current and prospective investors, and to arrange meetings with potential investors.

Accounting Services

Accounting services include the cost of our independent auditors for our annual audit, quarterly reviews, and services related to the filing forms with the Securities and Exchange Commission. Accounting services also includes costs related to the preparation of income tax returns, and the cost of maintaining our accounting system. Accounting services on our IPO were not included in this category. The costs related to the IPO were recorded as a reduction of proceeds of the offering and are part of additional paid-in capital on the September 30, 2023 balance sheet.

Consulting Services

Consulting Services are services provided by non-employees for general and administrative tasks. This includes human resources, finance, board compensation, and internet support.

Other

Other general and administrative costs include such items as office supplies, computer related costs, public relations costs, recruiting costs and conferences.

Stock-Based Compensation

Stock-based compensation is the expense related to stock options granted to our employees and board members and warrants granted to our independent consultants who work in the general and administrative aspects.

Other income and expenses

We earned interest income on our cash balances and investments in U.S. Treasury bills.

We incurred interest expense on our convertible notes through June 29, 2023. Accrued interest was converted into common stock upon commencement of our IPO.

We accumulated federal research and development tax credits in prior tax years that are recoverable through a refund of Social Security taxes paid in current fiscal periods.

Results of Operations

The following tables summarize our results of operations for the three months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		Increase (Decrease)
	2023	2022	
Operating expenses:			
Research and development costs	\$ 1,351,766	\$ 1,160,737	\$ 191,029
General and administrative costs	1,138,748	607,113	531,635
Total operating costs	<u>2,490,514</u>	<u>1,767,850</u>	<u>722,664</u>
Loss from operations	(2,490,514)	(1,767,850)	(722,664)
Other income (expense)	160,769	(7,017)	167,786
Net loss	<u>\$ (2,329,745)</u>	<u>\$ (1,774,867)</u>	<u>\$ (554,878)</u>

	Three Months Ended September 30,		Increase (Decrease)
	2023	2022	
Research and development costs by expense type:			
Salaries and payroll taxes	\$ 88,203	\$ 192,312	\$ (104,109)
Benefits	15,059	38,956	(23,897)
Stock based compensation	185,785	(16,896)	202,681
Clinical trial and other costs	1,062,719	946,365	116,354
	<u>\$ 1,351,766</u>	<u>\$ 1,160,737</u>	<u>\$ 191,029</u>

	Three Months Ended September 30,		Increase/ (Decrease)
	2023	2022	
General and administrative costs:			
Salaries and payroll taxes	\$ 103,936	\$ 74,662	\$ 29,274
Benefits	7,190	6,216	974
Legal	102,790	211,758	(108,968)
Patent and trademark	26,314	8,998	17,316
Insurance	288,066	17,765	270,301
Facilities and rent	4,763	36,104	(31,341)
Investor relations	48,671	32,498	16,173
Accounting services	192,133	56,416	135,717
Consulting services	103,424	18,411	85,013
Other	96,077	86,678	9,399
Stock-based compensation	165,384	57,607	107,777
	<u>\$ 1,138,748</u>	<u>\$ 607,113</u>	<u>\$ 531,635</u>

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

Research and Development expenses increased by 16.5%. Salaries and payroll taxes decreased by 54.1% from the third quarter of 2022 to the third quarter of 2023, primarily due to the decrease in two headcount. Additionally, the CEO devoted more time towards general and administrative in 2023 due to his work related to the IPO. Benefits decreased by 61.3% for these same reasons that salaries and payroll taxes decreased. Clinical trial and other research costs increased by \$116,354 primarily due to approximately \$307,300 of costs in 2023 related to the manufacture of our next batch of drug which is scheduled to occur in the fourth quarter of 2023. The Company also incurred approximately \$164,100 of preliminary costs related to the Phase 3 study on Sarcoma in 2023. Costs related to Studies IT-01 and IT-02 decreased since their enrollments were completed in June 2022 and August 2022, respectively. The increase in stock based compensation is predominantly due to the third quarter of 2022 having a reduction of approximately \$132,000 due to forfeited stock options.

General and Administrative expenses increased by 87.6%. Salaries and payroll taxes increased by \$29,274 due to a larger percentage of the CEO's time being spent on general and administrative activities and a salary increase to the Principal Accounting Officer. Legal expenses in 2022 include costs related to an unsuccessful attempt at an IPO. Insurance increased due to the additional directors and officers' insurance as a publicly held company. Accounting services increased due to quarterly reviews and accounting services related to activities as a publicly held company. Consulting service is predominantly the cost of our vice president of corporate finance.

Other income (expense) in the third quarter of 2022 was predominantly interest expense on the convertible notes which were converted to common stock on June 29, 2023. Other income (expense) in the third quarter of 2023 was predominantly interest income earned on marketable debt securities and cash and cash equivalents which increased in the third quarter of 2023 due to the proceeds from both the IPO and the sale of the overallotment shares.

The deemed dividend represents the value that was transferred to the Series B and C preferred stockholders upon triggering of anti-dilution provisions.

The following tables summarize our results of operations for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,		Increase (Decrease)
	2023	2022	
Operating expenses:			
Research and development costs	\$ 2,984,752	\$ 4,241,203	\$ (1,256,451)
General and administrative costs	1,981,594	1,834,966	146,628
Total operating costs	4,966,346	6,076,169	(1,109,823)
Loss from operations	(4,966,346)	(6,076,169)	1,109,823
Other income (expense)	(2,400,412)	4,613	(2,405,025)
Net loss	\$ (7,366,758)	\$ (6,071,556)	\$ (1,295,202)
Preferred stock deemed dividend	(1,323,535)	-	(1,323,535)
Net loss attributable to common shareholders	\$ (8,690,293)	\$ (6,071,556)	\$ (2,618,737)
	Nine Months Ended September 30,		Increase (Decrease)
	2023	2022	
Research and development costs by expense type:			
Salaries and payroll taxes	\$ 368,050	\$ 860,975	\$ (492,925)
Benefits	64,448	144,007	(79,559)
Stock based compensation	650,778	297,115	353,663
Clinical trial and other costs	1,901,476	2,939,106	(1,037,630)
	\$ 2,984,752	\$ 4,241,203	\$ (1,256,451)

	Nine Months Ended September 30,		Increase/ (Decrease)
	2023	2022	
General and administrative costs:			
Salaries and payroll taxes	\$ 274,283	\$ 231,469	\$ 42,814
Benefits	15,659	17,172	(1,513)
Legal	243,859	468,045	(224,186)
Patent and trademark	59,798	34,266	25,532
Insurance	321,766	58,717	263,049
Facilities and rent	71,320	107,598	(36,278)
Investor relations	115,227	132,740	(17,513)
Accounting services	280,187	232,774	47,413
Consulting services	137,907	139,814	(1,907)
Other	136,944	168,153	(31,209)
Stock-based compensation	324,644	244,218	80,426
	<u>\$ 1,981,594</u>	<u>\$ 1,834,966</u>	<u>\$ 146,628</u>

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

Research and Development expenses decreased by 29.6%. Salaries and payroll taxes decreased by 57.3% since 2022, predominantly due to four research employees leaving the Company from February 2022 through June 2023. Benefits decreased by 55.2% for the same reason. Clinical trial and other research costs decreased by approximately \$1.0 million predominantly due to studies IT-01 and IT-02 that completed their enrollments in June 2022 and August 2022 respectively. The end of enrollments resulted in a significant decrease in patient care costs. These decreases were slightly offset by the third quarter of 2023 costs related to the new manufacturing batch as preliminary work on the Phase 3 Sarcoma study noted earlier. Stock based compensation increased by approximately \$353,700 because the nine months ended September 30, 2022 include a reduction of approximately \$132,000 due to forfeited options from a former employee and the options and warrants issued in December 2022.

General and Administrative expenses increased by 8.0%. Salaries and payroll taxes increased by 18.5% due to a larger percentage of the CEO's time being spent on general and administrative activities and a salary increase to the Principal Accounting Officer. Legal expenses decreased by \$224,186; 2022 had legal costs related to unsuccessful attempts at an IPO. Insurance increased due to the additional directors and officers' insurance as a publicly held company. Facilities and rent decreased since we relocated our offices to a less expensive space that also locates us closer to an area where we believe will have better employee recruitment.

Other income (expense) in the first nine months of 2022 included interest expense on the convertible notes which were converted to common stock on June 29, 2023. Other income (expense) in the first nine months of 2023 includes approximately \$2.3 million loss on debt conversion at the time of the IPO, plus \$148,026 of interest income earned on marketable debt securities and cash and cash equivalents which increased in the third quarter of 2023 due to the proceeds of both our IPO and the sale of overallotment shares.

The deemed dividend represents the value that was transferred to the Series B and C preferred stockholders upon triggering of anti-dilution provisions.

Liquidity and Capital Resources

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of our product candidates. We expect that our research and development and general and administrative costs will continue to increase significantly, including in connection with conducting clinical trials for our product candidates, developing our manufacturing capabilities and building and qualifying our manufacturing facility to support clinical trials and commercialization and providing general and administrative support for our operations, including the cost associated with operating as a public company. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources.

We do not currently have any approved products and have never generated any revenue from product sales. We have financed our operations primarily through an initial investment from our founder, the issuance and sale of convertible debt notes, the issuance and sale of private equity financings, and an IPO, after which shares of our common stock began trading on the Nasdaq Capital Market ("Nasdaq") under the symbol "INTS" on June 30, 2023. As of September 30, 2023, our cash and cash equivalents and investments in U.S. treasury bills were approximately \$15.6 million. Based on our balances in cash, cash equivalents, and investments in U.S. treasury bills, we project to have sufficient cash to fund our current operating plan until July 2025. This operating plan includes the increase in staffing such as the Vice President of Clinical Operations and a manufacturing focused chemical engineer who began in September 2023.

The following table summarizes the net cash provided by (used in) operating activities and financing activities for the periods indicated:

	Nine Months Ended	
	September 30,	
	2023	2022
Net cash (used in) operating activities	\$ (6,257,833)	\$ (3,842,663)
Net cash (used in) investing activities	(8,844,379)	-
Net cash provided by financing activities	20,484,160	-
Net increase (decrease) in cash and cash equivalents	<u>\$ 5,381,948</u>	<u>\$ (3,842,663)</u>

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2023 was approximately \$6.3 million. This is primarily attributable to the loss of approximately \$7.4 million offset by: approximately \$2.3 million for the non-cash loss on the conversion of convertible notes into shares of common stock; approximately \$1.0 million for the non-cash stock based compensation; an increase of approximately \$0.9 million to prepaid insurance expense, and a decrease in accounts payable and accrued expenses of approximately \$1.6 million.

Net cash used in operating activities for the nine months ended September 30, 2022 was predominantly the net loss of approximately \$6.1 million. The predominant differences between the approximately \$6.1 million in operating loss and the approximately \$3.8 million in net cash flows from operating activities are approximately \$0.5 million in non-cash stock compensation and approximately \$1.6 million increase in accounts payable and accrued expenses.

Investing Activities

The Company invested approximately \$8.8 million of the proceeds of both the IPO and sale of the over-allotment shares in U.S. treasury bills with original maturities between approximately 3 and 6 months.

There was no cash provided by or used in investing activities for the nine months ended September 30, 2022.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2023 consisted predominantly of approximately \$22.4 million in gross proceeds from both the IPO and sale of the over-allotment shares, less underwriter fees and issuance costs of approximately \$2.2 million. The Company received approximately \$243,000 from the sale of convertible notes prior to the IPO and \$50,000 in proceeds from the exercise of warrants and option.

There was no net cash provided by financing activities for the nine months ended September 30, 2022.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of September 30, 2023.

Seasonality

Our business experiences limited seasonality.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. The preparation of our financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience, known trends and events, and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may materially differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our financial statements included elsewhere in this report, we believe that the following accounting policies are those most significant to the judgments and estimates used in the preparation of our financial statements.

Accrued Research and Development Expenses

Research and development costs are expensed as incurred. We record the estimated patient care costs as services are provided but not yet invoiced and include these costs in the accrued expenses in the balance sheet and within research other expense in the statement of operations.

Equity-Based Compensation

We recognize compensation costs related to stock option grants to employees and board members and warrant grants to nonemployees based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value and the resulting stock-based compensation expense using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards is recognized on a straight-line basis over the requisite service periods, which are generally the vesting period of the respective awards. Forfeitures are accounted for as they occur.

We historically have been a private company and lack company-specific historical and implied volatility information for our shares. Therefore, we estimate our expected share price volatility based on the historical volatility of publicly traded peer companies and expect to continue to do so until such time as we have adequate historical data regarding the volatility of our own traded share price.

JOBS Act Accounting Election

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Subject to certain conditions set forth in the JOBS Act, if, as an "emerging growth company", we choose to rely on such exemptions we may not be required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis), and (iv) disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of the CEO's compensation to median employee compensation. These exemptions will apply for a period of five years following the completion of our IPO or until we are no longer an "emerging growth company," whichever is earlier.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 4. Controls and Procedures

Historically, as a privately held company, we have maintained internal controls over financial reporting but we have a material weakness due to a lack of segregation of duties since we have a limited administrative staff. However, these internal controls have not been subject to the testing required under the standards of publicly traded companies by Section 404 of Sarbanes-Oxley. We are not currently required to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act, and are therefore not required to make a formal assessment of the effectiveness of our internal controls over financial reporting for that purpose. However, at such time as Section 404 of the Sarbanes-Oxley Act is applicable to us, we will be required to evaluate our internal controls over financial reporting.

Evaluation of Disclosure Controls and Procedures: We maintain disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”) that are designed to ensure that the information required to be disclosed by us in the reports filed or submitted by us under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and such information is accumulated and communicated to management, including the Chief Executive Officer, Executive Vice President of Corporate Finance, the Interim Chief Financial Officer (who is also the Controller and Principal Accounting Officer) and two other independent financial consultants, as appropriate, to allow timely decisions regarding required disclosure. Disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurances of achieving the desired controls.

As of September 30, 2023, we carried out an evaluation, under the supervision and with the participation of our management, including the Chief Executive Officer, Executive Vice President of Corporate Finance and the Interim Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures defined above. Based upon that evaluation, our Chief Executive Officer, Executive Vice President of Corporate Finance and Interim Chief Financial Officer have concluded that, as of September 30, 2023, our disclosure controls and procedures were not effective at the reasonable assurance level. In June 2023, the Company appointed an Interim Chief Financial Officer and Executive Vice President of Corporate Finance, but there continues to be a lack of segregation of duties due to a limited number of administrative employees and consultants resulting in a material weakness in internal controls.

In response to the above identified weakness, we are taking the following remediation measures:

- We are reassessing our accounting procedures and, as part of the financial reporting process, plan to implement the use of supplementary checks and additional reviews and evaluations of transactions to improve the accuracy and reliability of our financial information.
- We are adding appropriate resources to ensure that such procedures are implemented and adequate reviews are performed.

Our Chief Executive Officer, along with other key members of management, are and will be active participants in these remediation processes and such processes will be subject to audit committee oversight. We believe these steps will improve the effectiveness of our internal controls. While we plan to take the above steps to remediate these weaknesses, we cannot assure you that we will be able to fully remediate them, which could impair our ability to accurately and timely meet our public company reporting requirements.

Limitations on the Effectiveness of Controls Our management, including the Chief Executive Officer, Executive Vice President, Corporate Finance and the Chief Financial Officer, recognizes that any set of controls and procedures, no matter how well-designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired control objectives. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, with us have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of controls. For these reasons, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. This lack of segregation of duties from a limited number of administrative employees is a material weakness in internal controls. In our plan to start to address these weaknesses, in August 2021, the Company established a Chief Financial Officer position through a consulting agreement with Danforth Advisors in order to add an additional layer of oversight on the financial reporting process with assistance from another Danforth consultant to address this material weakness. In June 2023, to meet listing requirements of Nasdaq, our Principal Accounting Officer and Controller, John Wesolowski, became our full-time Interim Chief Financial Officer and James Ahlers became our Executive Vice President of Corporate Finance.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we are made aware of legal allegations arising in the ordinary course of our business. We are not currently a party to any actions, claims, suits or other legal proceedings the outcome of which, if determined adversely to Intensity, would individually or taken together have a material adverse effect on our business, operating results, cash flows or financial condition.

Item 1A. Risk Factors

As of the date of this Quarterly Report, other than the below, there have not been any material changes to the information related to the “Risk Factors” disclosure in the Company’s Final Prospectus on Form 424(b)(4) dated June 29, 2023. Our business involves significant risks. You should carefully consider the risks and uncertainties described in our Final Prospectus, together with all of the other information in this Quarterly Report on Form 10-Q, as well as our audited consolidated financial statements and related notes as disclosed in our Final Prospectus. The risks and uncertainties described in our prospectus are not the only ones we face.

Additional risk and uncertainties that we are unaware of or that we deem immaterial may also become important factors that adversely affect our business. The realization of any of these risks and uncertainties could have a material adverse effect on our reputation, business, financial condition, results of operations, growth and future prospects as well as our ability to accomplish our strategic objectives. In that event, the market price of our common stock could decline and you could lose part or all of your investment.

The recent attack by Hamas on Israel from the Gaza Strip could have an unpredictable effect on the global economy and on international and local securities markets, and adversely affect our business and results of operations.

On October 7, 2023, Hamas militants and members of other terrorist organizations infiltrated Israel’s southern border from the Gaza Strip and conducted a series of terror attacks on civilian and military targets. Thereafter, these terrorists launched extensive rocket attacks on Israeli population and industrial centers located along the Israeli border with the Gaza Strip. Shortly following the attack, Israel’s security cabinet declared war against Hamas. The intensity and duration of Israel’s current war against Hamas is difficult to predict.

A downturn in the worldwide economy resulting the recent attack by Hamas on Israel from the Gaza Strip and other conflicts with a global impact that may arise from time to time could have a material adverse effect on our business, results of operations, and/or financial condition.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit	Description
31.1*	<u>Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2*	<u>Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
32.1*	<u>Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
32.2*	<u>Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

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.

INTENSITY THERAPEUTICS, INC.

By: /s/ Lewis H. Bender
Lewis H. Bender
President and Chief Executive Officer
(principal executive officer)

Date: November 13, 2023

By: /s/ John Wesolowski
John Wesolowski
Interim Chief Financial Officer,
Principal Accounting Officer and Controller
(principal financial and accounting officer)

Date: November 13, 2023

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

I, Lewis H. Bender, certify that:

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

Date: November 13, 2023

By: _____ /s/ Lewis H. Bender

Lewis H. Bender
President and Chief Executive Officer

