
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10-Q

(Mark One)

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

For the quarterly period ended **September 30, 2024**

OR

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

For the transition period from _____ to _____
Commission file number **001-41109**

INTENSITY THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)
1 Enterprise Drive, Suite 430, Shelton, CT
(Address of Principal Executive Offices)

46-1488089
(I.R.S. Employer
Identification No.)
06484-4779
(Zip Code)

(203) 221-7381

Registrant's telephone number, including area code

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

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, \$0.0001 par value	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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<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 Act).

Yes No

As of November 12, 2024, the registrant had 13,867,697 shares of common stock outstanding.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this report, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “will,” “project,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- 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;
- our expectations related to the use of our cash and cash equivalents and investments;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and
- other factors discussed herein and under the heading “Risk Factors” in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the “SEC”) on March 14, 2024 (the “2023 Annual Report”), and this Quarterly Report on Form 10-Q.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this Quarterly Report on Form 10-Q, or in any document incorporated by reference, might not occur. Stockholders are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise except as required by law. All forward-looking statements in this Quarterly Report on Form 10-Q attributable to us or to any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

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

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Part I - Financial Information

Item 1. Condensed Financial Statements

INTENSITY THERAPEUTICS, INC.
CONDENSED BALANCE SHEETS
(in thousands, except share and per share amounts)

	September 30, 2024 (Unaudited)	December 31, 2023 *
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 2,782	\$ 8,556
Marketable debt securities	—	6,220
Prepaid expenses and other current assets	1,005	688
Total current assets	3,787	15,464
Right-of-use asset, net	128	147
Other assets	1,298	1,684
Total assets	<u>\$ 5,213</u>	<u>\$ 17,295</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 540	\$ 3,048
Accrued expenses	1,749	891
Lease liability, current portion	28	20
Total current liabilities	2,317	3,959
Other long-term liabilities	—	36
Lease liability, long-term portion	117	138
Total liabilities	<u>2,434</u>	<u>4,133</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value \$.0001. Authorized shares of 15,000,000 as of both September 30, 2024 and December 31, 2023. None issued and outstanding as of both September 30, 2024 and December 31, 2023.	—	—
Common stock, par value \$.0001. Authorized shares of 135,000,000 as of September 30, 2024 and December 31, 2023, respectively. Issued and outstanding shares of 13,863,947 and 13,709,377 as of September 30, 2024 and December 31, 2023, respectively.	1	1
Additional paid-in capital	66,380	63,676
Accumulated deficit	(63,602)	(50,515)
Total stockholders' equity	<u>2,779</u>	<u>13,162</u>
Total liabilities and stockholders' equity	<u>\$ 5,213</u>	<u>\$ 17,295</u>

*Derived from audited financial statements

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

INTENSITY THERAPEUTICS, INC.
CONDENSED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 2,151	\$ 1,352	\$ 8,529	\$ 2,985
General and administrative	1,419	1,139	4,853	1,982
Total operating expenses	<u>3,570</u>	<u>2,491</u>	<u>13,382</u>	<u>4,967</u>
Loss from operations	(3,570)	(2,491)	(13,382)	(4,967)
Other income (expense):				
Interest income	48	148	286	148
Interest expense	-	-	-	(305)
Loss on debt extinguishment	-	-	-	(2,262)
Other income (expense), net	9	14	9	20
Net loss	<u>\$ (3,513)</u>	<u>\$ (2,329)</u>	<u>\$ (13,087)</u>	<u>\$ (7,366)</u>
Preferred stock deemed dividend	-	-	-	(1,324)
Net loss attributable to common stockholders	<u>\$ (3,513)</u>	<u>\$ (2,329)</u>	<u>\$ (13,087)</u>	<u>\$ (8,690)</u>
Loss per share, basic and diluted	\$ (0.25)	\$ (0.17)	\$ (0.95)	\$ (1.26)
Weighted average number of shares of common stock, basic and diluted	13,804,651	13,660,627	13,742,325	6,899,984

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

INTENSITY THERAPEUTICS, INC.
CONDENSED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIENCY)
(in thousands, except share amounts)
(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
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balances at December 31, 2023	-	\$ -	-	\$ -	-	\$ -	13,709,377	\$ 1	\$ 63,676	\$ (50,515)	\$ 13,162
Exercise of warrants	-	-	-	-	-	-	2,500	-	8	-	8
Stock-based compensation expense	-	-	-	-	-	-	-	-	1,155	-	1,155
Net loss	-	-	-	-	-	-	-	-	-	(4,603)	(4,603)
Balances at March 31, 2024	-	-	-	-	-	-	13,711,877	1	64,839	(55,118)	9,722
Exercise of options	-	-	-	-	-	-	1,000	-	3	-	3
Stock-based compensation expense	-	-	-	-	-	-	-	-	591	-	591
Net loss	-	-	-	-	-	-	-	-	-	(4,971)	(4,971)
Balances at June 30, 2024	-	-	-	-	-	-	13,712,877	1	65,433	(60,089)	5,345
Exercise of options	-	-	-	-	-	-	87,500	-	263	-	263
Stock-based compensation expense	-	-	-	-	-	-	-	-	483	-	483
Issuance of common stock in exchange for services	-	-	-	-	-	-	11,750	-	51	-	51
Issuance of common stock in ATM offering, net of \$82 issuance costs	-	-	-	-	-	-	51,820	-	150	-	150
Net loss	-	-	-	-	-	-	-	-	-	(3,513)	(3,513)
Balances at September 30, 2024	-	\$ -	-	\$ -	-	\$ -	13,863,947	\$ 1	\$ 66,380	\$ (63,602)	\$ 2,779

	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	1,449,113	\$ -	1,800,606	\$ -	3,410,103	\$ -	\$ 23,555	\$ (38,653)	\$ (15,098)
Warrants issued to convertible note holders	-	-	-	-	-	-	-	-	159	-	159
Stock-based compensation expense	-	-	-	-	-	-	-	-	312	-	312
Net loss	-	-	-	-	-	-	-	-	-	(1,336)	(1,336)
Balances at March 31, 2023	5,000,000	10,000	1,449,113	-	1,800,606	-	3,410,103	-	24,026	(39,989)	(15,963)
Issuance of common stock in public offering for cash, net of \$3,031 issuance costs	-	-	-	-	-	-	3,900,000	-	16,468	-	16,468
Warrants issued to underwriters in connection with public offering	-	-	-	-	-	-	-	-	1,017	-	1,017
Issuance of preferred stock for anti-dilution clauses	-	-	100,189	-	164,518	-	-	-	-	-	-
Conversion of preferred stock into common stock	(5,000,000)	(10,000)	(1,549,302)	-	(1,965,124)	-	4,124,851	1	9,999	-	10,000

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Conversion of convertible notes into common stock	-	-	-	-	-	-	1,399,716	-	7,000	-	7,000
Deemed dividend	-	-	-	-	-	-	264,707	-	1,324	(1,324)	-
Stock-based compensation expense	-	-	-	-	-	-	-	-	312	-	312
Net loss	-	-	-	-	-	-	-	-	-	(3,701)	(3,701)
Balances at June 30, 2023	-	\$ -	-	\$ -	-	\$ -	13,099,377	\$ 1	\$ 60,146	\$ (45,014)	\$ 15,133
Issuance of common stock in public offering for cash, net of \$372 issuance costs	-	-	-	-	-	-	585,000	-	2,553	-	2,553
Warrants issued to underwriters in connection with public offering	-	-	-	-	-	-	-	-	153	-	153
Exercise of options	-	-	-	-	-	-	12,500	-	25	-	25
Exercise of warrants	-	-	-	-	-	-	12,500	-	25	-	25
Stock-based compensation expense	-	-	-	-	-	-	-	-	351	-	351
Net loss	-	-	-	-	-	-	-	-	-	(2,329)	(2,329)
Balances at September 30, 2023	-	\$ -	-	\$ -	-	\$ -	13,709,377	\$ 1	\$ 63,253	\$ (47,343)	\$ 15,911

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

INTENSITY THERAPEUTICS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (13,087)	\$ (7,366)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of discount on convertible notes	-	159
Change in carrying value of right-of-use asset	19	141
Stock-based compensation expense	2,229	975
Stock issued in exchange for services	25	-
Loss on debt extinguishment	-	2,262
Changes in operating assets and liabilities, net:		
Accrued interest on marketable debt securities	(134)	(111)
Prepaid expenses, other current assets, and other assets	96	(709)
Accounts payable, accrued expenses and other liabilities	(1,700)	(1,610)
Net cash used in operating activities	(12,552)	(6,259)
Cash flows from investing activities:		
Purchase of marketable debt securities	(3,056)	(8,844)
Redemption of marketable debt securities	9,410	-
Net cash provided by (used in) investing activities	6,354	(8,844)
Cash flows from financing activities:		
Proceeds from issuance of convertible note	-	243
Proceeds from ATM offering	232	-
Issuance costs related to ATM offering	(82)	-
Proceeds from Initial Public Offering and over-allotment	-	22,425
Issuance costs related to Initial Public Offering and over-allotment	-	(2,233)
Proceeds from exercise of warrants and options	274	50
Net cash provided by financing activities	424	20,485
Net (decrease) increase in cash and cash equivalents	(5,774)	5,382
Cash and cash equivalents at beginning of period	8,556	1,312
Cash and cash equivalents at end of period	\$ 2,782	\$ 6,694
Supplemental disclosure of non-cash financing activities:		
Common stock issued in exchange for services	\$ 51	\$ -
Right-of-use lease asset and operating lease liability	\$ -	\$ 155
Conversion of convertible notes and accrued interest into common stock	\$ -	\$ 4,737
Warrants issued in relation to issuance of convertible notes	\$ -	\$ 159
Warrants issued to underwriter in connection with stock issuance	\$ -	\$ 1,170
Preferred stock deemed dividend	\$ -	\$ 1,324

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

INTENSITY THERAPEUTICS, INC.
NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

Note 1. Description of Business

Intensity Therapeutics, Inc. (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. The Company is based in Connecticut and was incorporated in Delaware in December 2012.

As a result of its initial public offering (the “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 the IPO price of \$5.00 per share, at which time the Company issued 3,900,000 shares of its common stock for gross proceeds of \$19.5 million. After deducting offering expenses of \$2.0 million, the Company received net proceeds of \$17.5 million. On July 7, 2023, the Company sold the full over-allotment shares at the IPO price of \$5.00 per share, resulting in the issuance of 585,000 shares of its common stock for gross proceeds of \$2.9 million. After deducting offering expenses of \$0.2 million, the Company received an additional \$2.7 million in net cash proceeds.

Note 2. Liquidity and Plan of Operation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States (“GAAP”), which contemplate 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 has experienced net losses and negative cash flows from operations each year since its inception. Through September 30, 2024, the Company has an accumulated deficit of \$63.6 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, 2024 was \$13.1 million. 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.

Cash and cash equivalents totaled \$2.8 million as of September 30, 2024. Until such time the Company can generate substantial product revenue, the Company plans to finance its operations 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 existing Company stockholders may 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 and cash equivalents as of September 30, 2024, the Company believes that it has sufficient cash into the first quarter of 2025 for its projected current operations. As a result, the Company believes there is substantial doubt about its ability to continue as a going concern.

Note 3. Basis of Presentation and Summary of Significant Accounting Policies

Basis of presentation

The interim condensed financial statements included herein are unaudited. In the opinion of management, these statements include all adjustments, consisting only of normal, recurring adjustments, necessary for a fair presentation of the financial position of the Company at September 30, 2024, and its results of operations and its cash flows for the three and nine months ended September 30, 2024 and 2023. The interim results of operations are not necessarily indicative of the results to be expected for a full year. These interim unaudited financial statements should be read in conjunction with the audited financial statements for the years ended December 31, 2023 and 2022 and notes thereto. The accompanying financial statements have been prepared in accordance with GAAP and reflect the operations of the Company. Certain information and note disclosures normally included in financial statements prepared in accordance with GAAP have been omitted pursuant to such rules and regulations of the Securities and Exchange Commission relating to interim financial

statements. The December 31, 2023 balance sheet information was derived from the audited financial statements as of that date. The Company neither owns nor controls any subsidiary companies.

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.

As of September 30, 2024 and December 31, 2023, the Company invested zero and \$6.2 million, respectively in U.S. Treasury Bills, included in marketable debt securities, which were classified as available-for-sale. U.S. Treasury Bills were valued at market prices obtained from independent vendor services, which the Company believes to be reliable. In some cases, the pricing vendor may provide prices quoted by a single broker or market maker. U.S. Treasury Bills were categorized in Level 2 of the fair value hierarchy.

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.

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.

The Company had been a private company and lacked company-specific historical and implied volatility information for its shares. Therefore, the Company estimated its expected share price volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded share price.

Research and development costs

The Company is required to estimate its expenses resulting from its obligations under contracts with vendors, consultants, contract research organizations ("CRO"), and contract manufacturing organizations ("CMO") in connection with conducting research and development activities. The financial terms of these contracts vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts.

Research and development costs are expensed in the period in which they are incurred. External costs consist primarily of payments to outside consultants, third-party CROs, CMOs, clinical trial sites and central laboratories in connection with the Company's clinical manufacturing and clinical development activities. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to the Company by its service providers or its estimate of the level of service that has been performed at each reporting date. The Company tracks external costs based on research and development initiative, including preclinical, individual clinical study, and

manufacturing activities. Internal costs consist primarily of employee-related costs and costs related to compliance with regulatory requirements. The Company does not track internal costs by program because these costs are deployed across multiple programs and, as such, are not separately classified.

The Company makes estimates of accrued expenses as of each balance sheet date based on facts and circumstances known at that time. The Company periodically confirms the accuracy of its estimates with the service providers and makes adjustments if necessary. The significant estimates in its accrued research and development expenses include the costs incurred for services performed by vendors in connection with research and development activities for which the Company has not yet been invoiced.

In July 2024, the Company initiated a Phase 3 open-label, randomized study for certain soft tissue sarcoma subtypes, which is expected to span several years. In connection with this study, the Company recorded an advance payment of \$ 1.7 million in December 2023, which will be applied to future invoices during and at the end of the study. As of September 30, 2024 and December 31, 2023, the advance payment balances were \$ 1.2 million and \$1.7 million, respectively, and were recorded in Other Assets in the Balance Sheet.

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 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 the exercise of stock options and warrants are excluded from the computation of diluted weighted average shares outstanding listed in the table below because, when the Company is in a net loss position, they are anti-dilutive. There were no preferred shares or convertible notes outstanding at September 30, 2024 and 2023.

As of September 30, 2024 and 2023, the following shares of common stock underlying options and warrants were excluded from the computation of diluted weighted average shares outstanding:

	September 30,	
	2024	2023
Options outstanding	1,949,629	1,081,750
Warrants outstanding	829,450	689,200
	<u>2,779,079</u>	<u>1,770,950</u>

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.

Note 4. Cash and Cash Equivalents

Cash and cash equivalents consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Savings and checking accounts at major U.S. financial institutions	\$ 322	\$ 367
U.S. Treasury securities money market fund	2,460	8,189
Total	<u>\$ 2,782</u>	<u>\$ 8,556</u>

Note 5. Marketable Debt Securities

Marketable debt securities as of December 31, 2023 consisted entirely of U.S. Treasury Bills purchased with maturities over three months but less than twelve months. All marketable debt securities matured during 2024.

Note 6. Prepaid Expenses and Other Current Assets

Prepaid expenses consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Prepaid insurance	\$ 566	\$ 647
Prepaid research and development costs	311	—
Prepaid other	128	41
Total	<u>\$ 1,005</u>	<u>\$ 688</u>

Note 7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Accrued research and development costs	\$ 1,073	\$ 439
Accrued employee compensation-related expenses	616	392
Accrued other	60	60
Total	<u>\$ 1,749</u>	<u>\$ 891</u>

Note 8. Stockholders' Equity***Initial public offering***

On July 5, 2023, as described in Note 1, the Company completed its IPO, issuing 3,900,000 shares of common stock at the IPO price of \$5.00 per share. 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.

At The Market Offering Agreement

On July 3, 2024, the Company entered into an At The Market Offering Agreement (the "Sales Agreement") with H.C. Wainwright & Co., LLC ("Wainwright"), pursuant to which the Company may sell and issue, from time to time, up to \$15.0 million of shares of its common stock (the "Shares") through Wainwright as the Company's sales agent (the "ATM Offering"). The Company has no obligation to sell any of the Shares and may at any time suspend offers under the Sales Agreement or terminate the Sales Agreement pursuant to its terms. For the three and nine months ended September 30, 2024, the Company issued 51,820 shares of common stock under the ATM Agreement for net proceeds of \$0.2 million.

Note 9. Stock Based Compensation

The Company has a 2013 Stock Option Plan (the "2013 Plan"), which is administered by the Compensation Committee of the Company's board of directors. Under the 2013 Plan, stock options to purchase shares of common stock could be granted to eligible employees, officers, directors and consultants of the Company.

In 2021, the Company established 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. 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, 2024, an additional 479,828 shares were authorized under the 2021 Plan. As of September 30, 2024, 2,519,149 shares were available for issuance under the 2021 Plan.

The Company recorded total stock-based compensation for its outstanding stock options and warrants in its Statements of Operations as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	\$ 187	\$ 186	\$ 970	\$ 651
General and administrative	296	165	1,259	324
Total stock-based compensation expense	\$ 483	\$ 351	\$ 2,229	\$ 975

Stock options

The following table summarizes the range of assumptions used to estimate the fair value of stock options issued using the Black-Scholes-Merton option pricing model:

	Nine Months Ended September 30,	
	2024	2023
Stock price	\$3.76 to \$5.19	\$6.43
Exercise price	\$3.76 to \$5.19	\$6.43
Expected volatility	97.06% to 101.55%	99.74%
Risk free interest rates	4.12% to 4.46%	3.87%
Expected term (years)	5 to 7	5.75

For the nine months ended September 30, 2024 and 2023, a dividend yield of 0% was used because the Company has not historically paid and does not intend to pay a dividend on common stock in the foreseeable future. The expected stock price volatility assumption was estimated based on the historical volatilities for industry peers, as the Company had no active market for its stock prior to the IPO and limited history for issuance price of its stock. The risk-free rate assumption is determined using the yield currently available on U.S. Treasury zero coupon issues with a remaining term commensurate with the expected term of the award. The expected term of the option represents the period the options are expected to be outstanding.

The following table summarizes the activity for stock options for the nine months ended September 30, 2024:

	Options	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	1,239,750	\$ 8.00	6.4	\$ 1,865
Issued	798,379	\$ 5.06		
Exercised	(88,500)	\$ 3.01		
Forfeited and cancelled	—	\$ —		
Outstanding at September 30, 2024	1,949,629	\$ 7.02	7.5	\$ 81
Exercisable at September 30, 2024	1,053,525	\$ 8.24	6.0	\$ —

All options expire 10 years from date of grant. Options outstanding begin to expire in October 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.

The weighted average grant date fair value of stock options issued was \$.98 for the nine months ended September 30, 2024.

As of September 30, 2024, total unrecognized compensation cost related to options was approximately \$0.0 million and is expected to be recognized over the remaining weighted average service period of 2.5 years.

Warrants

The following table summarizes the range of assumptions used to estimate the fair value of warrants issued using the Black-Scholes-Merton option pricing model:

	Nine Months Ended September 30,	
	2024	2023
Stock price	\$4.50 to \$5.19	\$4.50 to \$5.00
Exercise price	\$4.50 to \$5.19	\$6.00 to \$6.25
Expected volatility	97.06% to 100.64%	101.46% to 103.85%
Risk free interest rates	4.12% to 4.39%	3.59% to 3.97%
Expected term (years)	5 to 6.25	3 to 5

For the nine months ended September 30, 2024 and 2023, a dividend yield of 0% was used because the Company has not historically paid and does not intend to pay a dividend on common stock in the foreseeable future. The expected stock price volatility assumption was estimated based on the historical volatilities for industry peers, as the Company had no active market for its stock prior to the IPO and limited history for issuance price of its stock. The risk-free rate assumption is determined using the yield currently available on U.S. Treasury zero coupon issues with a remaining term commensurate with the expected term of the award. The expected term of the warrant represents the period the warrants are expected to be outstanding.

The following table summarizes the activity for warrants for the nine months ended September 30, 2024:

	Warrants	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	801,950	\$ 6.30	3.9	\$ 2,096
Issued	50,000	\$ 4.85		
Exercised	(2,500)	\$ 3.00		
Forfeited and cancelled	(20,000)	\$ 3.00		
Outstanding at September 30, 2024	<u>829,450</u>	<u>\$ 6.31</u>	<u>3.7</u>	<u>\$ 42</u>
Exercisable at September 30, 2024	<u>760,200</u>	<u>\$ 6.36</u>	<u>3.3</u>	<u>\$ 42</u>

All warrants outstanding are exercisable for purchase of common stock.

As of September 30, 2024, total unrecognized compensation cost related to warrants was approximately \$0.3 million and is expected to be recognized over the remaining weighted average service period of 2.9 years.

Restricted Stock

In September 2024, the Company issued 11,750 restricted shares of its common stock (the "Restricted Stock") to a consultant as compensation for its services to the Company through the end October 2024 valued at \$51,000. The Restricted Stock will include a restricted legend for a period of at least six months from the date of issuance, after which time such restricted legend may be removed. During the three and nine months ended September 30, 2024, the Company recognized \$25,000 to general and administrative expenses and \$26,000 to prepaid expenses and other current assets.

Note 10. Leases

In January 2017, the Company entered into a lease for approximately 2,500 square feet of office space in Westport, Connecticut, (the “Westport Lease”), which was subsequently extended and increased to approximately 4,000 square feet. In June 2023, the Westport Lease was terminated.

In July 2023, the Company signed a 5.5-year lease for approximately 2,700 square feet of office space in Shelton, Connecticut, (the “Shelton Lease”). 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. A payment of approximately \$47,000 would be due at the end of month 36 if the Company exercises this option. This option is not reasonably certain to occur.

Rent expense for the three and nine months ended September 30, 2024 was approximately \$9,000 and \$26,000, respectively, and for the three and nine months ended September 30, 2023 was \$3,000 and \$55,000, respectively.

Cash paid for operating leases for the three and nine months ended September 30, 2024 was approximately \$7,000 and \$38,000, respectively, and for the three and nine months ended September 30, 2023 was zero and \$49,000, respectively.

The following table summarizes the balance sheet classification of the operating lease asset and related lease liabilities as of September 30, 2024 and December 31, 2023 (in thousands):

	September 30, 2024	December 31, 2023
Right-of-use asset, net	\$ 128	\$ 147
Lease liability, current portion	28	20
Lease liability, net of current portion	117	138
	<u>\$ 145</u>	<u>\$ 158</u>

The following variables were used to determine the right-of-use asset and the operating lease liabilities at September 30, 2023 and 2022:

	September 30, 2024	September 30, 2023
Weighted average remaining lease term	4.4 years	5.4 years
Weighted average operating lease discount rate	6.4 %	6.4 %

Future minimum lease payments under the lease agreement as of September 30, 2024 were as follows (in thousands):

Year ended	
2024 (remainder of year)	\$ 9
2025	36
2026	37
2027	39
2028 and thereafter	46
Total lease payments	167
Less: Amounts representing interest	(22)
Present value of lease liabilities	<u>\$ 145</u>

Note 11. Other Uncertainties

The Company holds one of its patents in Russia. The payment for this patent is paid until September 15, 2025. 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 12. Related Parties

In October 2023, the Company issued 80,000 warrants for consulting services to be rendered by two shareholders, which will vest over the subsequent twelve months. These warrants are valued at \$198,000 and will be expensed to general and administrative expense over the subsequent twelve-month period, of which \$4,500 and \$134,000 were expensed during the three and nine months ended September 30, 2024.

In April 2024, the Company entered into a non-material agreement with a service organization controlled by a board member. For both the three and nine months ended September 30, 2024, the Company expensed \$20,010 and paid \$10,850 to the service organization for services performed, which is recognized in research and development expenses on the statement of operations. As of September 30, 2024, the Company recognized \$9,160 in accrued expenses.

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

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and in our 2023 Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and financing needs, includes forward-looking statements that involve risks and uncertainties. Such statements should be read together with the "Risk Factors" sections of this Quarterly Report on Form 10-Q and the 2023 Annual Report, which discuss important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. See "Cautionary Statement Regarding Forward-Looking Statements".

Overview

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

Intratumoral ("IT") treatment, or treatment designed to contain a drug inside a tumor without spreading to the rest of the body, has been an objective of clinicians since discovery of chemotherapeutic agents. The challenge with IT treatment approaches is that a tumor's lipophilic, high fat, dense and pressurized microenvironment is incompatible with and does not absorb water-based products. We believe that this drug delivery challenge limits the effectiveness of prior and current IT treatments, which involve injecting aqueous drugs into a tumor without sufficient consideration of the tumor environment (regardless of the drug's mechanism or approach, i.e. the stimulation of an inflammatory response or efforts to attract immune cells into a hostile live tumor). 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 a product candidate with the necessary chemistry to overcome this local delivery challenge and achieve tumor killing with systemic immune activation and T-cell repertoire expansion in certain cancers.

Our platform has enabled us to create 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 an amphiphilic compound is mixed with therapeutic agents, such as chemotherapies, the agents 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, is primarily comprised of three components: (i) cisplatin, a proven anti-cancer cytotoxic agent, (ii) vinblastine sulfate, also a proven anti-cancer cytotoxic agent, and (iii) an amphiphilic molecule ("SHAO"), which enables the two cytotoxic agents to disperse through a tumor and diffuse into cancer cells following a direct intratumoral injection. These three components are mixed and combined into one vial at a fixed ratio. Cisplatin and vinblastine sulfate are both generic and available to purchase in bulk supply commercially. The United States Food & Drug Administration ("FDA") has approved both drugs as intravenous agents for several types of cancers. Cisplatin was first approved in 1978 for testicular cancer, and is also approved in ovarian and bladder cancer. The drug is also used widely in several other cancers including pancreatic and bile duct cancer. Vinblastine sulfate was first approved in 1965 and is also approved in generalized Hodgkin's disease, lymphocytic lymphoma, advanced carcinoma of the testis, and certain types of sarcoma. The drug is also used in breast and lung cancer.

Recent Developments

In September 2024, we received authorization from the Swiss Medic and the Swiss Ethics Commission to initiate the INVINCIBLE-4 Study in Switzerland, a Phase 2 randomized open-label, multicenter study, to analyze the clinical activity, safety, and tolerability of INT230-6 given before administration of the standard of care ("SOC") treatment in patients with early-stage, operable triple-negative breast cancer ("TNBC") and SOC alone.

In October 2024, we dosed the first patient in the INVINCIBLE-4 Study. The primary endpoint is the pathological complete response ("pCR") rate in the primary tumor and affected lymph nodes. The INVINCIBLE-4 Study is expected to enroll approximately 54 patients in Switzerland and France.

Our Clinical Programs

In July 2024, we dosed the first patients in the U.S. in a Phase 3 open-label, randomized study, or the INVINCIBLE-3 Study, testing INT230-6 as monotherapy compared to the SOC drugs in second and third line treatment

for certain soft tissue sarcoma subtypes. In the third quarter of 2024, we also received authorization from Health Canada and The European Medicines Agency to initiate the INVINCIBLE-3 Study in Canada and Europe, respectively. We plan to enroll 333 patients and initiate sites in eight countries in the INVINCIBLE-3 Study, and are in contract negotiations to approve and activate additional sites, which we estimate could take several months per site. The primary endpoint in the INVINCIBLE-3 Study is overall survival.

In 2017, we initiated a Phase 1/2 dose escalation study, IT-01, using INT230-6 in the United States under an investigational new drug application authorized by the FDA and in Canada under a preclinical trial application approved by Health Canada. Study IT-01 tested the safety and efficacy of INT230-6 in patients with refractory or metastatic cancers, and enrolled 110 patients in three arms: (i) INT230-6 used as a monotherapy, (ii) INT230-6 in combination with Merck's Keytruda® (pembrolizumab), and (iii) INT230-6 in combination with BMS Yervoy® (ipilimumab). We completed enrollment of IT-01 in June 2022, locked the IT-01 database in February 2023 and finalized the clinical study report in September 2023. We delivered the combination-specific reports and other information to our partners in the fourth quarter of 2023.

In 2021, we initiated a Phase 2 randomized study that tested INT230-6 as a monotherapy treatment in early-stage breast cancer for patients not suitable for presurgical chemotherapy, or the INVINCIBLE-2 Study. The study enrolled 91 subjects and the database was locked in November 2023. The key endpoint was whether INT230-6 could reduce a patient's cancer compared to no treatment (the current SOC) or a saline injection. Substantial reduction of cancer presurgically in aggressive forms of cancer has been shown to correlate with delaying disease recurrence. Other endpoints of the INVINCIBLE-2 Study were to understand the percentage of necrosis that can be achieved in tumors for a given dose, especially tumors larger than two centimeters in longest diameter, and whether either a local or whole body anti-cancer immune response could be induced. The INVINCIBLE-2 Study demonstrated a high order of necrosis in presurgical breast cancer tumors in the period from diagnosis to surgery, with some patients experiencing greater than 95% necrosis of the tumor. Data from the INVINCIBLE-2 Study demonstrated that INT230-6 had a favorable safety profile. An increase of certain types of immune cells (CD4+ and NK T-cells) in the tumor and blood was also shown. There was also an increase in the T-cells repertoire relative to control. In July 2024, we finalized the clinical study report for the INVINCIBLE-2 Study.

We have also successfully developed Phase 3 quality analytical methods for the three INT230-6 components and successfully manufactured a large-scale batch of INT230-6. In a meeting with the FDA in the fourth quarter of 2023, we agreed on a chemical manufacture and control ("CMC") plan for Phase 3 and product registration for our three key ingredients and INT230-6. If we successfully execute the agreed upon plan, the CMC portion of a New Drug Application ("NDA") should be acceptable to the FDA for product approval and registration (subject to final NDA review). In the first quarter of 2024, a portion of the batch was successfully delivered to our depot vendor, who will supply INT230-6 for the INVINCIBLE-3 and INVINCIBLE-4 studies.

Since our inception in 2012, our operations have included business planning, hiring personnel, raising capital, building our intellectual property portfolio, and performing 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, 2024, we had approximately \$2.8 million of cash and cash equivalents. Since our inception, we have incurred significant operating losses. We incurred net losses of \$13.1 million and \$7.4 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of \$63.6 million. We expect to incur significant expenses and operating losses for the next several years.

We expect our expenses to increase as we continue to:

- Fund our clinical studies in sarcoma and breast cancer;
- Incur manufacturing costs for additional Good Manufacturing Practice ("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 Expenses

- *Salaries and Benefits Related Costs* include employee-related expenses such as salaries and related benefits for employees engaged in research and development functions.
- *Clinical Trial Expenses* includes payments to third parties in connection with the clinical development of our product candidates, including CROs, and costs due to clinical trials for patient care.
- *Contract Manufacturing* includes:
 - Manufacturing of products for use in our preclinical studies and clinical trials, including payments to CMOs;
 - Manufacture of new enhancer compounds;
 - Manufacture and labelling of GMP product candidate;
 - Product candidate stability testing of GMP batches; and
 - Other costs such as shipping, storage, and analytical testing.
- *Consulting* costs related to non-employees involved in research, including 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* relates to stock options granted to employees and warrants granted to independent consultants engaged in research and development functions.

General and Administrative Expenses

- *Salaries and Benefits Related Costs* include employee-related expenses such as salaries and related benefits for employees engaged in fund raising, management, and corporate administration functions.
- *Legal Fees* include expenses for corporate, patent and trademark fees with outside law firms.
- *Audit Fees* consist of fees billed for professional services rendered for the audit of our annual financial statements, review of our interim financial statements, comfort and consent letters.
- *Consulting* services provided by non-employees for general and administrative tasks, includes accounting, tax, human resources, finance, investor relations, board compensation, and internet support.
- *Insurance* includes directors and officers insurance, workers compensation insurance, product liability insurance, business insurance, employee and cyber liability insurance.
- *Other* includes facility expenses, office supplies, computer related costs, public relations costs, recruiting costs and conferences.
- *Stock-based Compensation* relates 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.

Results of Operations

The following tables summarize our results of operations for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
Operating expenses:						
Research and development	\$ 2,151	\$ 1,352	\$ 799	\$ 8,529	\$ 2,985	\$ 5,544
General and administrative	1,419	1,139	280	4,853	1,982	2,871
Total operating expenses	3,570	2,491	1,079	13,382	4,967	8,415
Loss from operations	(3,570)	(2,491)	(1,079)	(13,382)	(4,967)	(8,415)
Interest income	48	148	(100)	286	148	138
Interest expense	-	-	-	-	(305)	305
Loss on debt extinguishment	-	-	-	-	(2,262)	2,262
Other income (expense), net	9	14	(5)	9	20	(11)
Net loss	\$ (3,513)	\$ (2,329)	\$ (1,184)	\$ (13,087)	\$ (7,366)	\$ (5,721)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
Research and development expenses:						
Salaries and benefits related costs	\$ 497	\$ 103	\$ 394	\$ 1,340	\$ 432	\$ 908
Clinical trial expenses	1,399	693	706	5,442	1,402	4,040
Contract manufacturing	20	307	(287)	651	324	327
Consulting	48	63	(15)	126	176	(50)
Stock-based compensation	187	186	1	970	651	319
Total research and development expenses	\$ 2,151	\$ 1,352	\$ 799	\$ 8,529	\$ 2,985	\$ 5,544

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
General and administrative expenses:						
Salaries and benefits related costs	\$ 325	\$ 111	\$ 214	\$ 949	\$ 290	\$ 659
Legal fees	113	129	(16)	544	303	241
Audit fees	113	171	(58)	286	259	27
Consulting	233	174	59	573	274	299
Insurance	157	288	(131)	718	322	396
Other	182	101	81	524	209	315
Stock-based compensation	296	165	131	1,259	325	934
Total general and administrative expenses	\$ 1,419	\$ 1,139	\$ 280	\$ 4,853	\$ 1,982	\$ 2,871

Three Months Ended September 30, 2024 Compared to Three Months Ended September 30, 2023

Research and development expenses during the three months ended September 30, 2024 increased \$0.8 million or 59%, compared to the three months ended September 30, 2023, and were primarily due to the following:

- Salaries and benefits related costs increased \$0.4 million due to the hiring of research employees in the fourth quarter of 2023 and first quarter of 2024.
- Clinical trial expenses increased \$0.7 million due to the initiation of the INVINCIBLE-03 Study, which was partially offset by lower costs in our completed IT-01 and INVINCIBLE-02 studies.
- Contract manufacturing expenses decreased as there were no manufacturing batches in process during the third quarter of 2024.

General and administrative expenses during the three months ended September 30, 2024 increased \$0.3 million or 25%, compared to the three months ended September 30, 2023, and were primarily due to the following:

- Salaries and benefits related costs increased by \$0.2 million due to salary and bonus accrual increases and the hiring of a new chief financial officer in the fourth quarter of 2023, along with \$0.1 million in higher stock-based compensation expense due to option and stock grants in 2024.
- Insurance expense decreased by \$0.1 million due to favorable renewal for directors and officers insurance premiums.

Interest income in 2024 related to interest earned on cash and investment balances from our IPO in June 2023.

Nine Months Ended September 30, 2024 Compared to Nine Months Ended September 30, 2023

Research and development expenses during the nine months ended September 30, 2024 increased \$5.5 million or 186%, compared to the nine months ended September 30, 2023, and were primarily due to the following:

- Salaries and benefits related costs increased \$0.9 million due to the hiring of research employees in the fourth quarter of 2023 and first quarter of 2024, along with \$0.3 million in higher stock-based compensation expense.
- Clinical trial expenses increased \$4.0 million due to the initiation of the INVINCIBLE-03 Study, which was partially offset by lower costs in our completed IT-01 and INVINCIBLE-02 studies.
- Contract manufacturing expenses increased entirely due to costs for manufacturing a new batch of INT230-6 in the first half of 2024.

General and administrative expenses during the nine months ended September 30, 2024 increased \$2.9 million or 145%, compared to the nine months ended September 30, 2023, and were primarily due to the following:

- Salaries and benefits related costs increased by \$0.7 million due to salary and bonus increases and the hiring of a new chief financial officer in the fourth quarter of 2023, along with \$0.9 million in higher stock-based compensation expense due to option grants in the first quarter of 2024.
- Insurance expense increased by \$0.4 million due to the additional directors and officers insurance obtained in connection with our IPO, net of a decrease in premiums due to favorable renewal terms beginning in July 2024.
- Legal, audit and consulting fees, and other expenses increased as we completed our IPO in mid-2023 and transitioned operations as a publicly traded company.

Interest income in 2024 related to interest earned on higher cash and investment balances from our IPO in June 2023. In 2023, interest expense was related to interest expense on convertible notes outstanding, which converted to common stock at the time of our IPO, upon which we recognized a \$2.3 million loss on debt conversion. In addition, at the time of our IPO, a preferred stock deemed dividend of \$1.3 million was recognized, representing the value that was transferred to the Series B and C preferred stockholders upon triggering of anti-dilution provisions.

Liquidity and Capital Resources

Our financial statements have been prepared assuming we will continue as a going concern. We have incurred losses from operations and negative cash flows that raise substantial doubt about our ability to continue as a going concern.

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. The sale of equity and convertible debt securities may result in dilution to our stockholders. Additional capital may not be available on reasonable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, scale back or discontinue the development of our product candidates.

On July 3, 2024, we filed a universal shelf registration statement on Form S-3, which was declared effective by the SEC on July 11, 2024, on which we registered for sale up to \$150 million of any combination of our common stock, preferred stock, debt securities, warrants, and/or units from time to time and at prices and on terms that we may determine, which includes up to \$15 million of common stock that we may issue and sell from time to time, through H.C. Wainwright & Co., LLC (“Wainwright”) acting as our sales agent, pursuant to the sales agreement that we entered into with Wainwright on July 3, 2024 for our “at-the-market” equity program (the “ATM Agreement”). Since inception, we have issued 51,820 shares of common stock under the ATM Agreement for net proceeds of \$0.2 million.

We have financed our operations primarily through an initial investment from our founder, the issuance and sale of convertible notes, private equity financings, and the IPO, after which shares of our common stock began trading on The Nasdaq Capital Market under the symbol “INTS” on June 30, 2023. As of September 30, 2024, our cash, cash equivalents and investments were approximately \$2.8 million. Based on our balances in cash and cash equivalents, we project to have sufficient cash to fund our current operating plan into the first quarter of 2025.

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

	Nine Months Ended September 30,	
	2024	2023
Net cash used in operating activities	\$ (12,552)	\$ (6,259)
Net cash provided by (used in) investing activities	6,354	(8,844)
Net cash provided by financing activities	424	20,485
Net (decrease) increase in cash and cash equivalents	\$ (5,774)	\$ 5,382

Operating Activities

Our cash used in operating activities for the nine months ended September 30, 2024 was \$12.6 million, comprising of (i) our net loss of \$13.1 million, as adjusted for \$2.3 million in non-cash expenses (primarily for non-cash stock based compensation of \$2.2 million), and (ii) net changes in operating assets and liabilities of \$1.7 million.

Our cash used in operating activities for the nine months ended September 30, 2023 was \$6.3 million, comprising of (i) our net loss of \$7.4 million, as adjusted for \$3.5 million in non-cash expenses (primarily for non-cash stock based compensation of \$1.0 million and the loss on debt extinguishment of \$2.3 million), and (ii) net changes in operating assets and liabilities of \$2.4 million.

Investing Activities

Our cash provided by investing activities during the nine months ended September 30, 2024 was \$6.4 million and was due to the redemption of marketable debt securities of \$9.4 million, partially offset by the purchase of marketable debt securities of \$3.1 million.

Our cash used in investing activities during the nine months ended September 30, 2023 was \$8.8 million and was comprised entirely of purchases of marketable debt securities.

Financing Activities

Our cash provided by financing activities during the nine months ended September 30, 2024 related to \$0.3 million in proceeds received from the exercise of options and warrants, and \$0.2 million in net proceeds received from the issuance of common stock.

Our cash provided by financing activities during the nine months ended September 30, 2023 primarily related to \$22.4 million of gross proceeds from the IPO (including the sale of the overallocation shares), less issuance costs of \$2.2 million. In addition, we received \$0.2 million from the sale of convertible notes and \$0.1 million in proceeds from the exercise of options and warrants.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of September 30, 2024.

Seasonality

Our business experiences limited seasonality.

Critical Accounting Policies and Estimates

Critical accounting estimates are those policies which are both important to the presentation of a company's financial condition and results and require management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. For a further discussion of our critical accounting estimates, see our 2023 Annual Report. No significant changes to our accounting policies took place during the nine months ended September 30, 2024.

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

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, Chief Financial Officer, and Principal Accounting Officer, 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, 2024, we carried out an evaluation over the effectiveness of the design and operation of our disclosure controls and procedures defined above. Based upon that evaluation, we have concluded that, as of September 30, 2024, our disclosure controls and procedures were not effective as a result of the material weaknesses identified in internal controls due to (i) a lack of segregation of duties due to limited administrative staff, (ii) limited reconciliation and review procedures over clinical contract accruals as we have rapidly expanded into new, late-stage clinical studies, and (iii) information technology matters regarding user access that aggregate to a material weakness.

Remediation Activities

In response to the above identified weakness, we have taken or continue to take 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.
- In December 2023, we hired a new Chief Financial Officer with extensive public-company reporting and technical accounting experience to provide additional financial reporting oversight and review.
- We have engaged additional technical accounting consultants to provide additional resources for the preparation and review of our quarterly close procedures.
- We will evaluate new accounting software systems to improve system controls, and have already implemented a new financial reporting and filing software platform to leverage system-controls and streamline quarterly SEC filings controls.

Our Chief Executive Officer, Chief Financial Officer, and Principal Accounting Officer are active participants in these ongoing remediation processes and such processes are subject to audit committee oversight. We believe these steps will improve the effectiveness of our internal controls. While we are taking 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 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.

Changes in Internal Control over Financial Reporting

There have been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2024 covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. Our risk factors have not changed materially from those described in "Part I, Item 1A. Risk Factors" of our 2023 Annual Report.

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

On June 29, 2023, our Registration Statement on Form S-1 (File No. 333-260565) was declared effective in connection with our IPO, pursuant to which we sold an aggregate of 3,900,000 shares of common stock to The Benchmark Company, LLC, as representative of the underwriters (the "Representative"), at a public offering price of \$5.00 per share for total gross proceeds of \$19.5 million. On July 10, 2023, we sold an additional 585,000 shares of common stock to the Representative in connection with its exercise in full of its over-allotment option at a public offering price of \$5.00 per share for additional gross proceeds of \$2.9 million. The net proceeds from our IPO have thus far been used primarily to (i) initiate and conduct studies related to our therapeutic treatments, (ii) conduct clinical trials and operations, (iii) develop our product candidates, and (iv) fund our working capital and general corporate activities.

In September 2024, the Company issued 11,750 restricted shares of its common stock (the "Restricted Stock") to a consultant as compensation for its services to the Company through the end October 2024. Such issuance was exempt from registration under Section 4(a)(2) under the Securities Act.

Item 3. Defaults Upon Senior Securities

None

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

During the three months ended September 30, 2024, no director or officer of the Company adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

Exhibit No.	Description
3.1	Sixth Amended and Restated Certificate of Incorporation of the Registrant, dated June 30, 2023 (incorporated by reference to Exhibit 3.1 of our Form 8-K filed on July 5, 2023).
3.2	Second Amended and Restated Bylaws, dated November 21, 2023 (incorporated by reference to Exhibit 3.1 of our Form 8-K filed on November 22, 2023).
31.1*	Certification of CEO Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of CFO Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of CEO Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of CFO Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.

** Furnished herewith.

Indicates a management contract or compensatory plan or arrangement.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Intensity Therapeutics, Inc.

Date: November 13, 2024

By: _____
/s/ Lewis H. Bender
Lewis H. Bender
President, Chief Executive Officer and Chairman

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
<u>/s/ Lewis H. Bender</u> Lewis H. Bender	President, Chief Executive Officer and Chairman (principal executive officer)	November 13, 2024
<u>/s/ Joseph Talamo</u> Joseph Talamo	Chief Financial Officer (principal financial officer)	November 13, 2024

**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 Quarterly Report on 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, 2024

By:

/s/ Lewis H. Bender

Lewis H. Bender
President and Chief Executive Officer
(Principal Executive Officer)

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

I, Joseph Talamo, certify that:

1. I have reviewed this Quarterly Report on 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, 2024

By:

/s/ Joseph Talamo

Joseph Talamo
Chief Financial Officer
(Principal Financial Officer)

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

In connection with the Quarterly Report of Intensity Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: November 13, 2024

By:

/s/ Lewis H. Bender

Lewis H. Bender
President and Chief Executive Officer
(Principal Executive Officer)

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

In connection with the Quarterly Report of Intensity Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: November 13, 2024

By:

/s/ Joseph Talamo

Joseph Talamo
Chief Financial Officer
(Principal Financial Officer)