

**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 **March 31, 2025**

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 LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

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

Large accelerated filer	<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 May 12, 2025, the registrant had 18,398,202 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 to complete our clinical trials and 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;
- our ability to remain listed on The Nasdaq Capital Market; 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 13, 2025 (the “2024 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.

Table of Contents

	Page
PART I - FINANCIAL INFORMATION	1
Item 1. Condensed Financial Statements (Unaudited)	1
Condensed Balance Sheets as of March 31, 2025 (Unaudited) and December 31, 2024	1
Condensed Statements of Operations for the Three Months Ended March 31, 2025 and 2024 (Unaudited)	2
Condensed Statements of Changes in Stockholders' Equity for the Three Months Ended March 31, 2025 and 2024 (Unaudited)	3
Condensed Statements of Cash Flows for the Three Months Ended March 31, 2025 and 2024 (Unaudited)	4
Notes to the Unaudited Condensed Financial Statements	5
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	14
Item 3. Quantitative and Qualitative Disclosures About Market Risk	21
Item 4. Controls and Procedures	21
PART II - OTHER INFORMATION	23
Item 1. Legal Proceedings	23
Item 1A. Risk Factors	23
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	23
Item 3. Defaults Upon Senior Securities	23
Item 4. Mine Safety Disclosures	23
Item 5. Other Information	23
Item 6. Exhibits	24
SIGNATURES	25

Part I - Financial Information
Item 1. Condensed Financial Statements

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

	March 31, 2025 (Unaudited)	December 31, 2024 *
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 929	\$ 2,590
Prepaid expenses and other current assets	722	773
Total current assets	1,651	3,363
Right-of-use asset, net	116	122
Other assets	1,298	1,298
Total assets	\$ 3,065	\$ 4,783
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,586	\$ 1,219
Accrued expenses	1,014	508
Lease liability, current portion	29	28
Total current liabilities	2,629	1,755
Lease liability, long-term portion	102	110
Total liabilities	2,731	1,865
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value \$.0001. Authorized shares of 15,000,000 as of both March 31, 2025 and December 31, 2024. None issued and outstanding as of both March 31, 2025 and December 31, 2024.	—	—
Common stock, par value \$.0001. Authorized shares of 135,000,000 as of March 31, 2025 and December 31, 2024, respectively. Issued and outstanding shares of 15,264,869 and 15,122,873 as of March 31, 2025 and December 31, 2024, respectively.	2	2
Additional paid-in capital	70,462	69,699
Accumulated deficit	(70,130)	(66,783)
Total stockholders' equity	334	2,918
Total liabilities and stockholders' equity	\$ 3,065	\$ 4,783

*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 March 31,	
	2025	2024
Operating expenses:		
Research and development	\$ 2,189	\$ 2,815
General and administrative	1,205	1,928
Total operating expenses	3,394	4,743
Loss from operations	(3,394)	(4,743)
Other income (expense):		
Interest income	15	140
Other income, net	32	-
Net loss	<u>\$ (3,347)</u>	<u>\$ (4,603)</u>
Loss per share, basic and diluted	\$ (0.22)	\$ (0.34)
Weighted average number of shares of common stock, basic and diluted	15,173,196	13,709,487

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

INTENSITY THERAPEUTICS, INC.
CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(in thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Stockholders' Equity
	Shares	Amount			
Balances at December 31, 2024	15,122,873	\$ 2	\$ 69,699	\$ (66,783)	\$ 2,918
Issuance of common stock in ATM offering, net of \$ 17 issuance costs	141,996	-	328	-	328
Stock-based compensation expense	-	-	435	-	435
Net loss	-	-	-	(3,347)	(3,347)
Balances at March 31, 2025	15,264,869	\$ 2	\$ 70,462	\$ (70,130)	\$ 334

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Stockholders' Equity
	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

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

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

	Three Months Ended March 31,	
	2025	2024
Cash flows from operating activities:		
Net loss	\$ (3,347)	\$ (4,603)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in carrying value of right-of-use asset	6	6
Stock-based compensation expense	435	1,155
Changes in operating assets and liabilities, net:		
Accrued interest on marketable debt securities	-	(79)
Prepaid expenses, other current assets, and other assets	51	602
Accounts payable, accrued expenses and other liabilities	866	(1,447)
Net cash used in operating activities	(1,989)	(4,366)
Cash flows from investing activities:		
Redemption of marketable debt securities	-	3,260
Net cash provided by investing activities	-	3,260
Cash flows from financing activities:		
Proceeds from ATM offering	345	-
Issuance costs related to ATM offering	(17)	-
Proceeds from exercise of warrants and options	-	8
Net cash provided by financing activities	328	8
Net decrease in cash and cash equivalents	(1,661)	(1,098)
Cash and cash equivalents at beginning of period	2,590	8,556
Cash and cash equivalents at end of period	\$ 929	\$ 7,458

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.

The Company has completed two clinical studies and enrolled over 200 patients using INT230-6 in a Phase 1/2 dose escalation study in metastatic cancers including sarcomas, and a Phase 2 randomized control clinical trial in locally advanced breast cancer in women without undergoing chemotherapy prior to their surgery. In 2024, the Company initiated a Phase 3 trial in soft tissue sarcoma (the "INVINCIBLE-3 Study"), testing INT230-6 as second or third-line monotherapy compared to the standard of care ("SOC") with overall survival as an endpoint. Also in 2024, the Company initiated a Phase 2 study in collaboration with The Swiss Group for Clinical Cancer Research, SAKK (the "INVINCIBLE-4 Study") evaluating INT230-6 followed by the SOC immunochemotherapy and the SOC alone for patients with presurgical triple-negative breast cancer, with pathological complete response as the endpoint.

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 March 31, 2025, the Company has an accumulated deficit of \$70.1 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 three months ended March 31, 2025 was \$3.3 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 \$0.9 million as of March 31, 2025. In April 2025, the Company completed a public offering of \$2.35 million, for net proceeds of \$1.9 million after deducting the fees and expenses (see Note 12). 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 March 31, 2025, plus the net proceeds received in the April 2025 public offering (see Note 12), the Company believes that it has sufficient cash into the third 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 March 31, 2025, and its results of operations and its cash flows for the three months ended March 31, 2025 and 2024. 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, 2024 and 2023 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, 2024 balance sheet information was derived from the audited financial statements as of that date. The Company neither owns nor controls any subsidiary companies.

The significant accounting policies used in preparation of the condensed consolidated financial statements are disclosed in our 2024 Annual report, and there have been no changes to the Company's significant accounting policies during the three months ended March 31, 2025.

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 for our product candidate. Internal costs consist primarily of employee-related costs and costs related to compliance with regulatory requirements. The Company does not track internal or consulting costs by research and development initiative 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 both March 31, 2025 and December 31, 2024, the advance payment balance was \$1.2 million, 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 outstanding at March 31, 2025 and 2024.

As of March 31, 2025 and 2024, the following shares of common stock underlying options and warrants were excluded from the computation of diluted weighted average shares outstanding:

	March 31,	
	2025	2024
Options outstanding	2,543,067	1,939,129
Warrants outstanding	2,041,563	804,450
	4,584,630	2,743,579

Recently issued pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. ASU 2023-09 is intended to improve income tax disclosure requirements by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) the disaggregation of income taxes paid by jurisdiction. The guidance makes several other changes to the income tax disclosure requirements. The guidance in ASU 2023-09 will be effective for annual reporting periods in fiscal years beginning after December 15, 2024. The Company discloses its income tax rate reconciliation in its annual financial statements only and does not expect the adoption of ASU 2023-09 to have a material impact on its financial statements.

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, as subsequently amended by ASU 2025-01 to clarify the effective date, which is intended to provide more detailed information about specified categories of expenses (purchases of inventory, employee compensation, depreciation and amortization) included in certain expense captions presented in the statement of operations. The guidance in this ASU is effective for annual reporting periods in fiscal years beginning after December 15, 2026, and interim periods in fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either (1) prospectively to financial statements issued for periods after the effective date of this ASU or (2) retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact that the adoption of ASU 2024-03 will have on its financial statement disclosures.

Note 4. Cash and Cash Equivalents

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

	March 31, 2025	December 31, 2024
Savings and checking accounts at major U.S. financial institutions	\$ 94	\$ 428
U.S. Treasury securities money market fund	835	2,162
Total	\$ 929	\$ 2,590

Note 5. Prepaid Expenses and Other Current Assets

Prepaid expenses consisted of the following (in thousands):

	March 31, 2025	December 31, 2024
Prepaid insurance	\$ 262	\$ 421
Prepaid research and development costs	219	239
Prepaid other	241	113
Total	\$ 722	\$ 773

Note 6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2025	December 31, 2024
Accrued research and development costs	\$ 910	\$ 374
Accrued employee compensation-related expenses	—	56
Accrued other	104	78
Total	<u>\$ 1,014</u>	<u>\$ 508</u>

Note 7. Stockholders' Equity***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. On November 21, 2024, the Company filed a prospectus supplement to reduce the maximum the Company may sell and issue under the Sales Agreement to \$7.0 million of its Shares, not including the Shares previously sold under the Sales Agreement. For the three months ended March 31, 2025, the Company issued 141,996 shares of common stock under the ATM Agreement for net proceeds of \$0.3 million. Since inception, we have issued 193,816 shares of common stock under the ATM Agreement for net proceeds of \$0.5 million.

Registered direct offering

On November 21, 2024, the Company entered into a Securities Purchase Agreement with a single healthcare focused institutional investor (the "Investor"), pursuant to which the Company agreed to issue and sell, in a registered direct offering by the Company directly to the Investor, 1,237,113 shares of common stock to the Investor, at a price of \$2.425 per share, for aggregate gross proceeds of approximately \$3.0 million before deducting the placement agents' fees and related offering expenses. In a concurrent private placement, the Company agreed to issue to the Investor common stock warrants to purchase up to 1,237,113 shares (the "Common Warrants") at an exercise price of \$2.950 per share, with a relative fair value of \$1.1 million. Each Common Warrant will be exercisable six months from the issuance date and will expire five and one-half years from the issuance date.

Note 8. 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. The 2013 Plan terminated in August 2023 on the tenth anniversary of the 2013 Plan's date of adoption by the board. No new awards were made under the 2013 Plan after such termination date, but awards previously granted may extend beyond such date.

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 8,000,000 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, 2023 and January 1, 2024, an additional 238,700 and 479,828 shares were authorized under the 2021 Plan. On January 1, 2025, an additional 529,300 shares were authorized under the 2021 Plan. As of March 31, 2025, 2,455,011 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 March 31,	
	2025	2024
Research and development	\$ 160	\$ 566
General and administrative	275	589
Total stock-based compensation expense	\$ 435	\$ 1,155

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:

	Three Months Ended March 31,	
	2025	2024
Stock price	n/a	\$5.19
Exercise price	n/a	\$5.19
Expected volatility	n/a	97.06%
Risk free interest rates	n/a	4.12%
Expected term (years)	n/a	5 to 6.25

The Company did not issue stock options for the three months ended March 31, 2025. For the three months ended March 31, 2024, 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 three months ended March 31, 2025:

	Options	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	2,587,129	\$ 6.14	7.9	\$ —
Issued	—	\$ —		
Exercised	—	\$ —		
Forfeited and cancelled	(44,062)	\$ 3.55		
Outstanding at March 31, 2025	2,543,067	\$ 6.18	7.6	\$ —
Exercisable at March 31, 2025	1,435,229	\$ 7.40	6.4	\$ —

All options expire 10 years from date of grant. Options outstanding begin to expire in September 2025. 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.

As of March 31, 2025, total unrecognized compensation cost related to options was approximately \$4.0 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:

	Three Months Ended March 31,	
	2025	2024
Stock price	n/a	\$5.19
Exercise price	n/a	\$5.19
Expected volatility	n/a	97.06%
Risk free interest rates	n/a	4.12%
Expected term (years)	n/a	6.25

The Company did not issue warrants for the three months ended March 31, 2025. For the three months ended March 31, 2024, 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 three months ended March 31, 2025:

	Warrants	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	2,041,563	\$ 4.32	4.7	\$ —
Issued	—	\$ —		
Exercised	—	\$ —		
Forfeited and cancelled	—	\$ —		
Outstanding at March 31, 2025	2,041,563	\$ 4.32	4.4	\$ —
Exercisable at March 31, 2025	753,450	\$ 6.50	3.2	\$ —

All warrants outstanding are exercisable for purchase of common stock.

As of March 31, 2025, total unrecognized compensation cost related to warrants was approximately \$0.2 million and is expected to be recognized over the remaining weighted average service period of 2.6 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 included a restricted legend for a period of at least six months from the date of issuance. The six-month period has elapsed, and the Restricted Stock is no longer restricted.

Note 9. Leases

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 each of the three months ended March 31, 2025 and 2024 was approximately \$9,000.

Cash paid for operating leases for the three months ended March 31, 2025 was approximately \$7,000. The Company paid \$3,000 for operating leases for the three months ended March 31, 2024.

The following table summarizes the balance sheet classification of the operating lease asset and related lease liabilities as of March 31, 2025 and December 31, 2024 (in thousands):

	March 31, 2025	December 31, 2024
Right-of-use asset, net	\$ 116	\$ 122
Lease liability, current portion	29	28
Lease liability, net of current portion	102	110
	\$ 131	\$ 138

The following variables were used to determine the right-of-use asset and the operating lease liabilities at March 31, 2025 and 2024:

	March 31, 2025	March 31, 2024
Weighted average remaining lease term	3.9 years	5.4 years
Weighted average operating lease discount rate	6.4 %	6.4 %

Future minimum lease payments under the lease agreement as of March 31, 2025 were as follows (in thousands):

Year ended	
2025 (remainder of year)	\$ 27
2026	37
2027	39
2028	39
2029	7
Total lease payments	149
Less: Amounts representing interest	(18)
Present value of lease liabilities	\$ 131

Note 10. Other Uncertainties

The Company holds patents in Russia and Israel, both of which are currently involved in military action. The outcomes of these military actions could impact our ability to maintain and protect these patents.

Note 11. Related Parties

In October 2023, the Company issued 80,000 warrants for consulting services to be rendered by two shareholders, which vested over the subsequent twelve months. These warrants are valued at \$198,000 and were expensed to general and administrative expense over the subsequent twelve-month period, of which \$5,000 was expensed during the three months ended March 31, 2024.

In April 2024, the Company entered into a non-material agreement with a service organization controlled by a board member. For the three months ended March 31, 2025, the Company expensed \$1,800 and paid \$1,800 to the service organization for services performed, which is recognized in research and development expenses on the statement of operations. As of March 31, 2025, the Company recognized \$1,800 in accrued expenses.

Note 12. Segments

The Company has a single segment and allocates resources based on cash resources and operating expense projections. The table below summarizes the significant expense categories regularly reviewed by the Company's president and chief executive officer, who is the Company's chief operating decision maker ("CODM"), for the three months ended March 31, 2025 and 2024:

	Three Months Ended March 31,	
	2025	2024
Research and development expenses:		
Clinical trial expenses:		
IT-01 Study (Phase 1/2 Metastatic Cancers)	\$ —	\$ 53
INVINCIBLE-2 Study (Phase 2 Breast)	—	103
INVINCIBLE-3 Study (Phase 3 Sarcoma)	1,596	1,419
INVINCIBLE-4 Study (Phase 2 Breast)	63	—
Clinical trial expenses	1,659	1,575
Contract manufacturing	24	214
Salaries and benefits related	329	394
Consulting & Other(a)	17	66
Stock-based compensation	160	566
Research and development expenses	2,189	2,815
General and administrative expenses:		
Salaries and benefits related	230	324
Legal fees	167	257
Audit fees	77	115
Consulting	196	173
Insurance	157	286
Other(b)	103	184
Stock-based compensation	275	589
General and administrative expenses	1,205	1,928
Loss from operations	(3,394)	(4,743)
Other segment items(c)	47	140
Net loss	\$ (3,347)	\$ (4,603)

(a) Consulting & Other includes research and development consulting costs and travel-related costs.

(b) Other includes facility expenses, office supplies, computer and software related costs, public relations costs, and travel-related costs.

(c) Other segment items include interest income, interest expense, and foreign exchange gains and losses.

Note 13. Subsequent Events
Public offering

On April 24, 2025, the Company commenced a best efforts public offering (the "Offering") of an aggregate of (i) 3,133,333 shares (the "Shares") of the Company's common stock, \$0.0001 par value per share (the "Common Stock"), (ii) 3,133,333 Series B-1 Common Warrants (the "Series B-1 Common Warrants") to purchase up to 3,133,333 shares of Common Stock (the "Series B-1 Common Warrant Shares"), (iii) 3,133,333 Series B-2 Common Warrants (the "Series B-2 Common Warrants" and together with the Series B-1 Warrants, the "Warrants") to purchase up to 3,133,333 shares of Common Stock (the "Series B-2 Common Warrant Shares" and together with the Series B-1 Common Warrant Shares, the

“Warrant Shares”). In connection with the Offering, the Company entered into a Securities Purchase Agreement on April 24, 2025 with certain institutional investors participating in the Offering. The Offering closed on April 28, 2025. Each Share was sold together with one Series B-1 Common Warrant to purchase one share of Common Stock and one Series B-2 Common Warrant to purchase one share of Common Stock. The combined offering price for each Share and accompanying Warrants was \$0.75. Each Warrant has an exercise price of \$0.85 and was immediately exercisable upon issuance. The Series B-1 Common Warrants will expire on the five-year anniversary of the date of issuance, and the Series B-2 Common Warrants will expire on the eighteen-month anniversary of the date of issuance. The Company raised an aggregate of \$2.35 million in the Offering, and net proceeds of the Offering, after deducting the fees and expenses were approximately \$1.9 million.

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 2024 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 2024 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

We are 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. Evidence shows the mechanism of tumor killing achieved by our drug candidate also leads to systemic immune activation and T-cell repertoire expansion 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 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 sarcomas. The drug is also used in breast and lung cancer.

Our Clinical Programs

In 2017, we initiated our first trial, a Phase 1/2 dose escalation study ("IT-01 Study") using INT230-6 in the United States under an investigational new drug application ("IND") authorized by the FDA and in Canada under a preclinical trial application ("CTA") approved by Health Canada. The study 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 Bristol Myers Squibb's ("BMS") Yervoy® (ipilimumab). We completed enrollment of the IT-01 Study in June 2022, locked the IT-01 Study 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 our second trial, 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 (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, which is the current standard of care ("SOC") for the majority of patients with early-stage breast cancer, or a saline injection. Substantial reduction of cancer presurgically in aggressive forms of cancer has been shown to correlate with delaying disease recurrence. The key endpoints of the INVINCIBLE 2 Study were to understand the percentage of necrosis that can be achieved in tumors of varying sizes for a given dose, especially for tumors larger than 2 centimeters in longest diameter. We also sought to determine whether 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. There was also an increase of certain types of immune cells (CD4+ and NK T-cells) in the tumor and blood. Additionally, there was an increase in the T-cells repertoire relative to control.

In July 2024, we initiated and dosed our first patient in a Phase 3 open-label, randomized study (the "INVINCIBLE-3 Study") testing INT230-6 as a monotherapy compared to the SOC drugs in second-and third-line treatment for certain soft tissue sarcoma subtypes. This 333-patient study with an endpoint of overall survival has been authorized by the FDA, Health Canada, the European Medicines Authority, and Australia's Therapeutics Goods Administration. In March 2025, we paused new site activations and patient enrollments due to funding constraints, and prioritized funding for the INVINCIBLE-4 Study (see below). Prior to this pause, the trial had enrolled 23 patients. We will continue to treat all patients enrolled in this study in cooperation with our third-party contract research organizations to reduce ongoing costs during this pause. Once sufficient funding is obtained, we plan to restart site activations and patient enrollment in the INVINCIBLE-3 Study.

In October 2024, in collaboration with the Swiss Group for Clinical Cancer Research SAKK ("SAKK"), we initiated and dosed our first patient in a Phase 2 study (the "INVINCIBLE-4 Study") to treat patients with localized triple-negative breast cancer ("TNBC"). We plan to enroll 54 patients and expect to complete enrollment by the end of the first quarter of 2026 provided that we are able to obtain sufficient additional funding, and the endpoint is the change in the pathological complete response rate for the combination compared to the SOC alone. In the event we are unable to obtain sufficient additional funding, we may have to defer completion of the study until such funding is obtained.

We have also successfully developed Phase 3 quality analytical methods for the three INT230-6 components and successfully manufactured multiple large-scale batches 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, we expect that 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). We also anticipate publishing a series of manuscripts on completed studies beginning in the second half of 2025.

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 net proceeds received from issuances of our Common Stock, preferred stock and convertible notes. As of March 31, 2025, we had approximately \$0.9 million of cash and cash equivalents. Since our inception, we have incurred significant operating losses. We incurred net losses of \$3.3 million and \$4.6 million for the three months ended March 31, 2025 and 2024, respectively. As of March 31, 2025, we had an accumulated deficit of \$70.1 million.

We expect to incur significant expenses and operating losses for the next several years as we continue to:

- Fund our INVINCIBLE-3 and INVINCIBLE-4 clinical studies;
- 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.

Results of Operations

The following tables summarize our results of operations for the three months ended March 31, 2025 and 2024 (in thousands):

	Three Months Ended March 31,		
	2025	2024	Change
Operating expenses:			
Research and development	\$ 2,189	\$ 2,815	\$ (626)
General and administrative	1,205	1,928	(723)
Total operating expenses	3,394	4,743	(1,349)
Loss from operations	(3,394)	(4,743)	1,349
Interest income	15	140	(125)
Other income, net	32	-	32
Net loss	\$ (3,347)	\$ (4,603)	\$ 1,256

	Three Months Ended March 31,		
	2025	2024	Change
Research and development expenses:			
Clinical trial expenses:			
IT-01 Study (Phase 1/2 Metastatic Cancers)	\$ —	\$ 53	\$ (53)
INVINCIBLE-2 Study (Phase 2 Breast)	—	103	(103)
INVINCIBLE-3 Study (Phase 3 Sarcoma)	1,596	1,419	177
INVINCIBLE-4 Study (Phase 2 Breast)	63	—	63
Clinical trial expenses	1,659	1,575	84
Contract manufacturing	24	214	(190)
Salaries and benefits related costs	329	394	(65)
Consulting & Other	17	66	(49)
Stock-based compensation	160	566	(406)
Total research and development expenses	\$ 2,189	\$ 2,815	\$ (626)

	Three Months Ended March 31,		
	2025	2024	Change
General and administrative expenses:			
Salaries and benefits related costs	\$ 230	\$ 324	\$ (94)
Legal fees	167	257	(90)
Audit fees	77	115	(38)
Consulting	196	173	23
Insurance	157	286	(129)
Other	103	184	(81)
Stock-based compensation	275	589	(314)
Total general and administrative expenses	\$ 1,205	\$ 1,928	\$ (723)

Three Months Ended March 31, 2025 Compared to Three Months Ended March 31, 2024

Research and development expenses during the three months ended March 31, 2025 decreased \$0.6 million or 22%, compared to the three months ended March 31, 2024, and were primarily due to the following:

- Salaries and benefits related costs decreased \$0.1 million as the Company did not accrue current year bonus accruals due to insufficient cash reserves and the current assessment that current year bonus payments are not reasonably probable to occur. In addition, stock-based compensation was \$0.4 million lower as no new equity grants were awarded in the first quarter of 2025.

- Clinical trial expenses increased marginally by \$0.1 million due to the ongoing site initiations and patient enrollment of the INVINCIBLE-03 Study. In March 2025, we paused new site activations and patient enrollments due to funding constraints, and prioritized funding for the INVINCIBLE-4 Study. Prior to this pause, the trial had enrolled 23 patients. We will continue to treat all patients enrolled in this study in cooperation with our third-party contract research organizations during this pause. Once sufficient funding is obtained, we plan to restart site activations and patient enrollment in the INVINCIBLE-3 Study.
- Contract manufacturing costs declined by \$0.2 million, as there were no manufacturing batches of INT230-6 in the first quarter of 2025.

General and administrative expenses during the three months ended March 31, 2025 increased \$0.7 million or 38%, compared to the three months ended March 31, 2024, and were primarily due to the following:

- Salaries and benefits related costs decreased \$0.1 million as the Company did not accrue current year bonus accruals due to insufficient cash reserves and the current assessment that current year bonus payments are not reasonably probable to occur. In addition, stock-based compensation was \$0.3 million lower as no new equity grants were awarded in the first quarter of 2025.
- Insurance expense decreased by \$0.1 million due to the favorable directors and officers insurance renewal terms obtained in June 2024 compared to the prior policy year.
- Legal, audit and other expenses decreased as a result of cost saving from the integration of new systems in the administrative areas.

Interest income in 2025 and 2024 related to interest earned on cash and investment balances.

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 193,816 shares of common stock under the ATM Agreement for net proceeds of \$0.5 million.

On November 21, 2024, we entered into a Securities Purchase Agreement with a single healthcare focused institutional investor (the “Investor”), pursuant to which we agreed to issue and sell, in a registered direct offering directly to the Investor, 1,237,113 shares of Common Stock to the Investor, at a price of \$2.425 per share, for aggregate gross proceeds of approximately \$3.0 million before deducting the placement agents’ fees and related offering expenses. In a concurrent private placement, we agreed to issue to the Investor Common Stock warrants to purchase up to 1,237,113 shares (the “Common Warrants”) at an exercise price of \$2.95 per share. Each Common Warrant will be exercisable six months from the issuance date and will expire five and one-half years from the issuance date.

On April 24, 2025, we commenced a best efforts public offering (the “Offering”) of an aggregate of (i) 3,133,333 shares (the “Shares”) of the our common stock, \$0.0001 par value per share (the “Common Stock”), (ii) 3,133,333 Series B-1 Common Warrants (the “Series B-1 Common Warrants”) to purchase up to 3,133,333 shares of Common Stock (the

“Series B-1 Common Warrant Shares”), (iii) 3,133,333 Series B-2 Common Warrants (the “Series B-2 Common Warrants” and together with the Series B-1 Warrants, the “Warrants”) to purchase up to 3,133,333 shares of Common Stock (the “Series B-2 Common Warrant Shares” and together with the Series B-1 Common Warrant Shares, the “Warrant Shares”). In connection with the Offering, we entered into a Securities Purchase Agreement on April 24, 2025 with certain institutional investors participating in the Offering. The Offering closed on April 28, 2025. Each Share was sold together with one Series B-1 Common Warrant to purchase one share of Common Stock and one Series B-2 Common Warrant to purchase one share of Common Stock. The combined offering price for each Share and accompanying Warrants was \$0.75. Each Warrant has an exercise price of \$0.85 and was immediately exercisable upon issuance. The Series B-1 Common Warrants will expire on the five-year anniversary of the date of issuance, and the Series B-2 Common Warrants will expire on the eighteen-month anniversary of the date of issuance. We raised an aggregate of \$2.35 million in the Offering, and net proceeds of the Offering, after deducting the fees and expenses were approximately \$1.9 million.

We have financed our operations primarily through an initial investment from our founder, the issuance and sale of convertible notes, and private and public equity financings. As of March 31, 2025, our cash and cash equivalents were approximately \$0.9 million. Based on our balances in cash and cash equivalents plus cash raised in our April 2025 Public Offering, we project to have sufficient cash to fund our current operating plan into the third 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):

	Three Months Ended March 31,	
	2025	2024
Net cash used in operating activities	\$ (1,989)	\$ (4,366)
Net cash provided by investing activities	—	3,260
Net cash provided by financing activities	328	8
Net decrease in cash and cash equivalents	<u>\$ (1,661)</u>	<u>\$ (1,098)</u>

Operating Activities

Our cash used in operating activities for the three months ended March 31, 2025 was \$2.0 million, comprising of (i) our net loss of \$3.3 million, as adjusted for \$0.4 million in non-cash expenses (primarily for non-cash stock based compensation of \$0.4 million), and (ii) net changes in operating assets and liabilities of \$0.9 million.

Our cash used in operating activities for the three months ended March 31, 2024 was \$4.4 million, comprising of (i) our net loss of \$4.6 million, as adjusted for \$1.2 million in non-cash expenses (primarily for non-cash stock based compensation), and (ii) net changes in operating assets and liabilities of \$0.9 million.

Investing Activities

There were no investing activities during the three months ended March 31, 2025.

Our cash provided by investing activities during the three months ended March 31, 2024 was \$3.3 million and was due to the redemption of marketable debt securities.

Financing Activities

Our cash provided by financing activities during the three months ended March 31, 2025 related \$0.3 million in net proceeds received from the issuance of common stock.

Our cash provided by financing activities during the three months ended March 31, 2024 related to proceeds received from the exercise of warrants.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of March 31, 2025.

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 2024 Annual Report. No significant changes to our accounting policies took place during the three months ended March 31, 2025.

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 March 31, 2025, 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 March 31, 2025, our disclosure controls and procedures were effective at a reasonable assurance level.

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 changes 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 March 31, 2025 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 2024 Annual Report, except for the addition of the following risk factor below.

Changes to U.S. tariff and import/export regulations may have an adverse effect on our business, financial condition and results of operations.

There have been significant changes and continue to be ongoing discussion and commentary regarding potential significant changes to U.S. trade policies, treaties and tariffs, creating significant uncertainty about the future relationship between the United States and other countries with respect to trade policies, treaties and tariffs. These developments, or the perception that any of them could occur, may have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global trade and, in particular, trade between the impacted nations and the United States. Any of these factors could depress economic activity and have a material adverse effect on our business, financial condition, results of operations, and the market price of our common stock.

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

During the three months ended March 31, 2025, 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: May 13, 2025

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)	May 13, 2025
<u>/s/ Joseph Talamo</u> Joseph Talamo	Chief Financial Officer (principal financial officer)	May 13, 2025

**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: May 13, 2025

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: May 13, 2025

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 March 31, 2025 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: May 13, 2025

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 March 31, 2025 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: May 13, 2025

By:

/s/ Joseph Talamo

Joseph Talamo
Chief Financial Officer
(Principal Financial Officer)