UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 13, 2025

Intensity Therapeutics, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	001-41109	46-1488089
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1 Enterprise Drive, Suite 430 Shelton, CT	06484-4779
(Address of Principal Executive Offices)	(Zip Code)

(203) 221-7381
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of Each Class:	Trading Symbol(s):	Name of Exchange on Which Registered:
Common Stock, $0.0001 par value per share	INTS	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

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

Item 2.02 Results of Operations and Financial Condition.

On May 13, 2025, Intensity Therapeutics, Inc. (the "Company") released its financial results for the three months ended March 31, 2025. A copy of the Company's press release is attached as Exhibit 99.1 to this Form 8-K and incorporated herein by reference.

The information in this report shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued May 13, 2025.
104	Cover Page Interactive Data File (formatted in Inline XBRL).

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Comments in this Current Report on Form 8-K and in the exhibit attached hereto contain certain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, which are based on management's good faith expectations and beliefs concerning future developments. Actual results may differ materially from these expectations as a result of many factors. These factors include, but are not limited to, the risks and uncertainties described in the "Risk Factors" and "Cautionary Note Regarding Forward Looking Statements" sections of the Company's Annual Report on Form 10-K, filed on March 13, 2025, and the Company's Quarterly Report on Form 10-Q, filed on May 13, 2025. The Company does not undertake any obligation to update such forward-looking statements. All market and industry data are based on Company estimates.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: May 13, 2025

Intensity Therapeutics, Inc.

By: /s/ Lewis H. Bender

Name: Lewis H. Bender

Title: Chief Executive Officer

[*Signature Page to the Form 8-K*]

Exhibit 99.1

Intensity Therapeutics Reports First Quarter 2025 Financial Results and Provides Corporate Update

- *Eight Swiss sites are activated in the INVINCIBLE-4 Study, and several patients have been treated*
- *European Medicines Agency Authorization to initiate INVINCIBLE-4-Study in France*

Shelton, Conn., May 13, 2025 – Intensity Therapeutics, Inc. (“Intensity” or “the Company”) (Nasdaq: INTS), a late-stage clinical biotechnology company focused on the discovery and development of proprietary, novel immune-based intratumoral cancer therapies designed to kill tumors and increase immune system recognition of cancers, announces first quarter 2025 financial results and provides a corporate update.

Corporate Update

INVINCIBLE-4 Study: 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. The primary endpoint is the change in the pathological complete response rate for the combination compared to the SOC alone. The INVINCIBLE-4 Study is recruiting patients in Switzerland and is expected to enroll 54 patients across Switzerland and France.

In April 2025, the Company and The Swiss Group for Clinical Cancer Research SAKK, a decentralized academic research institute that has been conducting clinical trials of cancer treatments in all major Swiss hospitals since 1965, announced that the European Medicines Agency has authorized the initiation of the INVINCIBLE-4 Study in France in collaboration with Unicancer. The Unicancer French breast intergroup (UCBG) is the French referent cooperative group in breast cancer. The French National Cancer Institute (INCa) accredited the group in 2013, thus acknowledging its academic excellence and operational capability. Since its creation, the group has conducted more than 40 national and international multicenter clinical trials, as well as various translational research projects.

INVINCIBLE-3 Study: Phase 3 open-label, randomized study testing INT230-6 as monotherapy compared to the SOC drugs in second and third line treatment for certain soft tissue sarcoma subtypes. The INVINCIBLE-3 Study is expected to enroll 333 patients and initiate sites in eight countries. This study has been authorized by the US FDA, Health Canada, the European Medicines Authority (for France, Germany, Italy, Poland and Spain), and Australia's Therapeutics Goods Administration. The primary endpoint in the INVINCIBLE-3 Study is overall survival.

In March 2025, the Company 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. The Company will continue to treat all patients enrolled in this study in cooperation with its third-party contract research organizations to reduce ongoing costs during this pause.

April 2025 Public Offering: In April 2025, the Company entered into a Securities Purchase Agreement with certain institutional investors participating in a public offering and raised an aggregate of $2.35 million, with net proceeds after deducting the fees and expenses of approximately $1.9 million.

“The first quarter saw continued progress in our important programs despite high volatility in the markets and funding constraints," stated Lewis H. Bender, Intensity Founder, President, and CEO. "Several patients in our sarcoma study had their first follow-up scans, which showed high levels of necrosis in the injected tumors. Site contracting, site activation and patient enrollment were increasing nicely. However, due to cash needs, we made the necessary decision to pause the Phase 3 sarcoma enrollment and site activation until additional funding becomes available. We are working closely with our vendors and sites to treat those patients enrolled in INVINCIBLE-3, while maintaining the pharmacovigilance, site monitoring and the study database. Meanwhile, our partners SAKK and Unicancer will continue to work with the leading hospitals in Switzerland and France to seek patients for our breast cancer trial, INVINCIBLE-4. We believe in the potential for our drug to positively impact the lives of metastatic sarcoma and presurgical breast cancer patients worldwide. As cancer deaths increase, new and improved alternatives to current therapies are needed now more than ever.”

First Quarter 2025 Financial Results

Research and development expenses were $2.2 million for the three months ended March 31, 2025, compared to $2.8 million for the same period in 2024. Clinical trial expenses increased marginally by $0.1 million due to the ongoing site initiations and patient enrollment of the INVINCIBLE-03 Study. Contract manufacturing costs declined by $0.2 million, as there were no manufacturing batches of INT230-6 in the first quarter of 2025. In addition, stock-based compensation was $0.4 million lower as no new equity grants were awarded in the first quarter of 2025.

General and administrative expenses were $1.2 million for the three months ended March 31, 2025, compared to $1.9 million for the same period in 2024. Legal, audit and other expenses decreased as a result of cost saving from the integration of new systems in the administrative areas. In addition, stock-based compensation was $0.3 million lower as no new equity grants were awarded in the first quarter of 2025.

Overall, net loss was $3.3 million for the three months ended March 31, 2025, compared to a net loss of $4.6 million for the three months ended March 31, 2024.

As of March 31, 2025, cash and cash equivalents totaled $0.9 million.

About INT230-6

INT230-6, Intensity's lead proprietary investigational product candidate, is designed for direct intratumoral injection. INT230-6 was discovered using Intensity's proprietary DfuseRx℠ technology platform. The drug is comprised of two proven, potent anti-cancer agents, cisplatin and vinblastine, and a penetration enhancer molecule (SHAO) that helps disperse potent cytotoxic drugs throughout tumors for diffusion into cancer cells. These agents remain in the tumor, resulting in a favorable safety profile. In addition to local disease control and direct tumor killing, INT230-6 causes a release of a bolus of neoantigens specific to the malignancy, leading to immune system engagement and systemic anti-tumor effects. Importantly, these effects are mediated without immunosuppression which often occurs with systemic chemotherapy.

About Intensity Therapeutics

Intensity is a late-stage clinical biotechnology company whose novel engineered chemistry enables aqueous cytotoxic-containing drug formulations to mix and saturate a tumor's dense, high-fat, pressurized environment following direct intratumoral injection. As a result of the saturation, Intensity's clinical trials have demonstrated the ability of INT230-6 to kill tumors and elicit an adaptive immune response within days of injection, representing a new approach to cancer cell death that holds the potential to shift the treatment paradigm and turn many deadly cancers into chronic diseases even for malignancies that do not respond to conventional immunotherapy. Intensity has completed two clinical studies and enrolled over 200 patients using INT230-6; a Phase 1/2 dose escalation study in metastatic cancers including sarcomas (NCT03058289), and a Phase 2 randomized control clinical trial in locally advanced breast cancer (the “INVINCIBLE-2 Study”) (NCT04781725) in women without undergoing chemotherapy prior to their surgery. The Company initiated a Phase 3 trial in soft tissue sarcoma (the “INVINCIBLE-3 Study”) (NCT06263231), testing INT230-6 as second or third line monotherapy compared to the standard of care ("SOC") with overall survival as an endpoint. Intensity also initiated a Phase 2 study in collaboration with The Swiss Group for Clinical Cancer Research SAKK (the "INVINCIBLE-4 Study") (NCT06358573) as part of a Phase 2/3 program evaluating INT230-6 followed by the SOC immunochemotherapy and the SOC alone for patients with presurgical triple-negative breast cancer. Pathological complete response ("pCR") is the endpoint. For more information about Intensity, including publications, papers and posters about its novel approach to cancer therapeutics, visit www.intensitytherapeutics.com.

Forward-Looking Statements

Certain statements in this press release may constitute "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995, as amended to date. These statements include, but are not limited to, statements relating to the Company's expected future plans, cash runway, development activities, projected milestones, business activities or results. When or if used in this communication, the words “may,” “could,” “should,” “anticipate,” “believe,” “estimate,” “expect,” “intend,” “plan,” “predict” and similar expressions and their variants, as they relate to the

Company or its management, may identify forward-looking statements. The forward-looking statements contained in this press release are based on management's current expectations and projections about future events, nevertheless, actual results or events could differ materially from the plans, intentions and expectations disclosed in, or implied by, the forward-looking statements. These risks and uncertainties, many of which are beyond our control, include: the initiation, timing, progress and results of future preclinical studies and clinical trials and research and development programs; the need to raise additional funding before the Company can expect to generate any revenues from product sales; plans to develop and commercialize product candidates; the timing or likelihood of regulatory filings and approvals; the ability of the Company's research to generate and advance additional product candidates; the implementation of the Company's business model, strategic plans for the Company's business, product candidates and technology; commercialization, marketing and manufacturing capabilities and strategy; the rate and degree of market acceptance and clinical utility of the Company's system; the Company's competitive position; the Company's intellectual property position; developments and projections relating to the Company's competitors and its industry; the Company's ability to maintain and establish collaborations or obtain additional funding; expectations related to the use of cash and cash equivalents and investments; estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and other risks described in the section entitled "Risk Factors" in the Company's SEC filings, which can be obtained on the SEC website at www.sec.gov. Readers are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date on which they are made and reflect management's current estimates, projections, expectations and beliefs. The Company does not plan to update any such forward-looking statements and expressly disclaims any duty to update the information contained in this press release except as required by law.

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Intensity Therapeutics, Inc.
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	$ (3,347)	$ (4,603)
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

Intensity Therapeutics, Inc.
Balance Sheets
(in thousands)

	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, net of current portion	102	110
Total liabilities	2,731	1,865
Total stockholders' equity	334	2,918
Total liabilities and stockholders' equity	$ 3,065	$ 4,783

*Derived from audited financial statements