

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): November 6, 2025

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

Delaware
(State or Other Jurisdiction
of Incorporation)

001-41109
(Commission File Number)

46-1488089
(IRS Employer
Identification No.)

1 Enterprise Drive, Suite 430
Shelton, CT
(Address of Principal Executive Offices)

06484-4779
(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 November 6, 2025, Intensity Therapeutics, Inc. (the “Company”) released its financial results for the three and nine months ended September 30, 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 November 6, 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, the Company's Quarterly Report on Form 10-Q, filed on May 13, 2025, the Company's Quarterly Report on Form 10-Q, filed on August 7, 2025, and the Company's Quarterly Report on Form 10-Q, filed on November 6, 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: November 6, 2025

Intensity Therapeutics, Inc.

By: /s/ Lewis H. Bender

Name: Lewis H. Bender

Title: Chief Executive Officer

[Signature Page to the Form 8-K]



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

- The Company expects to file a protocol amendment in the INVINCIBLE-4 Study to revise the dosing regimen for the INT230-6 treatment cohort, and to reinstate patient enrollment in the first quarter of 2026
- IT-01 Study manuscript published, featuring a comprehensive evaluation of data, including disease control rate, overall survival, immune activation, abscopal effects, tumor necrosis, dose ranging, and safety
- \$7.1 million cash and cash equivalents as of September 30, 2025, with an incremental \$6.1 million raised in the fourth quarter of 2025
- Cash runway extended until the end of the first quarter of 2027

Shelton, Conn., November 6, 2025 – Intensity Therapeutics, Inc. (“Intensity” or “the Company”) (Nasdaq: INTS), a late-stage clinical biotechnology company focused on the discovery and development of novel intratumoral cancer therapies that are designed to kill tumors and increase immune system recognition of cancers using its proprietary non-covalent conjugation technology, announces third 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 and SOC alone. The primary endpoint is the change in the pathological complete response rate for the combination compared to the SOC alone.

In October 2024, in collaboration with the Swiss Cancer Group, formerly the Swiss Cancer Group for Clinical Cancer Research (SAKK), the Company initiated and dosed our first patient in the INVINCIBLE-4 Study. In September 2025, the Company paused new patient enrollment to revise the dosing regimen for patients receiving INT230-6 in cohort A due to some patients in Cohort A experiencing localized skin irritation near the tumor site. The Company plans to file a protocol amendment for this revision in dosing in the first quarter of 2026, and expects to reinstate enrollment for the 54-patient study in the first quarter of 2026. The Company is targeting to complete enrollment by the end of 2026 and will likely add resources to help sites enroll.

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 specific soft tissue sarcoma subtypes. This study has been authorized by the US FDA, Health Canada, the European Medicines Agency (for France, Germany, Italy, Poland, and Spain), and Australia’s Therapeutic 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. Prior to this pause, the trial had enrolled 21 patients. The Company continues to treat patients enrolled in this study, maintain the database, conduct pharmacovigilance and other study related activities in cooperation with its third-party contract research organizations to reduce ongoing costs during this pause. Once sufficient funding is obtained, the Company plans to restart site activations and patient enrollment in the INVINCIBLE-3 Study.

IT-01 Study Manuscript Publication: On October 29, 2025, eBioMedicine, a *Lancet Discovery Science* journal, published the Company’s phase 1/2 IT-01 clinical study manuscript, “*Safety and Efficacy of Intratumorally Administered INT230-6 in Adult Patients with Advanced Solid Tumours: Results from an Open-Label Phase 1/2 Dose Escalation Study*,” for the treatment of metastatic or refractory cancers. The manuscript included the following data results:

- In heavily pretreated patients with advanced disease having over 20 different types of cancer who had progressed following multiple prior lines of therapy, intratumoral INT230-6 achieved:
 - A disease control rate of 75% (48/64 patients) and median overall survival (mOS) of 11.9 months; these results compare favorably in phase 1/2 studies that historically reported an mOS of 4 to 7 months

- In a metastatic sarcoma subset population receiving only INT230-6, the median overall survival was 21.3 months
- In an exploratory analysis comparing patients receiving INT230-6 at a total dose (in mL) that treated greater than 40% of the patient's total tumor burden ("TTB") compared to those treated with less than 40% of their TTB, the:
 - Disease control rate was 83.3% (40/48) compared to 50% (8/16)
 - Median overall survival was 18.7 months (95% CI: 11.5–23.5) compared to 3.1 months (95% CI: 1.6–5.9) with a hazard ratio (HR) of 0.17 (95% CI: 0.081–0.342); $P < 0.0001$
 - Improved survival was consistent across a range of low to high tumor burden and tumor sizes
- Approximately 20% of patients in the >40% group had uninjected tumors shrink, abscopal effects
- Fifteen of 64 patients survived for more than 21 months
- INT230-6 induced a qualitative decrease in proliferating cancer cells in injected tumors and a qualitative increase in activated T-cells infiltrating the tumor microenvironment
- No dose-limiting toxicities were reported among 64 monotherapy patients; seven patients had a grade 3 (10.9%) with no grade 4 or 5 treatment-related adverse events
- Pharmacokinetic results showed that greater than 95% of the active cytotoxic agents remained in the injected tumors

Capital Raises and Cash Runway: the Company has raised \$13.6 million in gross proceeds since the beginning of the third quarter of 2025.

- \$7.5 million raised in the third quarter of 2025 via the Company's ATM (net proceeds of \$7.2 million).
- \$2.1 million raised in October 2025 via the Company's ATM (net proceeds of \$2.0 million).
- \$4.0 million raised in October 2025 in a registered direct offering with an institutional investor, before deducting the placement agent's fees and related offering expenses (net proceeds of \$3.7 million).

With the capital raised to date, the Company has extended its cash runway until the end of the first quarter of 2027.

"In the past four months, we were able to substantially improve our balance sheet with multiple fundraising transactions. In particular, the October 2025 registered direct offering was significant, as this brought in a new long-term fundamental, healthcare-savvy investor. The new capital raised in 2025 enables us to execute on our business strategy until the end of the first quarter of 2027 without any additional funds. In addition, our peer-reviewed paper published in the Lancet Discovery Group's journal, eBioMedicine, provides another level of validation of the potential of our lead drug INT230-6, injected directly into tumors, to treat multiple types of cancer in both the metastatic and local disease settings. We believe this is the first peer-review publication of a local therapy alone to report disease control rate, the potential for an overall survival benefit and a 20% patient abscopal rate in metastatic disease," stated Lewis H. Bender, Intensity Founder, President and CEO. "Lastly, working with our collaboration partners at the Swiss Cancer Institute, we analyzed the data from the patients in the Phase 2 randomized controlled INVINCIBLE-4 study, and have identified a path forward to restarting the study, which is expected to be in the first quarter of 2026. The endpoint will remain pathological complete response, which is accepted by FDA for accelerated approval."

Third Quarter 2025 Financial Results

Research and development expenses were \$1.6 million for the three months ended September 30, 2025, compared to \$2.2 million for the same period in 2024. Clinical trial expenses decreased \$0.4 million primarily due to lower INVINCIBLE-3 Study costs. In March 2025, the Company paused new site activations and patient enrollments in the INVINCIBLE-3 Study, due to funding constraints. Prior to this pause, the trial had enrolled 21 patients. The Company will continue to treat all patients enrolled in this study in cooperation with our third-party contract research organizations during this pause, and once sufficient funding is obtained, the Company plans to restart site activations and patient enrollment.

General and administrative expenses were \$1.2 million for the three months ended September 30, 2025, compared to \$1.4 million for the same period in 2024. Consulting expense decreased due to less business development activity compared to the prior year period.

Overall, net loss was \$2.7 million for the three months ended September 30, 2025, compared to a net loss of \$3.5 million for the three months ended September 30, 2024.

As of September 30, 2025, cash and cash equivalents totaled \$7.1 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 DfuseRxSM technology platform. The drug consists of two proven, potent anti-cancer agents, cisplatin and vinblastine sulfate, and a diffusion and cell penetration enhancer molecule ("SHAO") that facilitates the dispersion of potent cytotoxic drugs throughout tumors, allowing the active agents to diffuse 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 (the "INVINCIBLE-4 Study") (NCT06358573) in collaboration with the Swiss Cancer Group, formerly the Swiss Group for Clinical Cancer Research SAKK, 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 risk that product candidates that appear promising in early research and clinical trials do not demonstrate safety and/or efficacy in larger-scale or later clinical trials; 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; our potential inability to satisfy the Nasdaq Capital Market's requirements for continued listing and be subject to delisting; 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 Annual Report on Form 10-K for the year ended December 31, 2024 and in the Company's subsequent 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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	\$ 1,553	\$ 2,151	\$ 5,283	\$ 8,529
General and administrative	1,180	1,419	3,549	4,853
Total operating expenses	2,733	3,570	8,832	13,382
Loss from operations	(2,733)	(3,570)	(8,832)	(13,382)
Other income (expense):				
Interest income	59	48	92	286
Other income, net	3	9	185	9
Net loss	\$ (2,671)	\$ (3,513)	\$ (8,555)	\$ (13,087)
Loss per share, basic and diluted	\$ (0.06)	\$ (0.25)	\$ (0.33)	\$ (0.95)
Weighted average number of shares of common stock, basic and diluted	43,042,691	13,804,651	25,796,756	13,742,325

Intensity Therapeutics, Inc.
Balance Sheets
(in thousands)

	<u>September 30, 2025</u>	<u>December 31, 2024</u>
	(Unaudited)	*
Assets		
Current assets:		
Cash and cash equivalents	\$ 7,067	\$ 2,590
Prepaid expenses and other current assets	1,119	773
Total current assets	8,186	3,363
Right-of-use asset, net	103	122
Other assets	1,296	1,298
Total assets	\$ 9,585	\$ 4,783
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,684	\$ 1,219
Accrued expenses	561	508
Lease liability, current portion	31	28
Total current liabilities	2,276	1,755
Lease liability, net of current portion	87	110
Total liabilities	2,363	1,865
Total stockholders' equity	7,222	2,918
Total liabilities and stockholders' equity	\$ 9,585	\$ 4,783

*Derived from audited financial statements