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 5, 2026

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):

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

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

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

o 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 x

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 5, 2026, Intensity Therapeutics, Inc. (the "Company") released its financial results for the three and nine months ended September 30, 2026. 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 5, 2026.
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 27, 2026, the Company's Quarterly Report on Form 10-Q, filed on May 7, 2026, the Company's Quarterly Report on Form 10-Q, filed on August 11, 2026, and the Company's Quarterly Report on Form 10-Q, filed on November 5, 2026. 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 5, 2026

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 Third Quarter 2026 Financial Results and Provides Business Update

- *New patient enrollment activities resumed in a limited number of U.S. sites in the soft tissue sarcoma Phase 3 INVINCIBLE-3 Study in the third quarter of 2026*
- *New patient enrollment and treatment resumed in the presurgical triple negative breast cancer ("TNBC") Phase 2 INVINCIBLE-4 Study in the third quarter of 2026*
- *Cash and cash equivalents of $8.5 million as of September 30, 2026*

Conference call begins at 8:00 a.m. Eastern time today

SHELTON, Conn., November 5, 2026 – 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 2026 financial results and provides a business update.

Management will host a conference call and live webcast at 8:00 a.m. Eastern time today to review financial results and provide an update. The archived webcast will be available for replay shortly after the close of the call.

Conference Call Details

Date: November 5, 2026

Time: 8:00 a.m. Eastern Time

Domestic Dial-In: (866) 652-5200

International Dial-In: (412) 317-6060

Webcast URL: https://event.choruscall.com/mediaframe/webcast.html?webcastid=b5XzhWmO

Business Update

INVINCIBLE-3 Study: *Phase 3 open-label, randomized controlled, multicenter study testing INT230-6 as monotherapy compared with standard-of-care ("SOC") in second- and third-line treatment of certain soft tissue sarcoma subtypes.*

In March 2025, the Company paused new site activations and patient enrollment due to funding constraints. At that time, the trial had enrolled 21 patients, and the Company continued to treat all patients, maintain the database, conduct pharmacovigilance, and conduct other study-related activities in cooperation with its contract research organizations at significantly reduced ongoing costs. During this pause, the Company obtained important feedback and recommendations about the trial from key investigators and sarcoma thought leaders, and modifications to the protocol were made.

In April 2026, with a strengthened balance sheet, the Company initiated activities to resume enrollment in a limited number of U.S. sites in the INVINCIBLE-3 Study using an FDA-reviewed amended protocol. New patient enrollment activities resumed in the third quarter of 2026. Several sites are now activated and patients have been identified. Submission of documentation necessary for restarting in the EU and Canada is in process. Increased site activation and patient enrollment rates are expected as sufficient incremental funding is obtained.

INVINCIBLE-4 Study: *Phase 2 open-label, randomized controlled, multicenter study to analyze the clinical activity, safety, and tolerability of INT230-6 given before SOC in patients with early-stage, operable TNBC (Cohort A) and SOC alone (Cohort B).*

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 experiencing localized skin irritation near the tumor site. A protocol

amendment has been approved by the Swissmedic, the Swiss Ethics Committee and the French National regulatory agency to use a lower drug volume per tumor volume ratio and a single injection of INT230-6 in Cohort A.

In July 2026, the Company restarted patient enrollment and treatment in the INVINCIBLE-4 Study and is currently targeting complete enrollment by the end of 2027. The Swiss Cancer Institute, the Company's collaborator in the INVINCIBLE-4 Study, has established an independent data monitory board ("IDMB") comprised of qualified experts to review the safety data and images of these newly treated patients to assess whether the skin irritation issue has been resolved. We plan to provide an update upon completion of IDMB review in the first quarter of 2027. In August 2026, the Company opened its first site in France for accrual and several sites have now been activated.

Preliminary data from the first 14 patients (seven in each cohort) showed a 71% pathological complete response ("pCR") in patients receiving INT230-6 in Cohort A and a 42% pCR in patients receiving the SOC alone (Cohort B). There was also a 44% reduction in grade 3 adverse events in Cohort A compared to Cohort B and fewer immune-related adverse events when our INT230-6 was added prior to the immunochemotherapy. In addition, no invasive breast cancer cells were detected in the axillary lymph nodes in 6 of the 7 patients in Cohort A after INT230-6 treatment, despite 5 (71%) of these patients being initially biopsy-proven node-positive. Results also showed tumor necrosis after 1 or 2 injections in all 7 Cohort A patients. In the pre-surgery MRI at the completion of neoadjuvant immunochemotherapy, four (57%) patients had RECIST 1.1 radiological complete response and three patients (43%) partial response. All patients exhibited necrosis in their tumors and all 7 patients met criteria for breast-conserving surgery, but one proceeded with mastectomy owing to a high-risk germline mutation.

Capital Raises

In March 2026, the Company established a $60 million at-the-market ("ATM") facility. During the third quarter of 2026, the Company raised net proceeds of $1.5 million under the ATM. During the nine months ended September 30, 2026, the Company raised net proceeds of $3.2 million under the ATM.

"We are excited that recruitment of patients has been reinitiated in both of our trials," stated Lewis H. Bender, President and CEO of Intensity Therapeutics, Inc. "In the Phase 3 INVINCIBLE-3 Study, the protocol adjustments have been well received by investigators, and several sites in the United States are now activated and identifying patients. We also met several of the INVINCIBLE-3 Study investigators from Europe and Canada at ESMO, who have expressed a strong desire to restart patient enrollment in their countries as well. In the Phase 2 INVINCIBLE-4 Study, we have met in person with several of our Swiss sites. The Swiss Cancer Institute is currently collecting safety data on the newly treated patients. We look forward to receiving our partner's planned IDMB report of the safety data and conclusions on the skin issue of these newly treated patients in Q1 2027. Assuming a positive report, we will have confidence that the skin issue is resolved. Coupled with the data so far on overall safety and the potential for improved efficacy, we believe there is good motivation for sites to enroll patients in the INVINCIBLE-4 Study. Finally, we continue to pursue business development opportunities, and have had follow-up discussions with several organizations at ESMO from our prior meetings at ASCO and BIO."

Third Quarter 2026 Financial Results

Research and development expenses were $2.4 million for the third quarter of 2026, compared with $1.6 million for the same period in 2025. The increase was primarily due to higher INVINCIBLE-3 Study costs as the Company resumed new patient enrollment activities in a limited number of U.S. sites in the third quarter of 2026. The Company paused new site activations and patient enrollments in March 2025 due to funding constraints. Research and development expenses also increased due to the initiation of a new INT230-6 manufacturing batch during the third quarter of 2026, an estimated bonus accrual during the third quarter of 2026 compared with no bonus accrual during the third quarter of 2025, and higher stock-based compensation.

General and administrative expenses were $1.2 million for the third quarter of 2026, unchanged compared with $1.2 million for the same period in 2025.

Net loss was $3.5 million for the third quarter of 2026, compared with a net loss of $2.7 million for the third quarter of 2025.

As of September 30, 2026, cash and cash equivalents totaled $8.5 million. During the third quarter of 2026, the Company raised $1.6 million under the ATM, for net proceeds of $1.5 million.

About Triple Negative Breast Cancer in the Presurgical Setting

Women with aggressive forms of breast cancer, such as TNBC, are often counseled to undergo neoadjuvant (presurgical) systemic therapy to reduce the risk of the disease returning. Having a pathological complete response, meaning the absence of live cancer at the time of surgery, has been shown to result in a lower risk of disease recurrence from 50% to 16% at 5 years. Approximately 11% to 17% of breast cancers test negative for estrogen receptors (“ER”), progesterone receptors (“PR”), and overexpression of human epidermal growth factor receptor 2 (“HER2”) protein, qualifying them as triple negative. There are approximately 56,000 new cases of TNBC in the US and 420,000 worldwide diagnosed each year, 85% of which are local to the breast. TNBC is considered to be more aggressive and has a poorer prognosis than other types of breast cancer, because there are fewer available targeted medicines. Most patients with local TNBC typically receive immunochemotherapy before surgery. Since the publication of Keynote-522, the standard neoadjuvant treatment for TNBC includes systemic chemotherapy (anthracyclines, cyclophosphamide, paclitaxel, carboplatin) and the anti-PD-1 monoclonal antibody pembrolizumab. pCR rates range from 50% to 65%, depending on tumor size. Rates are generally lower in the larger-sized tumors or with lymph node metastasis. The toxicity of the Keynote-522 regimen is high, with 77% of patients experiencing grade 3 or higher treatment-related adverse events, including treatment-related adverse events that lead to death in 0.5% of patients.

About Sarcoma

Soft tissue sarcoma is a rare type of cancer that starts with the growth of cells in the body's soft tissue, such as muscle, fat, blood vessels, nerves, tendons, and linings of the joints. The disease mostly occurs in the arms, legs and abdomen. There are 197,000 patients in the US living with sarcoma and more than 100 types of soft tissue sarcoma, the treatment of which first involves surgery. Other treatments might include radiation therapy and then chemotherapy. Using the U.S. SEER database, the Company estimated that 14,400 patients have regional or distal (metastatic) leiomyosarcoma, liposarcoma, and undifferentiated pleomorphic sarcoma.

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 consists of two proven, potent anti-cancer agents, cisplatin and vinblastine sulfate, and a diffusion and cell penetration enhancer molecule ("SHAO") that non-covalently conjugates to the two payload drugs, facilitating the dispersion of potent cytotoxic drugs throughout tumors and 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 that 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 controlled 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 with SOC, with overall survival as an endpoint. Intensity also initiated a Phase 2 study in collaboration with The Swiss Group for Clinical Cancer Research, formerly SAKK and now the Swiss Cancer Institute (the "INVINCIBLE-4 Study") (NCT06358573), as part of a Phase 2/3 program evaluating INT230-6 followed by SOC immunochemotherapy and SOC alone for patients with presurgical triple-negative breast cancer. 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 or review our SEC filings.

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, 2025 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.

Investor Relations Contact:
Justin Kulik
CORE IR
justin@coreir.com
(516) 222-2560

Media Contact:
Matt Cossel
CORE IR
PR@coreir.com

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,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$ 2,429	$ 1,553	$ 5,457	$ 5,283
General and administrative	1,194	1,180	3,776	3,549
Total operating expenses	3,623	2,733	9,233	8,832
Loss from operations	(3,623)	(2,733)	(9,233)	(8,832)
Other income (expense):				
Interest income	82	59	253	92
Other (expense) income, net	(3)	3	(5)	185
Net loss	$ (3,544)	$ (2,671)	$ (8,985)	$ (8,555)
Loss per share, basic and diluted	$ (1.09)	$ (1.55)	$ (3.17)	$ (8.29)
Weighted average number of shares of common stock, basic and diluted	3,257,109	1,721,708	2,835,194	1,031,870

Intensity Therapeutics, Inc.
Balance Sheets
(in thousands)

	September 30, 2026	December 31, 2025
	(Unaudited)	*
Assets		
Current assets:		
Cash and cash equivalents	$ 8,494	$ 11,921
Prepaid expenses and other current assets	1,008	788
Total current assets	9,502	12,709
Right-of-use asset, net	75	96
Other assets	710	1,296
Total assets	$ 10,287	$ 14,101
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,651	$ 583
Accrued expenses	897	1,532
Lease liability, current portion	34	31
Total current liabilities	2,582	2,146
Lease liability, net of current portion	53	79
Total liabilities	2,635	2,225
Total stockholders' equity	7,652	11,876
Total liabilities and stockholders' equity	$ 10,287	$ 14,101

*Derived from audited financial statements