

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): August 11, 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):

- ☐ 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 August 11, 2026, Intensity Therapeutics, Inc. (the “Company”) released its financial results for the three and six months ended June 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 August 11, 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, and the Company’s Quarterly Report on Form 10-Q, filed on August 11, 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: August 11, 2026

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 Second Quarter 2026 Financial Results and Provides Business Update

- *Initiated activities to resume enrollment in a limited number of U.S. sites in the soft tissue sarcoma Phase 3 INVINCIBLE-3 Study by the third quarter of 2026*
- *Patient treatment restarted in the presurgical triple negative breast cancer ("TNBC") Phase 2 INVINCIBLE-4 Study*
- *Cash and cash equivalents of \$9.5 million as of June 30, 2026*
- *Increased business development activities*

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

SHELTON, Conn., August 11, 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 second 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: August 11, 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=bZ7JyAJE>

Business Update

INVINCIBLE-3 Study: *Phase 3 open-label, randomized 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 April 2026, 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 based on important learnings from patients previously enrolled in the study. The Company paused new site activations and patient enrollment in March 2025 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. In addition, 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. The FDA has reviewed the amended protocol, which will be implemented for new patient enrollment. Submission of documentation necessary for restarting in the EU is in progress. Site activation and patient enrollment rates are expected to increase as sufficient 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 July 2026, the Company restarted patient treatment in the INVINCIBLE-4 Study and is currently targeting complete enrollment by the end of 2027. The Company paused new patient enrollment in September 2025 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. In March 2026, a protocol amendment was approved by the Swissmedic and the Swiss Ethics Committee to use a lower drug volume per tumor volume ratio and a single injection of INT230-6 in Cohort A. In August 2026, the Company opened its first site in France for accrual following EU submission of the modified protocol.

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 with Cohort B and fewer immune-related adverse events when INT230-6 was added prior to the immunochemotherapy.

Capital Raises

In March 2026, the Company established a \$60 million at-the-market (“ATM”) facility. During the second quarter of 2026, the Company raised net proceeds of \$1.6 million under the ATM. Subsequent to June 30, 2026, the Company has raised additional net proceeds of \$1.3 million under the ATM.

“We are pleased that the capital raised in 2025 and to date in 2026 provides the resources to reinitiate the Phase 3 INVINCIBLE-3 Study. In addition, during the 2025 pause, we evaluated and modified the protocol based on feedback from key investigators and sarcoma thought leaders. The FDA-reviewed amended protocol will first be implemented in select U.S. sites,” stated Lewis H. Bender, Founder, President and CEO of Intensity. “In the Phase 2 INVINCIBLE-4 Study, early data show potential for an improvement in the pCR rate with a reduction in the number of grade 3 adverse events including immune-related adverse events. These preliminary findings are encouraging, and we are excited that investigators have restarted treatment in patients in Switzerland. We look forward to enrolling new patients in this study in France now that sites are being activated. Lastly, we continue to pursue potential partnerships to advance our programs, and held meetings with potential strategic partners at the BIO International Conference in late June. While early, we are pleased with the interest expressed in our science and clinical trials, and we expect to continue discussions in the second half of 2026.”

Second Quarter 2026 Financial Results

Research and development expenses were \$1.8 million for the second quarter of 2026, compared with \$1.5 million for the same period in 2025. The increase was primarily due to higher INVINCIBLE-3 Study costs as the Company initiated activities to resume enrollment in a limited number of U.S. sites in April. The Company paused new site activations and patient enrollments in March 2025 due to funding constraints. Research and development expenses also increased due to an estimated bonus accrual during the second quarter of 2026 compared with no bonus accrual during the second quarter of 2025, which was partially offset by lower stock-based compensation.

General and administrative expenses were \$1.3 million for the second quarter of 2026, compared with \$1.2 million for the same period in 2025. The increase was due to an estimated bonus accrual during the 2026 quarter compared with no bonus accrual during 2025 quarter, and higher Delaware franchise costs. These increases were partially offset by lower stock-based compensation as no stock-based compensation awards were granted during the first half of 2026.

Net loss was \$3.0 million for the second quarter of 2026, compared with a net loss of \$2.5 million for the second quarter of 2025.

As of June 30, 2026, cash and cash equivalents totaled \$9.5 million. During the second quarter of 2026, the Company raised \$1.7 million under the ATM, for net proceeds of \$1.6 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 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 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.

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Intensity Therapeutics, Inc.
Statements of Operations
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	\$ 1,833	\$ 1,541	\$ 3,028	\$ 3,730
General and administrative	1,251	1,164	2,582	2,369
Total operating expenses	3,084	2,705	5,610	6,099
Loss from operations	(3,084)	(2,705)	(5,610)	(6,099)
Other income (expense):				
Interest income	77	17	171	33
Other (expense) income, net	—	151	(2)	182
Net loss	\$ (3,007)	\$ (2,537)	\$ (5,441)	\$ (5,884)
Loss per share, basic and diluted	\$ (1.11)	\$ (3.36)	\$ (2.08)	\$ (8.64)
Weighted average number of shares of common stock, basic and diluted	2,706,607	754,725	2,620,740	681,235

Intensity Therapeutics, Inc.
Balance Sheets
(in thousands)

	<u>June 30, 2026</u>	<u>December 31, 2025</u>
	(Unaudited)	*
Assets		
Current assets:		
Cash and cash equivalents	\$ 9,529	\$ 11,921
Prepaid expenses and other current assets	1,700	788
Total current assets	11,229	12,709
Right-of-use asset, net	82	96
Other assets	210	1,296
Total assets	\$ 11,521	\$ 14,101
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,009	\$ 583
Accrued expenses	1,203	1,532
Lease liability, current portion	33	31
Total current liabilities	2,245	2,146
Lease liability, net of current portion	62	79
Total liabilities	2,307	2,225
Total stockholders' equity	9,214	11,876
Total liabilities and stockholders' equity	\$ 11,521	\$ 14,101

*Derived from audited financial statements