

May 7, 2026



Intensity Therapeutics Reports First Quarter 2026 Financial Results and Provides Corporate Update

- *Cash and cash equivalents of \$10.2 million as of March 31, 2026*
- *Favorable efficacy and safety reported in a small sample of triple negative breast cancer ("TNBC") patients receiving INT230-6 prior to the standard of care ("SOC") compared to SOC alone in the INVINCIBLE-4 Study (as defined below)*
- *Approval to resume enrollment obtained in the INVINCIBLE-4 Study; plans to resume enrollment in the second quarter of 2026*
- *Decision to resume enrollment in a limited number of U.S. sites in the INVINCIBLE-3 Study (as defined below) by the third quarter of 2026*

SHELTON, Conn., May 7, 2026 /PRNewswire/ -- 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 first quarter 2026 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 SOC treatment in patients with early-stage, operable triple negative breast cancer and SOC alone.*

In March 2026, the Company reported the following:

- Preliminary observations of the INVINCIBLE-4 Study showed that five (5) out of seven (7) patients (71.4%) who received INT230-6 prior to SOC ("Cohort A") achieved a pathological complete response ("pCR") whereas two (2) out of six (6) (33%) patients in the SOC arm alone ("Cohort B") achieved a pCR, with one patient still to be evaluated.

- Forty-four percent (44%) fewer grade 3 or higher adverse events were observed in Cohort A compared to Cohort B.
- A protocol amendment was submitted to Swissmedic, Switzerland's regulatory authority, and the Switzerland Ethics Committee to resume enrollment. Full approval to resume enrollment was granted on March 26, 2026. The Company plans to resume enrollment in the second quarter of 2026.

The Company expects presentation of more detailed results for the seven (7) Cohort A patients at a future oncology conference.

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.*

In March 2025, the Company paused new site activations and patient enrollments due to funding constraints. Before this pause, the trial had enrolled 21 patients. The Company has continued to treat patients enrolled in this study, maintain the database, conduct pharmacovigilance, and conduct other study-related activities in cooperation with its third-party contract research organizations at significantly reduced ongoing costs during this pause. In April 2026, the Company decided to resume enrollment in the INVINCIBLE-3 Study in a limited number of U.S. sites by the third quarter of 2026, and has prioritized commencing full patient enrollment and site activations in this study once sufficient incremental funding is obtained.

Lewis H. Bender, Founder, President, and CEO, stated, "The Company made excellent progress in the first quarter. We announced early data from the INVINCIBLE-4 Study, our randomized controlled study in TNBC, showing the possibilities for INT230-6 to increase efficacy while also potentially improving safety. We are now seeking additional patients in our INVINCIBLE-4 Study in Switzerland and expect to initiate enrollment in France in the second or third quarter of 2026. Further, after a successful funding campaign in 2025 and the establishment of a \$60 million ATM facility in March 2026, we have made the decision to reinitiate enrollment of our INVINCIBLE-3 Study and plan to manage our cash burn judiciously. Both of our clinical trials focus on indications with high unmet medical need."

First Quarter 2026 Financial Results

Research and development expenses were \$1.2 million for the three months ended March 31, 2026, compared to \$2.2 million for the same period in 2025. The decrease was 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 has continued to treat all patients enrolled in this study in cooperation with our third-party contract research organizations during this pause. The Company plans to resume enrollment in the INVINCIBLE-3 Study in a limited number of U.S. sites by the third quarter of 2026, and has prioritized commencing full patient enrollment and site activations once sufficient funding is obtained. In addition, lower headcount-related costs in 2026 were entirely offset by an estimated bonus accrual during the three months ended March 31, 2026 compared to no bonus accrual during the three months ended March 31, 2025.

General and administrative expenses were \$1.3 million for the three months ended March 31, 2026, compared to \$1.2 million for the same period in 2025. The increase was due to an estimated bonus accrual during the three months ended March 31, 2026 compared to no bonus accrual during the three months ended March 31, 2025. This increase was partially offset by lower stock-based compensation and one-time expenses related to our reverse stock split in February 2026.

Overall, net loss was \$2.4 million for the three months ended March 31, 2026, compared to a net loss of \$3.3 million for the three months ended March 31, 2025.

As of March 31, 2026, cash and cash equivalents totaled \$10.2 million.

About Triple Negative Breast Cancer in the Presurgical Setting

Women with aggressive forms of breast cancer, such as Triple Negative Breast Cancer ("TNBC"), are often counseled to undergo pre-surgical (neoadjuvant) systemic therapy in advance 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 AEs, 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 belly. 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 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 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, now the Swiss Cancer Institute (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. 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 March 31,	
	2026	2025
Operating expenses:		
Research and development	\$ 1,195	\$ 2,189
General and administrative	1,331	1,205
Total operating expenses	<u>2,526</u>	<u>3,394</u>
Loss from operations	(2,526)	(3,394)
Other income (expense):		
Interest income	94	15
Other (expense) income, net	(2)	32
Net loss	<u>\$ (2,434)</u>	<u>\$ (3,347)</u>

Loss per share, basic and diluted	\$	(0.96)	\$	(5.51)
Weighted average number of shares of common stock, basic and diluted		2,533,918		606,928

Intensity Therapeutics, Inc.
Balance Sheets
(in thousands)

	<u>March 31, 2026</u>		<u>December 31, 2025</u>
	(Unaudited)		*
Assets			
Current assets:			
Cash and cash equivalents	\$ 10,245	\$	11,921
Prepaid expenses and other current assets	661		788
Total current assets	<u>10,906</u>		<u>12,709</u>
Right-of-use asset, net	89		96
Other assets	1,296		1,296
Total assets	<u>\$ 12,291</u>	\$	<u>14,101</u>
Liabilities and Stockholders' Equity			
Current liabilities:			
Accounts payable	\$ 636	\$	583
Accrued expenses	1,574		1,532
Lease liability, current portion	32		31
Total current liabilities	<u>2,242</u>		<u>2,146</u>
Lease liability, net of current portion	70		79
Total liabilities	<u>2,312</u>		<u>2,225</u>
Total stockholders' equity	9,979		11,876
Total liabilities and stockholders' equity	<u>\$ 12,291</u>	\$	<u>14,101</u>

*Derived from audited financial statements

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