

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

- Over \$11 million raised since the beginning of 2Q 2025
- Cash runway extended into the second half of 2026
- In the INVINCIBLE-4 Study, patients receiving INT230-6 prior to the start of standard of care achieved high levels of tumor necrosis in 8 days
- INT230-6 achieved 100% complete response rate in preclinical models of malignant peripheral nerve sheath tumors

SHELTON, Conn., Aug. 7, 2025 /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 second quarter 2025 financial results and provides a corporate update.



Corporate Update

<u>INVINCIBLE-4 Study</u>: 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 April, the European Medicines Agency authorized the initiation of the INVINCIBLE-4 Study in France in collaboration with Unicancer (UCBG), the French referent cooperative group in breast cancer accredited by the French National Cancer Institute (INCa).

The INVINCIBLE-4 Study is currently recruiting patients in Switzerland and France. The expected total is 54 patients. In June 2025 we showed images from the trial of a patient who received two doses of INT230-6. Prior to the injections, the tumor was active. In the post INT230-6 injection scans, the tumor became dark with only diminished live cancer observed at the interface of the healthy tissue and necrotic tumor.

<u>INVINCIBLE-3 Study</u>: 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, new patient enrollment and site activations were paused due to funding issues; however, patients who were already enrolled continue to be dosed, followed and monitored.

<u>Capital Raises and Cash Runway</u>: Since the beginning of the second quarter of 2025, the Company has raised an aggregate of \$11.3 million, with net proceeds of approximately \$10.1 million in two public offerings and At-the Market offerings (the "ATM"), and has extended its cash runway into the second half of 2026.

- 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.
- In June 2025, the Company entered into an Underwriting Agreement with ThinkEquity LLC in a public offering and raised an aggregate of \$2.3 million, with net proceeds after deducting the fees and expenses of approximately \$1.8 million.
- In July 2025, the Company raised an aggregate of \$6.6 million via its ATM, with net proceeds after deducting the fees and expenses of approximately \$6.3 million.

"In a challenging financial market, we were able to raise capital and lower our burn rate during the second guarter to continue to treat patients in our two studies, and in July 2025, high liquidity in our stock allowed us to raise additional gross proceeds of \$6.6 million at a lower incremental cost. This new capital extends our operating runway considerably, with the remaining capacity under the ATM facility to be used selectively and strategically. Given the capital raised to date, we also believe that we are now compliant with Nasdag's minimum stockholders' equity listing requirements, pending Nasdag's confirmation," stated Lewis H. Bender, Intensity Founder, President, and CEO. "In the INVINCIBLE-4 Study, scan images indicate a substantial decrease in tumor activity following two doses of our drug as patients begin their immune-chemo regimen. Based on our prior studies, we believe this effect should be beneficial in increasing the pathological response rate in the cohort of patients receiving our drug and expect to obtain pathology data in 2H of 2026. Lastly, as always, the Company is driven by a focus on patients. This quarter, we strengthen that commitment by forming a collaboration with the author, model, executive producer, speaker, and breast cancer survivor Christine Handy to raise patient awareness of new treatment options on the horizon for patients with early-stage disease."

Second Quarter 2025 Financial Results

Research and development expenses were \$1.5 million for the three months ended June 30, 2025, compared to \$3.6 million for the same period in 2024. Clinical trial expenses decreased \$1.5 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 23 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 June 30, 2025, compared to \$1.5 million for the same period in 2024. Insurance expense decreased due to the favorable directors and officers insurance renewal terms compared to the prior policy year, and legal and other expenses decreased as a result of cost saving from the integration of new systems in the administrative areas.

Overall, net loss was \$2.5 million for the three months ended June 30, 2025, compared to a net loss of \$5.0 million for the three months ended June 30, 2024.

As of June 30, 2025, cash and cash equivalents totaled \$2.2 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 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 <u>www.intensitytherapeutics.com</u>.

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 Nasdag 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 Er	nded June 30,	Six Months Ended June 30,	
	2025	2024	2025	2024
Operating expenses:		· .		
	\$	\$	\$	\$
Research and development	1,541	3,563	3,730	6,378
General and administrative	1,164	1,506	2,369	3,434
Total operating expenses	2,705	5,069	6,099	9,812
Loss from operations	(2,705)	(5,069)	(6,099)	(9,812)
Other income (expense):				
Interest income	17	98	33	238
Other income, net	151	_	182	_
	\$	\$	\$	\$
Net loss	(2,537)	(4,971)	(5,884)	(9,574)
	\$	\$	\$	\$
Loss per share, basic and diluted	(0.13)	(0.36)	(0.35)	(0.70)
Weighted average number of shares of common stock, basic and diluted	18,868,124	13,712,152	17,030,867	13,710,819

Intensity Therapeutics, Inc. Balance Sheets (in thousands)

	<u>June 30, 2025</u> (Unaudited)	<u>Decem</u>	<u>December 31, 2024</u> *	
Assets				
Current assets:				
	\$	\$		
Cash and cash equivalents	2,21	6	2,590	
Prepaid expenses and other current assets	82	2	773	
Total current assets	3,03	8	3,363	
Right-of-use asset, net	10	9	122	
Other assets	1,29	6	1,298	
-	\$	\$		
Total assets	4,44	3	4,783	
Liabilities and Stockholders' Equity Current liabilities:				
	\$	\$		
Accounts payable	1,19		1,219	
Accrued expenses	94	-	508	
Lease liability, current portion	3	0	28	
Total current liabilities	2,16	4	1,755	
Lease liability, net of current portion	9	5	110	
Total liabilities	2,25	9	1,865	
Total stockholders' equity	2,18	4	2,918	
	\$	\$		
Total liabilities and stockholders' equity	4,44	3	4,783	

^{*}Derived from audited financial statements

releases/intensity-therapeutics-reports-second-quarter-2025-financial-results-and-provides-corporate-update-302524797.html

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