March 13, 2025

Intensity Therapeutics Reports 2024 Year End Financial Results and Provides Corporate Update

- *32 sites are currently contracted in the INVINCIBLE-3 Study, and 25 patients have been screened*
- *Eight Swiss sites are activated in the INVINCIBLE-4 Study, and several patients have been screened*
- *Final sarcoma data from our first metastatic study and our INVINCIBLE-3 Study design was presented at the annual Connective Tissue Oncology Society Meeting in November 2024*
- *Final data from our first neoadjuvant breast cancer study and our INVINCIBLE-4 Study design was presented at the annual San Antonio Breast Cancer Society Meeting in December 2024*

SHELTON, Conn., March 13, 2025 /PRNewswire/ -- Intensity Therapeutics, Inc. ("Intensity" or "the Company") (Nasdaq: INTS), a late-stage clinical biotechnology company focused on the discovery and development of proprietary, novel immune-based intratumoral cancer therapies designed to kill tumors and increase immune system recognition of cancers, announces 2024 year-end financial results and provides a corporate update.

Corporate Update

INVINCIBLE-3 Study: Phase 3 open-label, randomized study testing INT230-6 as monotherapy compared to the standard of care ("SOC") drugs in second and third line treatment for certain soft tissue sarcoma subtypes. The INVINCIBLE-3 Study is expected to enroll 333 patients and initiate sites in eight countries. This study has been authorized by the US FDA, Health Canada, the European Medicines Authority (for France, Germany, Italy, Poland and Spain), and Australia's Therapeutics Goods Administration. The primary endpoint in the INVINCIBLE-3 Study is overall survival.

In July 2024, the Company initiated and dosed its first patient in the INVINCIBLE-3 Study. The trial is actively enrolling patients across the US, Canada, Europe and Australia. Up to 60 sarcoma-focused institutions are expected to participate from these regions. The Company has contracted 32 sites with 25 patients screened to date. The Company expects to complete enrollment in the first half of 2026.

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 ("TNBC") and SOC alone. The primary endpoint is the change in the pathological complete response rate for the combination compared to the SOC alone. The INVINCIBLE-4 Study is expected to enroll approximately 54 patients in Switzerland and France.

In October 2024, in collaboration with The Swiss Group for Cancer Research SAKK ("SAKK"), the Company initiated and dosed its first patient in Switzerland in the INVINCIBLE-4 Study. To date, the Company has activated eight sites in Switzerland and treated several patients. The Company expects to activate additional sites in Switzerland and France in the first half of 2025 and complete enrollment by the end of the first quarter of 2026.

"In 2024, Intensity Therapeutics finalized both Phase 3 and Phase 2 protocols, engaged leading hospitals around the world, and obtained regulatory authorization to recruit patients in 9 countries to initiate treatment," stated Lewis H. Bender, Intensity Founder, President, and CEO. "Our programs were again selected for presentation at major sarcoma and breast cancer societies. Many of the best sarcoma treatment centers from the US, Canada, Europe and Australia are either participating now or in contract discussions. For our breast cancer trial, our partners at SAKK have recruited interest by the leading hospitals in Switzerland and France to participate. Physicians are screening patients at an increasing rate. We believe in the potential for our drug to have a positive impact on the lives of metastatic sarcoma and presurgical breast cancer patients around the world, who so desperately need improved alternatives to current therapies."

2024 Year End Financial Results

Research and development expenses were $10.5 million for the year ended December 31, 2024, compared to $4.8 million for the year ended December 31, 2023. The increase was primarily due to an increase of $5.6 million in the INVINCIBLE-3 Study in 2024, in which we enrolled our first patient in the third quarter of 2024, and to a lesser extent, an increase of $0.5 million in the INVINCIBLE-4 Study, in which we enrolled and dosed our first patient in the fourth quarter of 2024. These increases were partially offset by a decrease of $1.1 million in our IT-01 Study due to the completion of enrollment in this study in mid-2022 and the completion of study-related costs in 2023. Research and development also increased due to higher salary, benefits, and stock-based compensation.

General and administrative expenses were $6.1 million for the year ended December 31, 2024, compared to $3.5 million for the year ended December 31, 2023. The increase was primarily due to increased expenses related to salary, benefits and stock-based compensation, higher legal and consulting fees, and higher directors and officers insurance.

Overall, net loss was $16.3 million for the year ended December 31, 2024, compared to a net loss of $10.5 million for the year ended December 31, 2023.

As of December 31, 2024, cash and cash equivalents totaled $2.6 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 is comprised of two proven, potent anti-cancer agents, cisplatin and vinblastine, and a penetration enhancer molecule (SHAO) that helps disperse potent cytotoxic drugs throughout tumors for diffusion 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 in collaboration with The Swiss Group for Clinical Cancer Research SAKK (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. 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 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; 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 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)

	Years Ended December 31,	
	2024	2023
Operating expenses:		
Research and development	$ 10,496	$ 4,786
General and administrative	6,089	3,533
Total operating expenses	16,585	8,319
Loss from operations	(16,585)	(8,319)
Other income (expense):		
Interest income	314	324
Interest expense	—	(305)
Loss on debt extinguishment	—	(2,262)
Other income (expense)	3	24
Net loss	$ (16,268)	$ (10,538)

Preferred stock deemed dividend	—	(1,324)
Net loss attributable to common stockholders	$ (16,268)	$ (11,862)
Loss per share, basic and diluted	$ (1.17)	$ (1.38)
Weighted average number of shares of common stock, basic and diluted	13,906,973	8,616,324

Intensity Therapeutics, Inc.
Balance Sheets
(in thousands)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash, cash equivalents and marketable debt securities	$ 2,590	$ 14,776
Prepaid expenses and other current assets	773	688
Total current assets	3,363	15,464
Right-of-use asset, net	122	147
Other assets	1,298	1,684
Total assets	$ 4,783	$ 17,295
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,219	$ 3,048
Accrued expenses	508	891
Lease liability, current portion	28	20
Total current liabilities	1,755	3,959
Other long-term liabilities	—	36
Lease liability, net of current portion	110	138
Total liabilities	1,865	4,133
Total stockholders' equity	2,918	13,162
Total liabilities and stockholders' equity	$ 4,783	$ 17,295

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