March 14, 2024

Intensity Therapeutics Reports Full Year 2023 Financial Results and Provides Corporate Update

- INT230-6, Intensity's lead drug candidate, advances into late-stage clinical programs in sarcoma and breast cancer
- Year-end cash and investments of $14.8 million expected to fund operations through the end of Q1 '25
- Focusing on clinical operational and regulatory progress for a new technology to treat cancer
- Multiple clinical opportunities in cancer types having high unmet medical need
- Upcoming clinical milestones

SHELTON, Conn., March 14, 2024 /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 full year 2023 financial results and provides a review of 2023 accomplishments and anticipated upcoming developments.

2023 and Other Recent Highlights

- Study May Proceed letter received from the U.S. Food and Drug Administration ("FDA") for the Company's Phase 3 protocol in soft tissue sarcoma using INT230-6 (the "INVINCIBLE-3" study)
- Completed IT-01 study, a 110-patient Phase 1/2 study using INT230-6 in refractory cancers
    - Dosing completed in over 20 different cancers, with favorable safety and strong signals of efficacy shown with immune activation
- Completed dosing, database lock and tables, listings and figures for a 91-patient Phase 2 study using INT230-6 in pre-adjuvant breast cancer (the "INVINCIBLE-2" study)
- Presented INVINCIBLE-2 data at the San Antonio Breast Cancer Symposium ("SABCS") in an oral podium spotlight discussion session
    - INT230-6 induced up to 95% necrosis in tumors following a single injection
    - Favorable safety profile observed

    - Increase in CD4 T-cells and NK cells observed within tumors
- Data presented at Connective Tissue Oncology Society ("CTOS") Annual Meeting showing INT230-6 extended survival in refractory soft tissue sarcoma subjects by 15 months compared to a synthetic control group with a 93% disease control rate when used as monotherapy
- Received Orphan Drug Designation for the three key ingredients in INT230-6 for the treatment of soft tissue sarcoma
- Presented two posters at the American Society of Clinical Oncology ("ASCO") Annual Meeting reporting anti-cancer immune activation in both breast cancer and sarcoma, which are cancers that are considered to be non-immunogenic
- Closed an up-sized initial public offering on the Nasdaq exchange with a full exercise of the underwriters' over-allotment option at the top of the range, raising over $22 million in gross proceeds
- Bolstered management team by adding Chief Financial Officer, Vice President of Clinical Operations, Vice President of Regulatory Affairs and manufacturing engineering staff

"We had a pivotal year in 2023 culminating with the receipt of an FDA 'Study May Proceed' letter to enter into Phase 3 clinical trials for our lead drug candidate, INT230-6 for metastatic soft tissue sarcoma," said Lewis H. Bender, Founder, President and Chief Executive Officer. "Our selection this year by the review committees at ASCO, CTOS and SABCS, including oral podium presentations, validated our science and indicated interest by oncologists in our results. We are on track to initiate our Phase 3 sarcoma study in mid-2024. Following our IPO, our cash position remains strong, and we believe we have sufficient runway to meet near term milestones."

In the INVINCIBLE-3 study, the Company plans to enroll 333 patients with an endpoint of overall survival. "Current U.S. standard-of-care drugs used for sarcoma after progression of the first line therapies require extensive safety monitoring. The standard-of-care ("SOC") medicines cause severe toxicities and provide median overall survival of only between 12 to 15 months depending on the drug and sarcoma subtype," stated Mr. Bender. "Our data suggests the potential for a significant survival increase with fewer and less severe toxicities. Sarcoma patients are in need of new and meaningful ways to treat their disease. A successful outcome of our Phase 3 survival study could be critical in treatment of other fatty, dense tumor types such as breast and pancreatic cancers."

The Company also plans to initiate a Phase 2/3 program in presurgical breast cancer with the start of a Phase 2 randomized controlled trial testing two doses of INT230-6 prior to SOC compared to the SOC alone (the "INVINCIBLE-4" study). The endpoint for this portion of the study is the change in the pathological complete response rate for the combination, which is an accepted FDA endpoint for accelerated approval. The Company expects to initiate INVINCIBLE-4 in mid-2024, which will provide data to size the Phase 3 portion of the program. As Dr. Angel Arnout M.D., MSc., and the Principal Investigator from the INVINCIBLE-2 study stated in San Antonio, "the ability for INT230-6 to induce necrosis and noted immune effects prior to a patient's surgery, while maintaining a favorable safety profile, would be a major move forward for the treatment paradigm of breast cancer and potentially many other cancers." The Company will provide further updates on the progress of this study in the coming months.

Anticipated Near-Term Milestones

- Initiate INVINCIBLE-3 Study in certain metastatic soft tissue sarcoma subtypes. The Company plans to enroll 333 patients with an endpoint of overall survival. The study will compare INT230-6 as a monotherapy treatment to the three current SOC drugs in 2nd and 3rd line soft tissue sarcoma subtypes.
- Initiate the Phase 2/3 program in presurgical breast cancer with the start of INVINCIBLE-4, a Phase 2 randomized controlled trial testing two doses of INT230-6 prior to SOC (immune-chemotherapy) compared to the SOC alone. The endpoint for this portion of the study is the change in the pathological complete response rate for the combination. The Company expects to initiate INVINCIBLE-4 in mid-2024, which will provide data to size the Phase 3 portion of the program.

Year-End 2023 Financial Results

Research and development expenses were $4.8 million for the year ended December 31, 2023, compared to $5.1 million for the same period in 2022. The decrease was primarily due to the completion of enrollment in the IT-01 study in mid-2022. This decrease was partially offset by higher 2023 expenses for start-up work on the INVINCIBLE-3 study and a new manufacturing batch of INT230-6.

General and administrative expenses were $3.5 million for the year ended December 31, 2023, compared to $2.4 million for the same period in 2022. The increase was primarily due to salary and bonus increases, including the hiring of a new chief financial officer in the fourth quarter of 2023, higher stock-based compensation expense, and overall higher accounting fees, consulting, directors and officers insurance and other expenses as we transitioned into a publicly traded company.

In 2023, the Company also recognized a non-cash $2.3 million loss on debt conversion at the time of the initial public offering, along with a non-cash preferred stock deemed dividend of $1.3 million, representing the value that was transferred to the Series B and C preferred stockholders upon triggering of anti-dilution provisions.

Overall, net loss was $10.5 million for the year ended December 31, 2023, compared to $7.6 million for the year ended December 31, 2022.

As of December 31, 2023, cash, cash equivalents and marketable debt securities totaled $14.8 million, which the Company expects will be sufficient to fund operations through the end of the first quarter in 2025.

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 composed 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, direct killing of the tumor by INT230-6 releases a bolus of neoantigens specific to the patient's malignancy, leading to engagement of the immune system and systemic anti-tumor effects.

Importantly, these effects are mediated without immunosuppression that so often occurs with systemic chemotherapy.

About Intensity Therapeutics

Intensity Therapeutics is a late-stage clinical biotechnology company that applies novel engineered chemistry to turn "cold" tumors "hot" by enabling its aqueous cytotoxic-containing drug product, INT230-6, to mix and saturate the dense, high-fat pressurized environment of the tumor. 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 novel approach to cancer cell death that holds the potential to shift the treatment paradigm and turn many deadly cancers into chronic diseases. INT230-6 has completed enrollment of over 200 patients in a Phase 1/2 dose escalation trial (NCT03058289) and Phase 2 randomized control clinical trial in breast cancer (the INVINCIBLE 2 study) (NCT04781725). The Company is initiating 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 with overall survival as an endpoint. The Company is also planning a Phase 2/3 program in presurgical triple negative breast cancer testing INT230-6 in combination with standard of care compared to standard of care alone. For more information about the Company, 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 expected future plans, development activities, projected milestones, business activities or results. We have based these forward-looking statements on our 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 we make. These risks and uncertainties, many of which are beyond our control, include: the risk that the anticipated milestones may be delayed or not occur or be changed, as well as 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.
Condensed Statement of Operations
(in thousands, except share and per share amounts)

	Years Ended December 31,	
	2023	**2022**
Operating expenses:		
	$	$
Research and development	4,786	5,132
General and administrative	3,533	2,418
Total operating expenses	8,319	7,550
Loss from operations	(8,319)	(7,550)
Other income (expense):		
Interest income	324	2
Interest expense	(305)	(82)
Loss on debt extinguishment	(2,262)	—
Other	24	48
Net loss	$ (10,538)	$ (7,582)
Preferred stock deemed dividend	(1,324)	—
Net loss attributable to common stockholders	$ (11,862)	$ (7,582)
Loss per share, basic and diluted	$ (1.38)	$ (2.22)
Weighted average number of shares of common stock, basic and diluted	8,616,324	3,410,103

Intensity Therapeutics, Inc.
Condensed Balance Sheets
(in thousands)

	December 31, 2023	**December 31, 2022**
Assets		
Current assets:		
		$
Cash, cash equivalents and marketable debt securities	$ 14,776	1,312
Prepaid expenses and other current assets	688	139
Total current assets	15,464	1,451
Right-of-use asset, net	147	139
Other assets	1,684	167
		$
Total assets	$ 17,295	1,757
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficiency)		
Current liabilities:		
Accounts payable	$ 3,048	$ 603
Accrued expenses	891	1,724
Lease liability, current portion	20	143
Convertible note and accrued interest	—	4,349
Total current liabilities	3,959	6,819
Other long-term liabilities	36	36
Lease liability, net of current portion	138	—
Total liabilities	4,133	6,855
Redeemable convertible preferred stock	—	10,000

Total stockholders' equity (deficiency)	13,162	(15,098)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficiency)	$ 17,295	$ 1,757

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