May 9, 2024

Intensity Therapeutics Reports First Quarter 2024 Financial Results and Provides Corporate Update

- INT230-6, Intensity's lead drug candidate, continues to advance into late-stage clinical programs in sarcoma and breast cancer
- Cash and investments of $10.5 million expected to fund operations through the end of the first quarter of 2025

SHELTON, Conn., May 9, 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 first quarter 2024 financial results and provides a corporate update.

Corporate Update

- In mid-2024, the Company intends on initiating a Phase 3 open-label, randomized study, or the INVINCIBLE-3 Study, testing INT230-6 as a monotherapy compared to the standard of care ("SOC") drugs in second and third line treatment for certain soft tissue sarcoma subtypes. We plan to enroll 333 patients with an endpoint of overall survival and have screened and qualified over 30 sites for the INVINCIBLE-3 Study. Contract negotiations to approve and activate these sites are in process. We estimate the sites could take between two to six months to complete their contracting processes.
- In mid-2024, the Company intends on initiating a Phase 2/3 program testing INT230-6 in combination with the SOC treatment (chemotherapy/immunotherapy) compared to SOC alone in women with triple negative breast cancer in presurgical (neoadjuvant) breast cancer. The endpoint for the Phase 2 portion of the study, or the INVINCIBLE-4 Study, is the change in the pathological complete response rate for the combination compared to the SOC alone. We expect to initiate the INVINCIBLE-4 Study in mid-2024, which will provide data to size a Phase 3 study. We are in the process of screening and qualifying sites for the INVINCIBLE-4 Study.

"We continue to make excellent progress towards the initiation of our INVINCIBLE-3 Study," said Lewis H. Bender, Founder, President and CEO of Intensity Therapeutics, Inc. "In the

first quarter, we were able to release our INT230-6 Phase 3 clinical supplies, successfully ship the entire batch to our main depot, and complete labeling of a portion of the vials for the United States sites. During the quarter, we completed evaluation of dozens of sites and are now in various stages of contract and budget discussions with over 30 different high-quality sarcoma centers. We continue to qualify new sarcoma specialty hospitals in the US and internationally, and top enrolling centers from our previous metastatic study have expressed interest in participating in the INVINCIBLE-3 trial." Mr. Bender continued, "Our INVINCIBLE-4 Study also continues to make excellent progress. Sites are being recruited and we continue to work towards initiating the study in mid-2024."

First Quarter 2024 Financial Results

Research and development expenses were $2.8 million for the three months ended March 31, 2024, compared to $0.8 million for the same period in 2023. The increase was primarily due to preliminary work related to the INVINCIBLE-3 Study, and to a lesser extent, costs for manufacturing a new batch of INT230-6 and increased expenses related to salary, benefits, and stock-based compensation.

General and administrative expenses were $1.9 million for the three months ended March 31, 2024, compared to $0.5 million for the same period in 2023. The increase was primarily due to increased expenses related to salary, benefits and stock-based compensation, higher legal, audit, and consulting fees, and higher directors and officers insurance.

Overall, net loss was $4.6 million for the three months ended March 31, 2024, compared to $1.3 million for the three months ended March 31, 2023.

As of March 31, 2024, cash, cash equivalents and marketable debt securities totaled $10.5 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 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.
Condensed Statement of Operations
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 2,815	$ 774
General and administrative	1,928	480
Total operating expenses	4,743	1,254
Loss from operations	(4,743)	(1,254)
Other income (expense):		
Interest income	140	—
Interest expense	—	(83)
Other income	—	1
Net loss	$ (4,603)	$ (1,336)
Loss per share, basic and diluted	$ (0.34)	$ (0.39)
Weighted average number of shares of common stock, basic and diluted	13,709,487	3,410,103

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

	March 31, 2024	**December 31, 2023**
Assets		
Current assets:		
Cash, cash equivalents and marketable debt securities	$ 10,497	$ 14,776
Prepaid expenses and other current assets	672	688
Total current assets	11,169	15,464
Right-of-use asset, net	141	147
Other assets	1,098	1,684
Total assets	$ 12,408	$ 17,295
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,219	$ 3,048
Accrued expenses	1,274	891
Lease liability, current portion	26	20
Total current liabilities	2,519	3,959

Other long-term liabilities	36	36
Lease liability, net of current portion	131	138
Total liabilities	2,686	4,133
Total stockholders' equity	9,722	13,162
Total liabilities and stockholders' equity	$ 12,408	$ 17,295

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