November 13, 2024

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

First patient dosed in randomized, Phase 2 study in presurgical triple negative breast cancer

SHELTON, Conn., Nov. 13, 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 third quarter 2024 financial results and provides a corporate update.

Corporate Update

INVINCIBLE-3 Study: a Phase 3 open-label, randomized study testing INT230-6 as monotherapy compared to the 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. The primary endpoint in the INVINCIBLE-3 Study is overall survival.

- July 2024: the first patients were dosed in the U.S. in the INVINCIBLE-3 Study.
- July 2024: authorization received from Health Canada to initiate the INVINCIBLE-3 Study in Canada.
- September 2024: authorization received from The European Medicines Agency to initiate the INVINCIBLE-3 Study in Europe.
- October 2024: authorization received from Australia's Therapeutic Goods Administration to initiate INVINCIBLE-3 Study in Australia.

INVINCIBLE-4 Study: a 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 ("TNBC") and SOC alone. The primary endpoint is the pathological complete response ("pCR") rate in the primary tumor and affected lymph nodes. The INVINCIBLE-4 Study is expected to enroll approximately 54 patients in Switzerland and France.

- September 2024: authorization from the Swiss Medic and the Swiss Ethics Commission to initiate the INVINCIBLE-4 Study.

- October 2024: first patient dosed in the INVINCIBLE-4 Study.

"This has been an excellent quarter of regulatory success in multiple countries. We received the regulatory authorizations needed to initiate sites in eight countries for our Phase 3 global sarcoma study and our Phase 2 breast cancer study in Switzerland," said Lewis H. Bender, Intensity Founder, President, and CEO. "Our efforts now turn to site activation and patient recruitment. We remain committed to exploring our new treatment that causes immunological cell death in severe diseases such as soft tissue sarcoma and triple-negative breast cancer. We are excited that our drug will be tested in multiple countries on three continents. INT230-6's ability to debulk tumors and activate an immune response is now in late-stage testing for two indications. We expect that the results from these ongoing studies could potentially demonstrate a meaningful clinical benefit for patients with high unmet need in both the metastatic and local disease settings."

Third Quarter 2024 Financial Results

Research and development expenses were $2.2 million for the three months ended September 30, 2024, compared to $1.4 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, increased expenses related to salary, benefits, and stock-based compensation.

General and administrative expenses were $1.4 million for the three months ended September 30, 2024, compared to $1.1 million for the same period in 2023. The increase was primarily due to increased expenses related to salary, benefits and stock-based compensation, and higher directors and officers insurance.

Overall, net loss was $3.5 million for the three months ended September 30, 2024, compared to a net loss of $2.3 million for the three months ended September 30, 2023.

As of September 30, 2024, cash and cash equivalents totaled $2.8 million, which the Company expects will be sufficient to fund operations into 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 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.

Investor Relations Contact:
Justin Kulik
justin@coreir.com
(558) 230-6401

Media Contact:
Jules Abraham
CORE IR
julesa@coreir.com

Intensity Therapeutics, Inc.
Condensed Statement of Operations
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
	$	$	$	$
Research and development	2,151	1,352	8,529	2,985
General and administrative	1,419	1,139	4,853	1,982
Total operating expenses	3,570	2,491	13,382	4,967
Loss from operations	(3,570)	(2,491)	(13,382)	(4,967)
Other income (expense):				
Interest income	48	148	286	148
Interest expense	—	—	—	(305)
Loss on debt extinguishment	—	—	—	(2,262)
Other income (expense)	9	14	9	20
Net loss	$ (3,513)	$ (2,329)	$ (13,087)	$ (7,366)
Preferred stock deemed dividend	—	—	—	(1,324)
Net loss attributable to common stockholders	$ (3,513)	$ (2,329)	$ (13,087)	$ (8,690)
Loss per share, basic and diluted	$ (0.25)	$ (0.17)	$ (0.95)	$ (1.26)
Weighted average number of shares of common stock, basic and diluted	13,804,651	13,660,627	13,742,325	6,899,984

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

	September 30, 2024	**December 31, 2023**
	(Unaudited)	*
Assets		
Current assets:		

Cash, cash equivalents and marketable debt securities	$ 2,782	$ 14,776
Prepaid expenses and other current assets	1,005	688
Total current assets	3,787	15,464
Right-of-use asset, net	128	147
Other assets	1,298	1,684
Total assets	$ 5,213	$ 17,295
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 540	$ 3,048
Accrued expenses	1,749	891
Lease liability, current portion	28	20
Total current liabilities	2,317	3,959
Other long-term liabilities	—	36
Lease liability, net of current portion	117	138
Total liabilities	2,434	4,133
Total stockholders' equity	2,779	13,162
Total liabilities and stockholders' equity	$ 5,213	$ 17,295

*Derived from audited financial statements

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