August 8, 2024

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

- First patient dosed in global randomized, Phase 3 study in metastatic soft tissue sarcoma
- Collaboration agreement with The Swiss Group for Clinical Cancer Research SAKK ("SAKK") to conduct a Phase 2 randomized, study in early-stage breast cancer in Europe
- Cash and investments of $6.3 million expected to fund operations into the first quarter of 2025

SHELTON, Conn., Aug. 8, 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 second quarter 2024 financial results and provides a corporate update.

Corporate Update

- In July 2024, the Company initiated and dosed its first patient in a Phase 3 open-label, randomized study (the "INVINCIBLE-3 Study") testing INT230-6, Intensity's lead drug candidate, as a monotherapy compared to the standard of care ("SOC") drugs in second- and third-line treatment for certain soft tissue sarcoma subtypes. The Company plans to enroll 333 patients with an endpoint of overall survival and has screened and qualified over 50 sites for the INVINCIBLE-3 Study. Contract negotiations are in process to approve and activate these sites, which is estimated to take up to six months per site.
- In May 2024, the Company executed a collaboration agreement with SAKK to conduct a Phase 2 randomized, controlled study (the "INVINCIBLE-4 Study") evaluating clinical and biological effects of INT230-6 followed by SOC vs. SOC alone in early-stage triple-negative breast cancer. The Company plans to enroll 54 to 60 patients in Europe. The INVINCIBLE-4 Study endpoint is the change in the pathological complete response

rate for the combination compared to the SOC alone. The Company expects that the data from INVINCIBLE-4 Study will provide data to size a follow-on Phase 3 study. The Company is in the process of screening and qualifying sites for the INVINCIBLE-4 Study, and plans to initiate the study in the third quarter of 2024.

- In May 2024, the Company appointed Thomas Dubin, J.D., MPH, to the Intensity board of directors, increasing the size of the board to five members. Mr. Dubin has extensive pharmaceutical business development, regulatory, and commercialization experience.

"The dosing of the first patient in our randomized controlled Phase 3 sarcoma trial is the most important development milestone Intensity has reached to date," said Lewis H. Bender, Intensity Founder, President and CEO. "A journey of 1,000 miles starts with the first step, and a successful clinical study outcome can only be achieved by initiating sites and enrolling patients. For our Phase 3 study, we have qualified over 50 sites and are in contract and budget negotiations to initiate treatment in multiple countries. Also, our collaboration with SAKK has progressed well during this quarter, and we are also looking forward to enrolling the first patient in the INVINCIBLE-4 study. Finally, I am excited that Tom Dubin joined our Board. Tom is a highly successful and sophisticated biotech executive who has already provided key insights."

Second Quarter 2024 Financial Results

Research and development expenses were $3.6 million for the three months ended June 30, 2024, compared to $0.9 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 $1.5 million for the three months ended June 30, 2024, compared to $0.4 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.

Upon the Company's initial public offering in June 2023, convertible notes outstanding converted to common stock, resulting in a $2.3 million loss on debt conversion. In addition, a preferred stock deemed dividend of $1.3 million was also recognized in June 2023, representing the value that was transferred to Series B and C preferred stockholders upon triggering of anti-dilution provisions concurrent with the initial public offering.

Overall, net loss was $5.0 million for the three months ended June 30, 2024, compared to a net loss of $3.7 million for the three months ended June 30, 2023.

As of June 30, 2024, cash, cash equivalents and marketable debt securities totaled $6.3 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 Therapeutics is a late-stage clinical biotechnology company that applies novel engineered chemistry 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 even for cancers that do not respond to immunotherapy. INT230-6 has completed enrollment of over 200 patients in two studies; a Phase 1/2 dose escalation trial (NCT03058289), and a Phase 2 randomized control clinical trial in breast cancer (the INVINCIBLE-2 study) (NCT04781725). 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 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. Information on the Phase 2 portion of the program (INVINCIBLE-4 Study) is listed under (NCT06358573). 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.

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 June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 3,563	$ 859	$ 6,378	$ 1,633
General and administrative	1,506	362	3,434	843
Total operating expenses	5,069	1,221	9,812	2,476
Loss from operations	(5,069)	(1,221)	(9,812)	(2,476)
Other income (expense):				
Interest income	98	—	238	—
Interest expense	—	(222)	—	(304)
Loss on debt extinguishment	—	(2,262)	—	(2,262)
Other income	—	4	—	5
Net loss	$ (4,971)	$ (3,701)	$ (9,574)	$ (5,037)
Preferred stock deemed dividend	—	(1,324)	—	(1,324)
Net loss attributable to common stockholders	$ (4,971)	$ (5,025)	$ (9,574)	$ (6,361)
Loss per share, basic and diluted	$ (0.36)	$ (1.43)	$ (0.70)	$ (1.84)
Weighted average number of shares of common stock, basic and diluted	13,712,152	3,516,579	13,710,819	3,463,635

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

	June 30, 2024 (Unaudited)	December 31, 2023 *
Assets		
Current assets:		
Cash, cash equivalents and marketable debt securities	$ 6,324	$ 14,776
Prepaid expenses and other current assets	1,116	688
Total current assets	7,440	15,464
Right-of-use asset, net	135	147
Other assets	1,098	1,684
Total assets	$ 8,673	$ 17,295
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,919	$ 3,048
Accrued expenses	1,258	891
Lease liability, current portion	27	20
Total current liabilities	3,204	3,959
Other long-term liabilities	—	36
Lease liability, net of current portion	124	138
Total liabilities	3,328	4,133
Total stockholders' equity	5,345	13,162
Total liabilities and stockholders' equity	$ 8,673	$ 17,295

*Derived from audited financial statements

View original content to download multimedia: https://www.prnewswire.com/news-releases/intensity-therapeutics-reports-second-quarter-2024-financial-results-and-provides-corporate-update-302218390.html

SOURCE Intensity Therapeutics Inc.