

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 14, 2023

Intensity Therapeutics, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation)	001-41109 (Commission File Number)	46-1488089 (IRS Employer Identification No.)
1 Enterprise Drive, Suite 430 Shelton, CT (Address of Principal Executive Offices)		06484-4779 (Zip Code)

(203) 221-7381
(Registrant's Telephone Number, Including Area Code)

61 Wilton Road, 3rd Floor
Westport, CT 06880
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	Trading Symbol(s):	Name of Exchange on Which Registered:
Common Stock, \$0.0001 par value per share	INTS	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On August 14, 2023, Intensity Therapeutics, Inc. (the "**Company**") released its financial results for the quarter ended June 30, 2023. A copy of the Company's press release is attached as Exhibit 99.1 to this Form 8-K and incorporated herein by reference.

The information in this report shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued August 14, 2023.
104	Cover Page Interactive Data File (formatted in Inline XBRL).

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Comments in this Current Report on Form 8-K and in the exhibit attached hereto contain certain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, which are based on management's good faith expectations and beliefs concerning future developments. Actual results may differ materially from these expectations as a result of many factors. These factors include, but are not limited to, the risks and uncertainties described in the "Risk Factors" and

“Cautionary Note Regarding Forward Looking Statements” sections of the Company’s prospectus, dated June 29, 2023 and filed on June 30, 2023 pursuant to Rule 424(b) under the Securities Act relating to the Company’s Registration Statement on Form S-1 (File No. 333-260565). The Company does not undertake any obligation to update such forward-looking statements. All market and industry data are based on Company estimates.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: August 14, 2023

Intensity Therapeutics, Inc.

By: /s/ Lewis H. Bender

Name: Lewis H. Bender

Title: Chief Executive Officer

[Signature Page to the Form 8-K]



Intensity Therapeutics Reports Second Quarter Financial Results and Provides Corporate Update

Closed Upsized IPO Priced at Top-Of-Range, Full Exercise of the Over-Allotment Nets \$20.4 Million in Proceeds

Data Presented at ASCO Showed that Lead Asset INT230-6 Prolongs Survival Alone or in Combination With Ipilimumab in Adult Patients with Relapsed, Refractory, Metastatic Sarcomas Compared To Synthetic Controls

INVINCIBLE Study Data Presented at ASCO Showed INT230-6 Following One Intratumoral Dose Can Cause Immune Priming in Historically Quiescent Breast Cancers

WESTPORT, Conn., August 14, 2023 – Intensity Therapeutics, Inc. (Nasdaq: INTS), a clinical-stage 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, today reported financial results for the second quarter ended June 30, 2023, and provided a corporate update.

“The second quarter of 2023 was transformative for Intensity Therapeutics, during which, we closed an upsized initial public offering (IPO), priced at top-of-the-range, despite a turbulent biotech capital market environment. The \$20.5 million of net proceeds now allows us to further the development of our lead product candidate, INT230-6, into registration studies,” stated Lewis H. Bender, President and Chief Executive Officer of Intensity Therapeutics. “Notably, in June, our trial investigators presented new data at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting from the IT-01 phase 1/2 clinical study of INT230-6, either as monotherapy or in combination with ipilimumab in patients with relapsed, refractory and metastatic sarcomas, as well as from the phase 2 INVINCIBLE study of INT230-6 in presurgical breast cancer patients. The data demonstrated that, for all sarcoma patients receiving at least one dose of INT230-6, alone, the median overall survival was 21.3 months, compared to the typical 7 to 10 months in historical phase 1/2 studies. As a result of this compelling data, interest in our novel approach was especially high among the physicians who treat sarcoma, a deadly disease in desperate need of new therapeutic approaches. We intend to submit an Investigational New Drug (IND) application for a phase 3 study of INT-230-6 in soft tissue sarcoma by the end of this year.

“Additionally, Angel Arnaout, M.D., Scientist and Surgical Oncologist at the Ottawa Hospital, and Professor of Surgery at the University of Ottawa was the lead author on the poster reporting INVINCIBLE results at ASCO on the use of INT230-6 in early stage breast cancer. Results from Part 2 of our INVINCIBLE study showed high levels of tumor necrosis, expression levels of dendritic cells, macrophages and CD4 T-cells tumor influx, post treatment using INT230-6, when comparing patients treated with drug versus those in the control group. Dr. Arnaout commented on how our new drug may shift the way all cancer patients awaiting surgery are treated. Looking ahead, we expect to report additional data from the INVINCIBLE study by year end and are planning to launch a phase 2/3 program in a presurgical breast cancer setting,” concluded Mr. Bender.



Recent Company Highlights

- June 2023: Closed an upsized IPO of 3.9 million shares of common stock at a public offering price of \$5.00 per share, representing the top-of-the-range, raising net proceeds of \$20.5 million after full 15% over-allotment.
- In June: Reported data at ASCO from 29 metastatic sarcoma patients enrolled in the IT-01 study of lead product, INT230-6, a locally delivered potent cytotoxic treatment; data showed extended survival in refractory soft tissue sarcoma subjects by nearly 450 days compared to a synthetic control and that treatment with INT230-6 induced an immune response in sarcoma tumors. Safety data was favorable with the majority of adverse events being low grade.
- In June: Presented data at ASCO meeting from the INVINCIBLE study of INT230-6 in presurgical breast cancer, which reported that gene enrichment pathway analysis demonstrated INT230-6 induced signaling in the post-treatment samples, immune priming in historically quiescent breast cancers and induced T-Cell receptor signaling, macrophage markers, and IL-18 and B-Cell Receptor signaling. Previously at ASCO and other oncology conferences, the Company reported that INT230-6 resulted in major pathological reduction in several early breast cancer patients with up to 100% tumor necrosis after one intratumoral (IT) dose.
- Completed first drafts of the IT-01 clinical study reports for INT230-6 alone, in combination with Merck’s immunotherapy drug pembrolizumab and in combination with Bristol-Myers Squibb’s immunotherapy drug, ipilimumab.

Anticipated 2023 Clinical Milestones

- Report additional results from IT-01 phase 1/2 clinical trial of INT230-6 involving metastatic sarcomas.
- Report additional results from the phase 2 INVINCIBLE study in presurgical breast cancer.
- File an Investigational New Drug (IND) application for a phase 3 study of INT230-6 in soft tissue sarcoma.
- Finalize the study design and a protocol for a phase 2/3 program in presurgical breast cancer.

Second Quarter 2023 Financial Highlights

Research and Development (R&D) Expenses were \$0.9 million for the three months ended June 30, 2023 as compared to \$1.4 million for the same period last year. The 38.0% decrease reflects the fact that Study IT-01 and Study IT-02 no longer have patient care costs and the drafting of results is nearly complete. Phase 3 IT-03 in sarcoma and phase 2/3 IT-04 in presurgical breast cancer will continue to incur planning, multiple regulatory filing, manufacturing, study initiation and trial preparation costs in 2023.

General and Administrative (G&A) Expenses were \$363,000 for the three months ended June 30, 2023 as compared to \$545,000 for the same period in 2022. The decrease is primarily due to the prior year having higher costs relating to SEC filings and IPO expenses. The accounting services and legal costs related to the IPO in 2023 were charged directly to the equity section of the balance sheet as a reduction of additional paid in capital.

Interest Expense for the three months ended June 30, 2023 were \$222,000 as compared to \$15,000 for the three months ended June 30, 2022. The increase is due to the



Net Operating Loss for the second quarter ended June 30, 2023 was \$1.2 million as compared to \$1.9 million for the three months ended June 30, 2022. The current quarter includes a non-operating loss of \$2.3 million which is the discount from the IPO price that was given to convertible debt holders as part of their agreements.

Cash and Cash Equivalents as of June 30, 2023, were approximately \$136,000. After accounting for the total net cash proceeds received following the closing of the IPO, of approximately \$20.5 million, the Company expects to have sufficient cash to fund current operations until early in the third quarter of 2025.

Conference Call and Webcast Information

The Company will hold a conference call today at 8AM EDT.

To participate in the conference call, please dial 1-877-317-6789 (domestic) or 1-412-317-6789 (international). To access a live webcast of the call, please visit: <https://ir.intensitytherapeutics.com/news-events/events-presentations>.

An archived replay of the webcast will be available for one year on the Intensity Therapeutics website at: <https://ir.intensitytherapeutics.com/news-events/events-presentations>.

About Intensity Therapeutics

Intensity Therapeutics, Inc. is a clinical-stage biotechnology company pioneering a new immune-based approach to treat solid tumor cancers. Intensity leverages its DfuseRx™ technology platform to create proprietary drug formulations that following direct injection rapidly disperse throughout a tumor and diffuse therapeutic agents into cancer cells. Intensity's product candidates have the potential to induce an adaptive immune response that not only attacks the injected tumor, but also non-injected tumors. The Company's lead product candidate, INT230-6, is in development for the treatment of patients with solid tumors, such as sarcoma and breast cancer. Intensity has a clinical collaboration agreement with Merck Sharpe & Dohme (Merck) to evaluate INT230-6 with pembrolizumab. In addition, the Company has a clinical collaboration agreement with Bristol-Myers Squibb to evaluate the combination INT230-6 with Bristol-Myers Squibb's anti-CTLA-4 antibody, ipilimumab. Intensity has also executed agreements with the Ottawa Hospital Research Institute (OHRI) and the Ontario Institute of Cancer Research (OICR) to study INT230-6 in a randomized controlled neoadjuvant phase 2 study in women with early stage breast cancer (the INVINCIBLE study) (NCT04781725). Additionally, the Company executed a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute's (NCI) Vaccine Branch. For more information, please visit www.intensitytherapeutics.com and follow the Company on Twitter @IntensityInc.

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 in 2023 or beyond 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.

Contact Information

Investor Relations Contact:

Rx Communications Group
Michael Miller
(917)-633-6086
mmiller@rxir.com

US Media Contact:

KOGS Communication
Edna Kaplan
+1 781 639 1910
kaplan@kogspr.com



	June 30,		June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development costs	\$ 859,212	\$ 1,385,966	\$ 1,632,986	\$ 3,080,466
General and administrative costs	362,490	543,830	842,846	1,227,853
Total operating expenses	1,221,702	1,929,796	2,475,832	4,308,319
Loss from operations	(1,221,702)	(1,929,796)	(2,475,832)	(4,308,319)
Other income (expense):				
Interest income	171	213	487	856
Interest expense	(221,779)	(14,959)	(305,161)	(29,754)
Loss on debt extinguishment	(2,261,581)	-	(2,261,581)	-
Other	4,349	16,900	5,074	40,528
Net loss	\$ (3,700,542)	\$ (1,927,642)	\$ (5,037,013)	\$ (4,296,689)
Preferred stock deemed dividend	(1,323,535)	-	(1,323,535)	-
Net loss attributable to common stockholders	\$ (5,024,077)	\$ (1,927,642)	\$ (6,360,548)	\$ (4,296,689)
Loss per share, basic and diluted	\$ (1.43)	\$ (0.57)	\$ (1.84)	\$ (1.26)
Weighted average number of shares of common stock, basic and diluted.	3,516,579	3,410,103	3,463,635	3,410,103

The accompanying notes are an integral part of these financial statements.



Intensity Therapeutics, Inc.
Condensed Balance Sheets
(Unaudited)

	June 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 135,765	\$ 1,311,877
Stock subscriptions receivable	17,765,000	-
Other current assets	159,460	138,459
Total current assets	18,060,225	1,450,336
Right-of-use asset, net	-	139,089
Other assets	167,738	167,738
Total assets	\$ 18,227,963	\$ 1,757,163
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
Current liabilities:		
Accounts payable	\$ 1,581,812	\$ 603,176
Accrued expenses	1,476,633	1,723,400
Current lease liability	-	143,221
Convertible note and accrued interest	-	4,348,548
Total current liabilities	3,058,445	6,818,345
Related party deposit	36,000	36,000
Total liabilities	3,094,445	6,854,345
Series A redeemable convertible preferred stock, par value \$.0001. Authorized, issued, and outstanding shares of none and 5,000,000 as of June 30, 2023 and December 31, 2022, respectively.	-	10,000,000
STOCKHOLDERS' EQUITY (DEFICIENCY)		
Authorized preferred stock is 15,000,000 shares as of June 30, 2023. None issued or outstanding as of June 30, 2023.		
Series B convertible preferred stocks, par value \$.0001. Authorized, issued, and outstanding shares of none and 1,449,113 as of June 30, 2023 and December 31, 2022, respectively.	-	145
Series C convertible preferred stocks, par value \$.0001. Authorized, issued, and outstanding shares of none and 1,800,606 as of June 30, 2023 and December 31, 2022, respectively.	-	180
Common stock, par value \$.0001. Authorized shares of 135,000,000 and 50,000,000 as of June 30, 2023 and December 31, 2022, respectively. Issued and outstanding shares of 13,099,377 and 3,410,103 as of June 30, 2023 and December 31, 2022, respectively.	1,310	341
Additional paid in capital	60,145,764	23,555,160
Accumulated deficit	(45,013,556)	(38,653,008)
Total stockholders' equity (deficiency)	15,133,518	(15,097,182)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficiency)	\$ 18,227,963	\$ 1,757,163

The accompanying notes are an integral part of these financial statements.