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): November 13, 2023

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

Delaware	001-41109	46-1488089
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1 Enterprise Drive, Suite 430 Shelton, CT	06484-4779
(Address of Principal Executive Offices)	(Zip Code)

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

Not Applicable
(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 November 13, 2023, Intensity Therapeutics, Inc. (the "***Company***") released its financial results for the quarter ended September 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 November 13, 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: November 13, 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 Third Quarter Financial Results and Provides Corporate Update

Presented positive Phase 1/2 clinical data for INT230-6 in patients with refractory soft tissue sarcoma at Connective Tissue Oncology Society ("CTOS"), demonstrating 93% disease control rate in patients on monotherapy and survival extension of nearly 15 months vs. synthetic control group

Received Orphan Drug Designation for the three components of INT230-6 for the treatment of soft tissue sarcoma

Closed upsized IPO and full exercise of over-allotment option for $20.2 million in net proceeds

On track to file IND for Phase 3 study of INT230-6 in soft tissue sarcoma and to report additional Phase 2 INVICIBLE study results for presurgical breast cancer by end of 2023

SHELTON, Conn., November 13, 2023 – Intensity Therapeutics, Inc. (Nasdaq: INTS), a late-stage biotechnology company that applies novel engineered chemistry to discover and develop proprietary, novel immune-based intratumoral cancer therapies designed to kill tumors and increase immune system recognition of cancers, today reported financial results for the third quarter ended September 30, 2023, and provided a corporate update.

"Metastatic soft tissue sarcoma continues to plague cancer patients who have poor survival outcomes and insufficient therapeutic options. The positive overall survival and disease control rate data from our Phase 1/2 clinical trial of INT230-6 positions our lead candidate as a potential much needed reprieve, keeping the drug inside the tumor while sparing the body of toxicity. We expect to file an IND for a Phase 3 study of INT230-6 in soft tissue sarcoma by the end of 2023 and look forward to progressing this study," said Lewis H. Bender, President and Chief Executive Officer of Intensity.

Mr. Bender added: "To continue the momentum built from our successful upsized IPO in July, we also look forward to reporting additional results from our Phase 2 INVINCIBLE study in presurgical breast cancer at a medical meeting and finalizing the study design and protocol for a Phase 2/3 program in presurgical breast cancer before year end. I am pleased with our pace of progress to advance the clinical development of INT230-6 and am strongly encouraged by data to date, which reinforces the potential of INT230-6 to shift the treatment paradigm of cancer."

Recent Company Highlights

- **Presented Positive INT230-6 Data in Patients with Refractory Soft Tissue Sarcoma at the Connective Tissue Oncology Society (CTOS)** In November, the Company presented positive data from its ongoing Phase 1/2 clinical trial of INT230-6 at the CTOS annual meeting. The data presented demonstrated a strong disease control rate of 93% for subjects in the monotherapy arm while also extending survival in subjects by nearly 15 months when compared to a synthetic control group. INT230-6 was found to be generally safe and well tolerated with the majority of treatment-emergent adverse events being grade 1 or 2.

- **Received Orphan Drug Designation for Components of INT230-6 for the Treatment of Soft Tissue Sarcoma**. In September, Intensity was granted orphan drug designation (ODD) by the US Food and Drug Administration for three active moieties comprising its lead candidate INT230-6: cisplatin, vinblastine sulfate, and the diffusion enhancer SHAO-FA (8-((2-hydroxybenzoyl) amino)octanoate).

- **Completed Upsized Initial Public Offering (IPO) with Full Exercise of the Over-Allotment Option**. In July, Intensity announced that it had closed its IPO with the full exercise of its over-allotment option. Intensity received a total of $20.2 million in net proceeds from the transaction, providing sufficient cash and cash equivalents to fund operations into the second half of 2025.

Anticipated Near-Term Milestones

- Report additional results from the Phase 2 INVINCIBLE study in presurgical breast cancer at a medical meeting in 4Q 2023
- File an Investigational New Drug (IND) application for a Phase 3 study of INT230-6 in soft tissue sarcoma in 4Q 2023
- Finalize the study design for a Phase 2/3 program in presurgical breast cancer in 4Q 2023

Third Quarter 2023 Financial Highlights

Research and Development (R&D) Expenses were $1.4 million for the three months ended September 30, 2023, as compared to $1.2 million for the same period last year. The increase is due to ongoing Phase 3 IT-03 in sarcoma and phase 2/3 IT-04 in presurgical breast cancer, which will continue to incur planning, multiple regulatory filing, manufacturing, study initiation and trial preparation costs in 2023.

General and Administrative (G&A) Expenses were $1.1 million for the three months ended September 30, 2023, as compared to $0.6 million for the same period in 2022. The increase is primarily due to the costs of operating as a public company. 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 September 30, 2023, were $0 as compared to $15,123 for the three months ended September 30, 2022. The decrease is due to the convertible notes and accrued interest being converted to common stock at the time of the IPO.

Net Operating Loss for the third quarter ended September 30, 2023, was $2.3 million as compared to $1.8 million for the three months ended September 30, 2022.

Cash, Cash Equivalents and Marketable Securities as of September 30, 2023, were approximately $15.6 million. The Company expects to have sufficient cash to fund current operations into the second half of 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' Clinical Studies

INT230-6 has completed enrollment of over 200 patients in two phase 2 and phase 1 dose escalation clinical trials (NCT03058289 and NCT04781725) with various advanced solid tumors; IT-01 in metastatic disease, and IT-02 the INVINCIBLE study, in presurgical breast cancer. The Company has a clinical collaboration agreement with Merck Sharpe & Dohme (Merck) to evaluate the combination of INT230-6, Intensity's lead product candidate, and KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 (programmed death receptor-1) therapy, in patients with advanced pancreatic, colon, squamous cell and bile duct malignancies. The Company also 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, in patients with advanced liver, breast and sarcoma cancers. Intensity managed the individual combination arms separately with each respective partner via a joint development committee. The Company also executed agreements with the Ottawa Hospital Research Institute (OHRI) and the Ontario Institute of Cancer Research (OICR) to study INT230-6 in the INVINCIBLE study, a randomized controlled neoadjuvant phase 2 study in women with early-stage breast cancer. Near-term, Intensity expects to file an Investigational New Drug (IND) application for a Phase 3 study of INT230-6 in soft tissue sarcoma as well as finalizing the study design and protocol for a Phase 2/3 program in presurgical breast cancer.

About Intensity Therapeutics

Intensity Therapeutics is a late-stage 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 if INT230-6 to kill tumors and elicit an adaptive immune response within days of injection, representing a truly novel approach to cancer cell death that holds the potential to shift the treatment paradigm and turn many deadly cancers into chronic diseases. 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
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development costs	$ 1,351,766	$ 1,160,737	$ 2,984,752	$ 4,241,203
General and administrative costs	1,138,748	607,113	1,981,594	1,834,966
Total operating expenses	2,490,514	1,767,850	4,966,346	6,076,169
Loss from operations	(2,490,514)	(1,767,850)	(4,966,346)	(6,076,169)
Other income (expense):				
Interest income	147,539	988	148,026	1,844
Interest expense	-	(15,123)	(305,161)	(44,877)
Loss on debt extinguishment	-	-	(2,261,581)	-
Other	13,230	7,118	18,304	47,646
Net loss	$ (2,329,745)	$ (1,774,867)	$ (7,366,758)	$ (6,071,556)
Preferred stock deemed dividend	-	-	(1,323,535)	-
Net loss attributable to common stockholders	$ (2,329,745)	$ (1,774,867)	$ (8,690,293)	$ (6,071,556)
Loss per share, basic and diluted	$ (0.17)	$ (0.52)	$ (1.26)	$ (1.78)
Weighted average number of shares of common stock, basic and diluted.	13,660,627	3,410,103	6,899,984	3,410,103

Intensity Therapeutics, Inc.
Condensed Balance Sheets
(Unaudited)

	September 30, 2023 (unaudited)	December 31, 2022 (audited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,693,825	$ 1,311,877
Marketable debt securities	8,955,316	-
Prepaid expenses	971,239	62,924
Other current assets	14,366	75,535
Total current assets	16,634,746	1,450,336
Right-of-use asset, net	152,605	139,089
Other assets	28,438	167,738
Total assets	$ 16,815,789	$ 1,757,163
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
Current liabilities:		
Accounts payable	$ 358,404	$ 603,176
Accrued expenses	355,006	1,723,400
Current lease liability	10,556	143,221
Convertible note and accrued interest	-	4,348,548
Total current liabilities	723,966	6,818,345
Long-term lease liability	144,891	-
Related party deposit	36,000	36,000
Total liabilities	904,857	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 September 30, 2023 and December 31, 2022, respectively.	-	10,000,000
STOCKHOLDERS' EQUITY (DEFICIENCY)		
Authorized preferred stock is 15,000,000 shares as of September 30, 2023. None issued or outstanding as of September 30, 2023.		
Series B convertible preferred stock, par value $.0001. Authorized, issued, and outstanding shares of none and 1,449,113 as of September 30, 2023 and December 31, 2022, respectively.	-	145
Series C convertible preferred stock, par value $.0001. Authorized, issued, and outstanding shares of none and 1,800,606 as of September 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 September 30, 2023 and December 31, 2022, respectively. Issued and outstanding shares of 13,709,377 and 3,410,103 as of September 30, 2023 and December 31, 2022, respectively.	1,371	341
Additional paid-in capital	63,252,862	23,555,160
Accumulated deficit	(47,343,301)	(38,653,008)

Total stockholders' equity (deficiency)	15,910,932	(15,097,182)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficiency)	$ 16,815,789	$ 1,757,163