

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): December 4, 2025

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)

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 3.01. Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

As previously reported, on June 6, 2025, Intensity Therapeutics, Inc. (the “Company”) received a letter (the “June 2025 Nasdaq Letter”) from The Nasdaq Stock Market (“Nasdaq”) notifying the Company that for the preceding 30 consecutive business days the Company’s common stock did not maintain a minimum closing bid price of \$1.00 per share as required by Nasdaq Listing Rule 5550(a)(2) (the “Rule”) for continued listing on Nasdaq (the “Minimum Bid Price Requirement”). The June 2025 Nasdaq Letter stated that the Company had 180 calendar days, or until December 3, 2025 (the “Initial Compliance Date”), to demonstrate compliance with the Minimum Bid Price Requirement.

On December 4, 2025, the “Company received a second letter (the “December 2025 Nasdaq Letter”) from Nasdaq stating that the Company is eligible for an additional 180 calendar days, or until June 1, 2026, to regain compliance with the Minimum Bid Price Requirement, in accordance with Nasdaq Listing Rule 5810(c)(3)(A).

The Staff of the Nasdaq (the “Staff”) determined that the Company is eligible for the second 180 calendar day period, or until June 1, 2026, to regain compliance with the Rule based on the Staff’s determination that the Company must continue to meet the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on the Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement, and the Company’s written notice of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. If at any time during this additional time period, the closing bid price of the Company’s common stock on the Nasdaq is at least \$1.00 per share for a minimum of ten (10) consecutive business days, the Staff will provide written confirmation of compliance with the Rule and this matter will be closed. The December 2025 Nasdaq Letter from Nasdaq also stated that if the Company chooses to implement a reverse stock split, it must complete the split no later than ten (10) business days prior to the expiration date in order to timely regain compliance.

If compliance with the Rule cannot be demonstrated by June 1, 2026, the Staff will provide written notification that the Company’s common stock will be delisted from the Nasdaq. At that time, the Company may appeal the Staff’s determination to a Hearings Panel (the “Panel”). If the Company appeals, it will be asked to provide a plan to regain compliance to the Panel, and that historically Panels have generally viewed a near-term reverse stock split as the only definitive plan acceptable to resolve a deficiency of the Minimum Bid Price Requirement.

An indicator will continue to be broadcast over Nasdaq’s market data dissemination network noting the Company’s non-compliance. In addition, a list of all non-compliant Nasdaq companies and the reason(s) for such non-compliance is posted on Nasdaq’s website at listingcenter.nasdaq.com. The Company will continue to be included in this list until it regains compliance. Nonetheless, the December 2025 Nasdaq Letter has no immediate effect on the Company’s continued listing on the Nasdaq Capital Market, subject to the Company’s compliance with the other continued listing requirements of Nasdaq.

The Company intends to actively monitor the closing bid price of its common stock and will consider available options to regain compliance with the Minimum Bid Price Requirement and the other Nasdaq listing requirements. Such available options will include effecting a reverse stock split of the Company’s common stock, if necessary, in order to maintain the Company’s Nasdaq listing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued December 5, 2025.
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 Annual Report on Form 10-K, filed on March 13, 2025, the Company’s Quarterly Report on Form 10-Q, filed on May 13, 2025, the Company’s Quarterly Report on Form 10-Q, filed on August 7, 2025, and the Company’s Quarterly Report on

Form 10-Q, filed on November 6, 2025. 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: December 5, 2025

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 Granted 180-Day Extension to Regain Compliance with Nasdaq's Minimum Bid Price Requirement

Shelton, Conn., December 5, 2025 – Intensity Therapeutics, Inc. ("Intensity" or "the Company") (Nasdaq: INTS), a late-stage clinical biotechnology company focused on the discovery and development of novel intratumoral cancer therapies that are designed to kill tumors and increase immune system recognition of cancers using its proprietary non-covalent conjugation technology, today announced that it has been granted a 180 calendar day extension from The Nasdaq Stock Market LLC ("Nasdaq") to regain compliance with the Nasdaq's minimum \$1.00 bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) (the "Rule") for continued listing on Nasdaq (the "Minimum Bid Price Requirement"), following the expiration of the initial 180 calendar day period to regain compliance on December 3, 2025, which was initially granted on June 6, 2025. The Company now has until June 1, 2026 to meet the Minimum Bid Price Requirement set forth in Nasdaq Listing Rule 5550(a)(2).

The notification has no immediate effect on the listing or trading of the Company's shares of common stock, which will continue to trade on the Nasdaq Capital Market under the symbol "INTS." To regain compliance with the Rule, the Company must maintain a closing bid price of at least \$1.00 per share for a minimum of ten (10) consecutive business days on or prior to the 180-day extension period, or June 1, 2026. The Company intends to actively monitor the closing bid price of its common stock between now and the end of the extension period and intends to take all appropriate actions to cure the deficiency and regain compliance with the Rule prior to the end of the compliance period.

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 (the "INVINCIBLE-4 Study") (NCT06358573) in collaboration with the Swiss Cancer Group, formerly the Swiss Group for Clinical Cancer Research SAKK, 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.

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 DfuseRxSM technology platform. The drug consists of two proven, potent anti-cancer agents, cisplatin and vinblastine sulfate, and a diffusion and cell penetration enhancer molecule ("SHAO") that facilitates the dispersion of potent cytotoxic drugs throughout tumors, allowing the active agents to diffuse 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.

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 risk that product candidates that appear promising in early research and clinical trials do not demonstrate safety and/or efficacy in larger-scale or later clinical trials; 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; our potential inability to satisfy the Nasdaq Capital Market's requirements for continued listing and be subject to delisting; 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 Annual Report on Form 10-K for the year ended December 31, 2024 and in the Company's subsequent 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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