

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): September 10, 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 8.01. Other Events.

On September 10, 2025, Intensity Therapeutics, Inc. (the “Company”) announced an update on its INVINCIBLE-4 study. The update reported that a pathological complete response (“pCR”) was observed in the first patient evaluated in Cohort A, where each patient received two doses of INT230-6 eight days apart, followed by the standard of care immunochemotherapy, and that to date, the safety profile looks favorable in Cohort A. However, some patients in Cohort A experienced localized skin irritation near the tumor site and therefore, new patient enrollment has been paused to evaluate the data collected and to implement necessary adjustments prior to reopening patient enrollment.

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: September 10, 2025

Intensity Therapeutics, Inc.

By: /s/ Lewis H. Bender

Name: Lewis H. Bender

Title: Chief Executive Officer