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): October 29, 2025

INTELLIA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-37766**	**36-4785571**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

40 Erie Street, Suite 130 **Cambridge, Massachusetts** **(Address of principal executive offices)**	**02139** **(Zip Code)**

Registrant's telephone number, including area code: (857) 285-6200

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:

☐ 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 each exchange on which registered
Common Stock (Par Value $0.0001)	NTLA	The Nasdaq Global Market

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 October 29, 2025, the United States Food and Drug Administration (the "FDA") verbally informed the Company that the FDA has placed a clinical hold on the Investigational New Drug applications for the MAGNITUDE and MAGNITUDE-2 Phase 3 clinical trials for nexiguran ziclumeran ("nex-z"). FDA indicated that it would provide a formal Clinical Hold Letter within 30 calendar days.

The clinical hold follows the previously disclosed report of Grade 4 liver transaminases and increased total bilirubin in a patient who was dosed with nex-z in the MAGNITUDE trial. As previously announced on October 27, 2025, the Company had temporarily paused dosing and screening in the MAGNITUDE and MAGNITUDE-2 Phase 3 clinical trials for nex-z based on the MAGNITUDE trial's protocol-defined pausing criteria.

The Company intends to work with the FDA to address the clinical hold as expeditiously as possible.

Forward-Looking Statements

This current report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, but are not limited to, express or implied statements regarding Intellia's beliefs and expectations regarding: the safety, tolerability, efficacy, success and advancement of its clinical programs for "nex-z" (also known as NTLA-2001), including the ability resolve the clinical hold on nex-z and to resume and successfully complete its MAGNITUDE and MAGNITUDE-2 trials for nex-z. Any forward-looking statements in this current report on Form 8-K are based on management's current expectations and beliefs of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: uncertainty as to when the clinical hold may be resolved, including the actions or studies that the Company may be required to take or conduct in order to resolve the clinical hold**;** uncertainties related to Intellia's ability to resume the MAGNITUDE and MAGNITUDE-2 trials, the implications of the clinical hold on the safety and efficacy of nex-z and further development of nex-z; regulatory agencies' evaluation of regulatory filings and other information related to our product candidates, including nex-z; uncertainties related to the authorization, initiation and conduct of studies and other development requirements for our product candidates, including uncertainties related to regulatory approvals to conduct clinical trials; the risk that any one or more of Intellia's product candidates, including nex-z, will not be successfully developed and commercialized; risks related to Intellia's ability to protect and maintain its intellectual property position; risks related to valid third party intellectual property; risks related to Intellia's relationship with third parties, including its licensors and licensees; risks related to the ability of its licensors to protect and maintain their intellectual property position; the risk that the results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies for the same product candidate or Intellia's other product candidates; and risks related to Intellia's reliance on collaborations, including that its collaboration with Regeneron Pharmaceuticals, Inc. will not continue or will not be successful. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause Intellia's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Intellia's most recent annual report on Form 10-K and quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in Intellia's other filings with the Securities and Exchange Commission. All information in this current report on Form 8-K is as of the date of the report, and Intellia undertakes no duty to update this information unless required by law.

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.

Intellia Therapeutics, Inc.
(Registrant)

Date: October 29, 2025

By: /s/ John M. Leonard
Name: John M. Leonard
Title: Chief Executive Officer and President