

**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 18, 2023

INTELLIA THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-37766
(Commission
File Number)

36-4785571
(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 per share	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 7.01. Regulation FD Disclosure.

On October 18, 2023, Intellia Therapeutics, Inc. (“Intellia”) issued a press release titled “Intellia Therapeutics Announces FDA Clearance of Investigational New Drug (IND) Application to Initiate a Pivotal Phase 3 Trial of NTLA-2001 for the Treatment of Transthyretin (ATTR) Amyloidosis with Cardiomyopathy.” A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information under this Item 7.01, including Exhibit 99.1 hereto, is being furnished herewith and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On October 18, 2023, Intellia announced that the United States Food and Drug Administration has cleared the Company’s Investigational New Drug application for NTLA-2001 for the treatment of transthyretin (ATTR) amyloidosis with cardiomyopathy. The global Phase 3 study of NTLA-2001, an *in vivo* CRISPR-based gene editing candidate, is expected to initiate by year-end 2023.

Forward Looking Statements.

This Current Report on Form 8-K and certain of the materials furnished or filed herewith contain 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, efficacy, success and advancement of its pipeline of investigational gene editing therapies, including its clinical program for NTLA-2001 for the treatment of transthyretin (ATTR) amyloidosis with cardiomyopathy pursuant to its clinical trial applications and investigational new drug application; the initiation, enrollment, dosing and completion of its clinical trials, including its ability to initiate a global Phase 3 study of NTLA-2001 by year-end 2023.

Any forward-looking statements are based on management’s current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that could cause actual results to differ materially and adversely from those set forth in or implied by any forward-looking statements. These risks, uncertainties and factors include, but are not limited to: 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; uncertainties related to the authorization, initiation, enrollment and conduct of studies and other development requirements for its product candidates, including NTLA-2001; the risk that any one or more of Intellia’s product candidates will not be successfully developed and commercialized; the risk that the results of preclinical studies or clinical studies, such as its clinical studies of NTLA-2001, will not be predictive of future results of 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 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 filed with the Securities and Exchange Commission (“SEC”), as well as discussions of potential risks, uncertainties, and other important factors in Intellia’s other filings with the SEC, including those contained or incorporated by reference. Any forward-looking statements represent Intellia’s views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. Intellia explicitly disclaims any obligation to update any forward-looking statements, except as required by law.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated October 18, 2023.
104	104 Cover Page Interactive Data File (embedded within the Inline XBRL document).

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.

Date: October 18, 2023

Intellia Therapeutics, Inc.

By: /s/ John M. Leonard

Name: John M. Leonard

Title: Chief Executive Officer and President

A decorative horizontal bar consisting of a series of vertical squares in various shades of blue, red, and orange, interspersed with thin white lines.

PRESS RELEASE

**Intellia Therapeutics Announces FDA Clearance of
Investigational New Drug (IND) Application to Initiate a Pivotal Phase 3 Trial of NTLA-2001 for the Treatment of Transthyretin (ATTR)
Amyloidosis with Cardiomyopathy**

- *NTLA-2001 is the first-ever investigational in vivo CRISPR-based gene editing therapy cleared to enter late-stage clinical development*

CAMBRIDGE, Mass., Oct. 18, 2023 – Intellia Therapeutics, Inc. (NASDAQ:NTLA), a leading clinical-stage genome editing company focused on developing potentially curative therapies leveraging CRISPR-based technologies, today announced that the U.S. Food and Drug Administration (FDA) has cleared the company’s Investigational New Drug (IND) application for NTLA-2001 for the treatment of transthyretin (ATTR) amyloidosis with cardiomyopathy. The global Phase 3 study of NTLA-2001, an *in vivo* CRISPR-based gene editing candidate, is expected to initiate by year-end 2023.

“The FDA clearance of the NTLA-2001 IND application allows us to initiate a pivotal Phase 3 trial in the United States, marking the first *in vivo* CRISPR-based candidate to begin late-stage clinical development. This is another important step forward for Intellia and our collaborator, Regeneron, as we aim to establish a new standard of care for the treatment of ATTR amyloidosis,” said Intellia President and Chief Executive Officer John Leonard, M.D. “We are thrilled to further advance NTLA-2001 and our pipeline of investigational gene editing therapies as we embark on a new era in medicine. We look forward to sharing additional information about the Phase 3 study at our upcoming quarterly earnings webcast, being held on Thursday, November 9.”

About NTLA-2001

Based on Nobel Prize-winning CRISPR/Cas9 technology, NTLA-2001 could potentially be the first single-dose treatment for ATTR amyloidosis. NTLA-2001 is the first investigational CRISPR therapy candidate to be administered systemically, or through a vein, to edit genes inside the human body. Intellia's proprietary non-viral platform deploys lipid nanoparticles to deliver to the liver a two-part genome editing system: guide RNA specific to the disease-causing gene and messenger RNA that encodes the Cas9 enzyme, which carries out the precision editing. Robust preclinical and clinical data, showing deep and long-lasting transthyretin (TTR) reduction following *in vivo* inactivation of the target gene, supports NTLA-2001's potential as a single-administration therapeutic. Intellia leads development and commercialization of NTLA-2001 as part of a multi-target discovery, development and commercialization collaboration with Regeneron. The global Phase 1 trial is an open-label, multi-center, two-part study of NTLA-2001 in adults with hereditary transthyretin amyloidosis with polyneuropathy (ATTRv-PN) or transthyretin amyloidosis with cardiomyopathy (ATTR-CM). The trial is now closed for enrollment. Visit [clinicaltrials.gov \(NCT04601051\)](https://clinicaltrials.gov/ct2/show/study/NCT04601051) for more details.

About Transthyretin (ATTR) Amyloidosis

Transthyretin amyloidosis, or ATTR amyloidosis, is a rare, progressive and fatal disease. Hereditary ATTR (ATTRv) amyloidosis occurs when a person is born with mutations in the *TTR* gene, which causes the liver to produce structurally abnormal transthyretin (TTR) protein with a propensity to misfold. These damaged proteins build up as amyloid in the body, causing serious complications in multiple tissues, including the heart, nerves and digestive system. ATTRv amyloidosis predominantly manifests as polyneuropathy (ATTRv-PN), which can lead to nerve damage, or cardiomyopathy (ATTRv-CM), which can lead to heart failure. Some individuals without the genetic mutation produce non-mutated, or wild-type TTR proteins that become unstable over time, misfolding and aggregating in disease-causing amyloid deposits. This condition, called wild-type ATTR (ATTRwt) amyloidosis, primarily affects the heart. There are an estimated 50,000 people worldwide living with ATTRv amyloidosis and between 200,000 and 500,000 people with ATTRwt amyloidosis.

About Intellia Therapeutics

Intellia Therapeutics, a leading clinical-stage genome editing company, is developing novel, potentially curative therapeutics leveraging CRISPR-based technologies. To fully realize the transformative potential of CRISPR-based technologies, Intellia is pursuing two primary approaches. The company's *in vivo* programs use intravenously administered CRISPR as the therapy, in which proprietary delivery technology enables highly precise editing of disease-causing genes directly within specific target tissues. Intellia's *ex vivo* programs use CRISPR to create the therapy by using engineered human cells to treat cancer and autoimmune diseases. Intellia's deep scientific, technical and clinical development experience, along with its robust intellectual property portfolio, have enabled the company to take a leadership role in harnessing the full potential of genome editing to create new classes of genetic medicine. Learn more at intelliatx.com. Follow us on X (formerly known as Twitter) @intelliatx.

Forward-Looking Statements

This press release contains “forward-looking statements” of Intellia Therapeutics, Inc. (“Intellia” or the “Company”) within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, express or implied statements regarding Intellia’s beliefs and expectations regarding: the safety, efficacy, success and advancement of its pipeline of investigational gene editing therapies, including its clinical program for NTLA-2001 for the treatment of transthyretin (ATTR) amyloidosis with cardiomyopathy pursuant to its clinical trial applications and investigational new drug application; the initiation, enrollment, dosing and completion of its clinical trials, including its ability to initiate a global Phase 3 study of NTLA-2001 by year-end 2023.

Any forward-looking statements in this press release 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: risks related to Intellia’s ability to protect and maintain its intellectual property position; 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; uncertainties related to the authorization, initiation, enrollment and conduct of studies and other development requirements for its product candidates, including NTLA-2001; the risk that any one or more of Intellia’s product candidates will not be successfully developed and commercialized; the risk that the results of preclinical studies or clinical studies, such as its clinical studies of NTLA-2001, will not be predictive of future results of 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 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 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 press release is as of the date of the release, and Intellia undertakes no duty to update this information unless required by law.

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