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): January 31, 2024

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 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 January 31, 2024, the Company issued a press release titled "Intellia Therapeutics Announces Publication of Positive Interim Phase 1 Data for NTLA-2002 in Patients with Hereditary Angioedema in the New England Journal of Medicine." 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, are being furnished herewith and shall not be deemed "filed" for the purposes of Section 18 of 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated January 31, 2024.
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 thereunto duly authorized.

Intellia Therapeutics, Inc.

Date: February 1, 2024

By: /s/ John M. Leonard

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

PRESS RELEASE

Intellia Therapeutics Announces Publication of Positive Interim Phase 1 Data for NTLA-2002 in Patients with Hereditary Angioedema in the New England Journal of Medicine

- *Data reinforce the potential of NTLA-2002 to eliminate angioedema attacks in people living with hereditary angioedema (HAE) after a single dose*
- *A single dose of NTLA-2002 led to 95% mean reduction in monthly HAE attack rate with 9 of 10 patients remaining completely attack free following the 16-week primary observation period through the latest follow-up reported*
- *NTLA-2002 was well-tolerated at all dose levels*
- *Second* NEJM *publication of initial clinical data for Intellia's* in vivo *CRISPR-based investigational therapies*

CAMBRIDGE, Mass., Jan. 31, 2024 (GLOBE NEWSWIRE) -- Intellia Therapeutics, Inc. (NASDAQ:NTLA), a leading clinical-stage gene editing company focused on revolutionizing medicine with CRISPR-based therapies, today announced that interim results from the Phase 1 portion of the Phase 1/2 study of NTLA-2002 were published online in the *New England Journal of Medicine* (*NEJM*). NTLA-2002 is an investigational *in vivo* CRISPR-based gene editing therapy in development as a single-dose treatment for hereditary angioedema (HAE), a rare genetic condition that leads to potentially life-threatening swelling attacks.

"Despite currently available treatments, people living with hereditary angioedema continue to face frequent anxiety about their next swelling attack. The interim NTLA-2002 clinical data published suggest that a single dose of NTLA-2002 may eliminate angioedema attacks for people suffering from hereditary angioedema," said Intellia President and Chief Executive Officer John Leonard, M.D. "We are highly encouraged by these data and look forward to presenting extended follow-up from the Phase 1 and results from the Phase 2 portion later this year. Additionally, we remain on track to initiate a global pivotal study for NTLA-2002 in the second half of 2024, subject to regulatory feedback. This marks the second consecutive Intellia *in vivo* CRISPR-based program to have its initial clinical data published in the *New England Journal of Medicine*, further supporting the immense potential impact our proprietary gene editing platform could have on the future of human health."

The reported data showed that a single dose of NTLA-2002 led to a 95% mean reduction in monthly HAE attack rate across all 10 patients in the Phase 1 portion. Nine out of 10 patients remained completely

attack-free following the 16-week primary observation period through the latest follow-up. Further, all patients who discontinued concomitant long-term HAE prophylaxis treatment after NTLA-2002 administration (n=6) have reported no HAE attacks since discontinuation. NTLA-2002 has been well tolerated at all dose levels. The most frequent adverse events reported were mild, transient infusion-related reactions and fatigue. The data were previously shared in a late-breaking presentation at the 2023 European Academy of Allergy and Clinical Immunology Hybrid Congress.

About the NTLA-2002 Clinical Program
Intellia's ongoing Phase 1/2 study is evaluating the safety and activity of NTLA-2002 in adults with Type I or Type II hereditary angioedema (HAE). The Phase 1/2 is an international, open-label study designed to identify a dose level of NTLA-2002 for further evaluation in a Phase 3 study. Enrollment of the Phase 1/2 is complete. Intellia plans to initiate the global, pivotal Phase 3 study in the second half of 2024, subject to regulatory feedback. Visit clinicaltrials.gov (NCT05120830) for more details.

About NTLA-2002

Based on Nobel-prize winning CRISPR/Cas9 technology, NTLA-2002 has the potential to become the first one-time treatment for hereditary angioedema (HAE). NTLA-2002 is designed to prevent HAE attacks by inactivating the *kallikrein B1 (KLKB1)* gene, which encodes for prekallikrein, the kallikrein precursor protein. Interim Phase 1 clinical data showed dramatic reductions in attack rate, as well as consistent, deep and durable reductions in kallikrein levels. NTLA-2002 has received five notable regulatory designations, including Orphan Drug and RMAT Designation by the U.S. Food and Drug Administration, the Innovation Passport by the U.K. Medicines and Healthcare products Regulatory Agency (MHRA), Priority Medicines (PRIME) Designation by the European Medicines Agency, as well as Orphan Drug Designation by the European Commission.

About Hereditary Angioedema

Hereditary angioedema (HAE) is a rare, genetic disease characterized by severe, recurring and unpredictable inflammatory attacks in various organs and tissues of the body, which can be painful, debilitating and life-threatening. It is estimated that one in 50,000 people are affected by HAE. Although there is no known cure for HAE, there are preventative and on-demand treatment options to help manage the condition, including long- and short-term prophylaxis used to prevent swelling attacks. Current treatment options often include life-long therapies, which may require chronic intravenous (IV) or subcutaneous (SC) administration as often as twice per week or daily oral administration to ensure constant pathway suppression for disease control. Despite chronic administration, breakthrough attacks still occur. Kallikrein inhibition is a clinically validated strategy for the preventive treatment of HAE attacks.

About Intellia Therapeutics

Intellia Therapeutics, Inc. (NASDAQ:NTLA) is a leading clinical-stage gene editing company focused on revolutionizing medicine with CRISPR-based therapies. The company's *in vivo* programs use CRISPR to enable precise editing of disease-causing genes directly inside the human body. Intellia's *ex vivo* programs use CRISPR to engineer human cells outside the body for the treatment of cancer and autoimmune diseases. Intellia's deep scientific, technical and clinical development experience, along with its people, is helping set the standard for a new class of medicine. To harness the full potential of gene editing, Intellia continues to expand the capabilities of its CRISPR-based platform with novel editing and delivery technologies. Learn more at intelliatx.com and follow us @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 clinical program for NTLA-2002 for the treatment of hereditary angioedema (HAE) pursuant to its clinical trial applications and investigational new drug application, including the initiation of a global pivotal study for NTLA-2002 in the second half of 2024 subject to regulatory feedback, the potential for NTLA-2002 to eliminate angioedema attacks after a single dose in people living with HAE, and the expected timing of future data releases such as the presentation of extended follow-up data from the Phase 1 portion and results from the Phase 2 portion of the Phase 1/2 study later this year; and the potential impact its proprietary gene editing platform could have on the future of human health.

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-2002; the risk that NTLA-2002 will not be successfully developed and commercialized; and the risk that the results of preclinical studies or clinical studies, such as the clinical study of NTLA-2002, will not be predictive of future results in connection with future studies for the same product candidate or Intellia's other product candidates. 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 press release is as of the date of the release, and Intellia undertakes no duty to update this information unless required by law.

Intellia Contacts:

Investors:

Ian Karp
Senior Vice President, Investor Relations and Corporate Communications
ian.karp@intelliatx.com

Lina Li
Senior Director, Investor Relations and Corporate Communications
lina.li@intelliatx.com

Media:
Matt Crenson
Ten Bridge Communications
media@intelliatx.com
TBCIntellia@tenbridgecommunications.com