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): June 11, 2023

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 June 11, 2023, Intellia Therapeutics, Inc. (the "Company" or "Intellia") issued a press release titled "Intellia Therapeutics Announces New Positive Clinical Data from Phase 1 Study of NTLA-2002, an Investigational In Vivo CRISPR Genome Editing Treatment for Hereditary Angioedema (HAE)." 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.

Interim Clinical Data of NTLA-2002

On June 11, 2023, the Company announced updated interim results from the Phase 1 portion of the ongoing Phase 1/2 study of NTLA-2002, an in vivo, systemically administered CRISPR candidate being developed as a single-dose treatment for hereditary angioedema ("HAE"). The data were shared in a late-breaking presentation at the European Academy of Allergy and Clinical Immunology ("EAACI") Hybrid Congress 2023, being held June 9-11 in Hamburg, Germany, and virtually. The data presented were from 10 adult patients with HAE in the Phase 1, dose-escalation portion of the study, with a data cut-off date of February 17, 2023. Single doses of 25 mg (n=3), 50 mg (n=4) and 75 mg (n=3) of NTLA-2002 were administered via intravenous infusion, and HAE attacks and plasma kallikrein protein levels were measured for each patient. The first analysis of HAE attack rates occurred at the end of the pre-specified 16-week primary observation period.

	Monthly HAE Attack Rate Reduction from Baseline[1]			
	25 mg (n=3)	50 mg (n=4)	75 mg (n=3)	All Patients (N=10)
Week 1-16	91%	97%	80%	89%
Week 5-16	89%	100%	87%	92%
On-study period[2]	95%	98%	93%	95%

1 Investigator confirmed HAE attack rate.

2 On-study period is defined as the time from the dosing of NTLA-2002 through the last assessment of HAE attacks as of the data cut-off date.

Across all patients, a 95% mean reduction in monthly attack rate was observed after a single dose of NTLA-2002 through the latest follow-up. The median duration of follow-up was 9.0 months (range of 5.6 - 14.1 months). The first three patients dosed in the study with the longest follow-up to date have experienced attack-free durations of approximately one year or longer. The three patients with the highest historic monthly HAE attack rates at the start of the study (16.8, 14.0 and 4.4 attacks per month, respectively) all became attack free by the end of the 16-week primary observation period and remained free of attacks through the latest follow-up. The longest attack-free duration in this patient group has been 11.5 months.

All nine patients who achieved greater than 60% plasma kallikrein reduction remain attack free since the 16-week observation period. There was one patient in the lowest 25 mg dose cohort who did not achieve the targeted 60% minimum kallikrein reduction post-NTLA-2002 administration. Following 12.3 months of being attack free, this patient reported a single, mild HAE attack after experiencing minor hand swelling precipitated by a sports injury. The event did not require any medical intervention or acute therapy. The patient has not experienced any subsequent HAE attacks following this event.

Six of the 10 patients were receiving long-term HAE prophylaxis medications prior to the administration of NTLA-2002. Subsequently, they were permitted to withdraw their medication at the investigator's discretion. All six patients have discontinued their prophylactic therapy and have not experienced any subsequent HAE attacks.

Administration of NTLA-2002 led to dose-dependent, robust and durable reductions in plasma kallikrein. These deep reductions in plasma kallikrein continue to be sustained through the latest follow-up, as described below, which ranged from 24 to 48 weeks across all three dose cohorts.

Dose Level	Plasma Kallikrein Level Mean % Reduction from Baseline at Latest Follow-up
25 mg (n=3)	67% (Week 48)
50 mg (n=4)	84% (Week 24)
75 mg (n=3)	95% (Week 32)

At all three dose levels, NTLA-2002 has been well tolerated, and the majority of adverse events were mild in severity. Consistent with previously reported results, the most frequent adverse events were infusion-related reactions and fatigue, which were mostly Grade 1 and resolved within two days. There have been no dose-limiting toxicities, no serious adverse events and no adverse events of Grade 3 or higher observed to date. No clinically significant laboratory abnormalities were observed in any patient.

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: its ability to conduct and complete clinical studies for NTLA-2002 for the treatment of hereditary angioedema (“HAE”); the safety, efficacy, success and advancement of its clinical program for NTLA-2002 for the treatment of HAE pursuant to its clinical trial applications and investigational new drug application, including the expected completion of enrollment for the Phase 2 portion of the Phase1/2 study for NTLA-2002 this year, the potential for NTLA-2002 to be a functional cure for people living with HAE, and the potential of NTLA-2002 to address the significant treatment burden that exists, despite currently available, chronically administered therapies.

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 the successful enrollment of patients in the Phase 1/2 study for NTLA-2002 for the treatment of HAE; risks related to Intellia’s ability to protect and maintain its intellectual property position; risks related to the authorization, initiation and conduct of studies and other development requirements, including manufacturing, for its *in vivo* and *ex vivo* product candidates, including NTLA-2002; the risk that any one or more of Intellia’s product candidates, including NTLA-2002, will not be successfully developed and commercialized; the risk that the results of preclinical studies or clinical studies, including for NTLA-2002, will not be predictive of future results in connection with future studies; and the risk that Intellia will not be able to demonstrate its platform’s modularity and replicate or apply results achieved in preclinical studies to develop additional product candidates, including to apply its proprietary CRISPR/Cas9 technology platform successfully to additional product candidates to treat other genetic diseases. For a discussion of these and other risks, 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

Exhibit No.	Description
99.1	Press release dated June 11, 2023.
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: June 12, 2023

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

PRESS RELEASE

Intellia Therapeutics Announces New Positive Clinical Data from Phase 1 Study of NTLA-2002, an Investigational *In Vivo* CRISPR Genome Editing Treatment for Hereditary Angioedema (HAE)

- *Extended Phase 1 data reinforce the potential of NTLA-2002 to be a functional cure for people living with hereditary angioedema (HAE)*
- *Across all patients (n=10), a single dose of NTLA-2002 led to a 95% mean reduction in monthly HAE attack rate through the latest follow-up*
- *All patients who achieved greater than 60% plasma kallikrein reduction (n=9) remain completely attack free following the 16-week primary observation period through the latest follow-up; longest attack-free interval is 13.0 months and ongoing*
- *All patients who discontinued concomitant long-term HAE prophylaxis treatment after NTLA-2002 administration (n=6) have reported no HAE attacks since discontinuation through the latest follow-up*
- *NTLA-2002 has been well tolerated at all dose levels*
- *Intellia to host investor webcast on Monday, June 12, at 8 a.m. ET*

CAMBRIDGE, Mass., June 11, 2023 (GLOBE NEWSWIRE) — Intellia Therapeutics, Inc. (NASDAQ:NTLA), a leading clinical-stage genome editing company focused on developing potentially curative therapeutics leveraging CRISPR-based technologies, today announced updated interim results from the Phase 1 portion of the ongoing Phase 1/2 study of NTLA-2002. NTLA-2002 is an *in vivo*, systemically administered CRISPR candidate being developed as a single-dose treatment for hereditary angioedema (HAE). The data, with a cut-off date of February 17, 2023, were shared in a late-breaking presentation at the European Academy of Allergy and Clinical Immunology (EAACI) Hybrid Congress 2023, being held June 9-11 in Hamburg, Germany, and virtually.

“After a single dose of our investigational CRISPR-based therapy, patients living with hereditary angioedema experienced durable elimination of their attacks. We are thrilled to see that the earliest-dosed patients are attack free for approximately a year or longer, with NTLA-2002 demonstrating a very favorable safety profile. These remarkable attack rate reductions have been consistent, even in patients with the most severe symptoms,” said Intellia President and Chief Executive Officer John Leonard, M.D. “While early, these unprecedented interim data from the Phase 1 study continue to reinforce our belief that NTLA-2002 could be a potential functional cure for people with hereditary angioedema. In addition, these data strengthen our view that NTLA-2002 could address the significant treatment burden that exists, despite currently available, chronically administered therapies.”

In the Phase 1 portion of the study, single doses of 25 mg (n=3), 50 mg (n=4) and 75 mg (n=3) of NTLA-2002 were administered via intravenous infusion, and HAE attacks and plasma kallikrein protein levels were measured for each patient. The first analysis of HAE attack rates occurred at the end of the pre-specified 16-week primary observation period. HAE attacks and plasma kallikrein protein levels will continue to be assessed through the end of the study.

HAE Attack Rate Reduction

	Monthly HAE Attack Rate Reduction from Baseline[1]			
	25 mg (n=3)	50 mg (n=4)	75 mg (n=3)	All Patients (N=10)
Week 1-16	91%	97%	80%	89%
Week 5-16	89%	100%	87%	92%
On-study period[2]	95%	98%	93%	95%

1 Investigator confirmed HAE attack rate.

2 On-study period is defined as the time from the dosing of NTLA-2002 through the last assessment of HAE attacks as of the data cut-off date.

Across all patients, a 95% mean reduction in monthly attack rate was observed after a single dose of NTLA-2002 through the latest follow-up. The median duration of follow-up was 9.0 months (range of 5.6 - 14.1 months). At each dose level tested, a robust level of HAE attack rate reduction was achieved. Importantly, the elimination of HAE attacks has been sustained and long lasting. The first three patients dosed in the study with the longest follow-up to date have experienced attack-free durations of approximately one year or longer. Additionally, the reduction in HAE attacks has been persistent in patients with the most severe HAE symptoms. The three patients with the highest historic monthly HAE attack rates at the start of the study (16.8, 14.0 and 4.4 attacks per month, respectively) all became attack free by the end of the 16-week primary observation period and remained free of attacks through the latest follow-up. The longest attack-free duration in this patient group is 11.5 months and ongoing.

All nine patients who achieved greater than 60% plasma kallikrein reduction, the target level expected to yield a highly meaningful clinical response, remain completely attack free since the 16-week observation period. There was one patient in the lowest 25 mg dose cohort who did not achieve the targeted 60% minimum kallikrein reduction post-NTLA-2002 administration. Following 12.3 months of being attack free, this patient reported a single, mild HAE attack after experiencing minor hand swelling precipitated by a sports injury. The event did not require any medical intervention or acute therapy. The patient has not experienced any subsequent HAE attacks following this event.

Six of the 10 patients were receiving long-term HAE prophylaxis medications prior to the administration of NTLA-2002. Subsequently, they were permitted to withdraw their medication at the investigator's discretion. All six patients have discontinued their prophylactic therapy and have not experienced any subsequent HAE attacks.

Plasma Kallikrein Reduction

As previously reported, administration of NTLA-2002 led to dose-dependent, robust and durable reductions in plasma kallikrein. These deep reductions in plasma kallikrein continue to be sustained through the latest follow-up, as described below, which ranged from 24 to 48 weeks across all three dose cohorts.

Dose Level	Plasma Kallikrein Level Mean % Reduction from Baseline at Latest Follow-up
25 mg (n=3)	67% (Week 48)
50 mg (n=4)	84% (Week 24)
75 mg (n=3)	95% (Week 32)

Safety

At all three dose levels, NTLA-2002 has been well tolerated, and the majority of adverse events were mild in severity. Consistent with previously reported results, the most frequent adverse events were infusion-related reactions and fatigue, which were mostly Grade 1 and resolved within two days. There have been no dose-limiting toxicities, no serious adverse events and no adverse events of Grade 3 or higher observed to date. No clinically significant laboratory abnormalities were observed in any patient.

As previously announced, the Phase 2 portion of this Phase 1/2 clinical trial of NTLA-2002 has begun dosing patients, and Intellia expects to complete enrollment in the second half of this year.

Intellia Therapeutics Investor Webcast Information

Intellia will host a live webcast, Monday, June 12, 2023, at 8:00 a.m. ET to review the new data. Joining the Intellia management team will be Dr. Timothy J. Craig, tenured professor of Medicine, Pediatrics and Biomedical Sciences at Penn State University, to provide an overview of the current treatment landscape and unmet medical need for people living with HAE.

To join the webcast, please visit this link, or the Events and Presentations page of the Investors & Media section of the company's website at www.intelliatx.com. A replay of the webcast will be available on Intellia's website for at least 30 days following the call.

About the NTLA-2002 Clinical Program

Intellia's global Phase 1/2 study is evaluating the safety, tolerability, pharmacokinetics and pharmacodynamics of NTLA-2002 in adults with Type I or Type II hereditary angioedema (HAE). This includes the measurement of plasma kallikrein protein levels and activity, as well as HAE attack rate. The Phase 1 portion of the study is an open-label, single-ascending dose design used to identify two dose levels of NTLA-2002 for further evaluation in the Phase 2, randomized, placebo-controlled portion of the study. The Phase 1/2 study will identify the dose of NTLA-2002 for use in future studies. Patient screening and dosing in the Phase 2 portion of the study is ongoing. Visit clinicaltrials.gov (NCT05120830) for more details.

About NTLA-2002

Based on Nobel-prize winning CRISPR/Cas9 technology, NTLA-2002 is the first single-dose investigational treatment being explored in clinical trials for the potential to continuously reduce kallikrein activity and prevent attacks in people living with hereditary angioedema (HAE). NTLA-2002 is a wholly owned investigational CRISPR therapeutic candidate designed to inactivate the *kallikrein B1 (KLKB1*) gene, which encodes for prekallikrein, the kallikrein precursor protein. NTLA-2002 is Intellia's second investigational CRISPR therapeutic candidate to be administered systemically, by intravenous infusion, to edit disease-causing genes inside the human body with a single dose of treatment. 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 together carry out the precision editing.

About Hereditary Angioedema

Hereditary angioedema (HAE) is a rare, genetic disorder 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, and 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, 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 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 clinical program for NTLA-2002 for the treatment of hereditary angioedema pursuant to its clinical trial applications and investigational new drug application, including the expected completion of enrollment for the Phase 2 portion of the Phase1/2 study for NTLA-2002 this year, the potential for NTLA-2002 to be a functional cure for people living with HAE, and the potential of NTLA-2002 to address the significant treatment burden that exists, despite currently available, chronically administered therapies.

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.

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