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 4, 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)	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 2.02 Results of Operations and Financial Condition.

Although it has not finalized its full financial results for the fourth quarter and fiscal year ended December 31, 2023, Intellia Therapeutics, Inc. (the "Company") announced on January 4, 2024, that it expects to report that it had approximately $1.0 billion of cash, cash equivalents and marketable securities as of December 31, 2023.

The information contained in Item 2.02 of this Form 8-K is unaudited and preliminary and does not present all information necessary for an understanding of the Company's financial condition as of December 31, 2023. The audit of the Company's consolidated financial statements for the year ended December 31, 2023, is ongoing and could result in changes to the information set forth above.

The information in this Item 2.02 is being furnished herewith and shall not be deemed "filed" for 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 it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure.

On January 4, 2024, the Company issued a press release titled "Intellia Therapeutics Highlights its Three-Year Strategic Priorities and Anticipated 2024 Key Milestones." 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 8.01. Other Events.

On January 4, 2024, the Company announced its strategic priorities through 2026 and key anticipated 2024 milestones that support the Company's mission to transform the lives of patients and bring forth a new era in medicine.

Recent Pipeline Advancement and Corporate Updates

- **NTLA-2001 for Transthyretin (ATTR) Amyloidosis:** Initiated and actively enrolling the pivotal Phase 3 MAGNITUDE trial in adults with ATTR amyloidosis with cardiomyopathy (ATTR-CM).
- **NTLA-2002 for Hereditary Angioedema (HAE):** Completed enrollment and dosing in the Phase 2 portion of the Phase 1/2 study in adults with HAE.
- **NTLA-3001 for Alpha-1 Antitrypsin Deficiency (AATD)-Associated Lung Disease:** Submitted a clinical trial application to initiate a first-in-human Phase 1 study of NTLA-3001 ahead of previous Q1 2024 expectation.
- **Organizational Streamlining:** Following an internal strategic review, the Company will be streamlining company-wide operations to further focus resources on key strategic priorities and programs. These changes will result in a pause of select exploratory research-stage programs and a workforce reduction of approximately 15%.
- **Cash Runway:** The Company ended the fourth quarter of 2023 with approximately $1.0 billion in cash, cash equivalents and marketable securities. The cash position is expected to fund operations into mid-2026.
- **Board Update:** In December, the Company announced the departure of John Crowley from its board of directors following his appointment as Chief Executive Officer of the Biotechnology Innovation Organization (BIO), the life sciences industry's leading trade and advocacy association.

2024 – 2026 Strategic Priorities

1. **Complete patient enrollment for pivotal studies of NTLA-2001 and NTLA-2002**, including planned biologics license application (BLA) submission for NTLA-2002 in 2026;

2. **Launch clinical trials for next wave of *in vivo* and *ex vivo* programs**, validating CRISPR-based *in vivo* targeted gene insertion and an allogeneic cell engineering solution designed to avoid NK cell-mediated rejection; and

3. **Expand the range of diseases that can be targeted by deploying new editing and delivery innovations**, including advancing gene editing in tissues outside the liver and DNA writing technology.

Anticipated 2024 Milestones

- **NTLA-2001 for ATTR Amyloidosis:**
  - Dose the first patient in MAGNITUDE trial of NTLA-2001 for the treatment of ATTR-CM in Q1 2024.
  - Continue to open new sites and enroll patients, globally, in the MAGNITUDE study.
  - Prepare for the Phase 3 study of NTLA-2001 for the treatment of ATTR amyloidosis with polyneuropathy (ATTRv-PN) in 2024.
  - Present updated clinical data from the ongoing Phase 1 study of NTLA-2001 in 2024.
- **NTLA-2002 for HAE:**
  - Initiate the global pivotal Phase 3 trial of NTLA-2002 in 2H 2024, subject to regulatory feedback.
  - Present updated data from Phase 1 and new data from Phase 2 portion in 2024.
- **NTLA-3001 for AATD-Associated Lung Disease:**
  - Dose first patient in Phase 1 study of NTLA-3001 in 2024.

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 the Company’s beliefs and expectations regarding: its ability to expand and validate its industry-leading gene editing platform, including the advancement of novel gene editing technologies, such as DNA writing, and delivery to other tissues outside of the liver; the safety, efficacy, success and advancement of its clinical programs for NTLA-2001 for the treatment of transthyretin (“ATTR”) amyloidosis, NTLA-2002 for the treatment of hereditary angioedema (“HAE”), and NTLA-3001 for the treatment of alpha-1 antitrypsin deficiency (“AATD”)-associated lung disease, including the expected timing of data releases, regulatory filings, and the initiation, dosing, and completion of clinical trials, such as the dosing of the first patient in the pivotal Phase 3 MAGNITUDE trial of NTLA-2001 for ATTR amyloidosis with cardiomyopathy (“ATTR-CM”) in Q1 2024, the preparation for a Phase 3 study of NTLA-2001 for the treatment of ATTR amyloidosis with polyneuropathy (“ATTRv-PN”) in 2024, the presentation of updated clinical data from the ongoing Phase 1 study of NTLA-2001 in 2024, the initiation of a global pivotal Phase 3 trial of NTLA-2002 in 2H 2024, the presentation of additional data from the Phase 1/2 trial of NTLA-2002 in 2024, the submission of a biologics license application for NTLA-2002 in 2026, and the dosing of the first patient in the Phase 1 study of NTLA-3001 for the treatment of AATD-associated lung disease in 2024; the advancement of additional development candidates and expectations of advancing such development candidates and releasing data related to such technologies and development candidates, including its ability to launch clinical trials for its next wave of in vivo and ex vivo programs and to validate CRISPR-based in vivo targeted gene insertion and an allogeneic cell engineering solution designed to avoid NK cell-mediated rejection ; its ability to optimize the impact of its collaborations on its development programs, including its collaboration with Regeneron Pharmaceuticals, Inc. and their co-development program for ATTR amyloidosis, and to advance additional development candidates; and its ability to fund operations into mid-2026.

Any forward-looking statements in this Current Report on Form 8-K and certain materials furnished or filed herewith 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 the Company's ability to protect and maintain its intellectual property position; risks related to the Company's relationship with third parties, including its contract manufacturers, 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 and conduct of preclinical and clinical studies and other development requirements for its product candidates, including uncertainties related to regulatory approvals to conduct clinical trials; risks related to the ability to develop and commercialize any one or more of the Company's product candidates successfully; risks related to the results of preclinical studies or clinical studies not being predictive of future results in connection with future studies; the risk that clinical study results will not be positive; risks related to the development and advancement of novel platform capabilities, such as DNA writing technology and gene editing in tissues outside the liver; risks related to the Company's future financial condition and its ability to fund its operations; and risks related to the Company's collaborations with Regeneron Pharmaceuticals, Inc. or its other collaborations not continuing or not being successful. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in the Company's most recent quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in the Company'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 Report indicated above, and the Company undertakes no duty to update this information unless required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated January 4, 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: January 4, 2024

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

PRESS RELEASE

Intellia Therapeutics Highlights its Three-Year Strategic Priorities and Anticipated 2024 Key Milestones

- *Core priorities through 2026 include completion of Phase 3 study and BLA submission for NTLA-2002, completion of patient enrollment in the pivotal study of NTLA-2001, clinical validation of modular in vivo gene insertion technology and advancement of earlier-stage pipeline and platform innovations*
- *On track to dose the first patient in the pivotal Phase 3 MAGNITUDE trial of NTLA-2001 for the treatment of transthyretin (ATTR) amyloidosis with cardiomyopathy in Q1 2024*
- *Expect to present results from the Phase 2 study of NTLA-2002 for the treatment of hereditary angioedema (HAE) and to initiate the Phase 3 study in 2024*
- *On track to dose the first patient in the Phase 1 study of NTLA-3001 for the treatment of alpha-1 antitrypsin deficiency (AATD)-associated lung disease in 2024*
- *Ended 2023 in a strong financial position with approximately $1.0 billion in cash; cash runway extended into mid-2026*

CAMBRIDGE, Mass., Jan. 4, 2024 – Intellia Therapeutics, Inc. (NASDAQ:NTLA), a leading clinical-stage gene editing company focused on revolutionizing medicine with CRISPR-based therapies, today announced its strategic priorities through 2026 and key anticipated 2024 milestones that support the company's mission to transform the lives of patients and bring forth a new era in medicine.

"2023 was a momentous year for Intellia as our lead investigational therapy, NTLA-2001, advanced into the final stage of clinical development for the treatment of transthyretin amyloidosis with cardiomyopathy," said Intellia President and Chief Executive Officer John Leonard, M.D. "Looking ahead, we will continue to turn groundbreaking science into real-world medicines by capitalizing on our extensive experience and capabilities to edit disease-causing genes. We are rapidly expanding the potential to treat an even larger range of diseases, including those that originate outside of the liver, by deploying our novel delivery and editing technologies. With our comprehensive gene editing toolbox, we are well-positioned to harness the full potential of CRISPR-based medicines for patients."

Recent Pipeline Advancement and Corporate Updates

- **NTLA-2001 for Transthyretin (ATTR) Amyloidosis:** Initiated and actively enrolling the pivotal Phase 3 MAGNITUDE trial in adults with ATTR amyloidosis with cardiomyopathy (ATTR-CM).
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- **Cash Runway:** Intellia ended the fourth quarter of 2023 with approximately $1.0 billion in cash, cash equivalents and marketable securities. The cash position is expected to fund operations into mid-2026.
- **Board Update:** In December, Intellia announced the departure of John Crowley from its board of directors following his appointment as Chief Executive Officer of the Biotechnology Innovation Organization (BIO), the life sciences industry's leading trade and advocacy association.

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- **NTLA-2002 for HAE:**
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- **NTLA-3001 for AATD-Associated Lung Disease:**
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Presentation at the 42nd Annual J.P. Morgan Healthcare Conference

John Leonard, M.D., President and Chief Executive Officer of Intellia, will present a company overview at the 42nd Annual J.P. Morgan Healthcare Conference in San Francisco on Tuesday, January 9, at 5:15 p.m. PT (8:15 p.m. ET). A live webcast will be available through the Events and Presentations page of the Investors & Media section on Intellia's website, www.intelliatx.com. A replay of the webcast will be available on Intellia's website for a limited time following the conference.

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

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