
**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): February 22, 2024

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 2.02 Results of Operations and Financial Condition.

On February 22, 2024, Intellia Therapeutics, Inc. announced its financial results and business updates for the quarter and year ended December 31, 2023. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 on this Current Report on Form 8-K.

The information in this report furnished pursuant to Item 2.02 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. It may only be incorporated by reference in another filing under the Exchange Act or the Securities Act of 1933, as amended, if such subsequent filing specifically references the information furnished pursuant to Item 2.02 of this report.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits**

Exhibit No.	Description
99.1	Press release dated February 22, 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 22, 2024

By: /s/ John M. Leonard

Name: John M. Leonard

Title: Chief Executive Officer and President

advance novel gene editing treatments directly to the lung in patients with cystic fibrosis. These pipeline and platform efforts move us closer to setting a new standard of care for people living with serious diseases and expanding Intellia's impact as the leading gene editing company."

Fourth Quarter 2023 and Recent Operational Highlights

Transthyretin (ATTR) Amyloidosis

- **NTLA-2001:** NTLA-2001 is an investigational *in vivo* CRISPR-based therapy designed to inactivate the *TTR* gene in the liver and thereby prevent the production of transthyretin (TTR) protein for the treatment of ATTR amyloidosis. NTLA-2001 offers the possibility of halting and reversing the disease by driving a deep, consistent and potentially lifelong reduction in TTR protein after a single dose. Intellia leads development and commercialization of NTLA-2001 in collaboration with Regeneron.
 - **ATTR Amyloidosis with Cardiomyopathy (ATTR-CM):**
 - Intellia is actively enrolling patients, including in the U.S., in the pivotal Phase 3 MAGNITUDE trial. The Company is on track to dose the first patient in Q1 2024 and continues to open new clinical sites.
 - **Hereditary ATTR Amyloidosis with Polyneuropathy (ATTRv-PN):**
 - Intellia is actively preparing for a global pivotal Phase 3 study of NTLA-2001 for the treatment of ATTRv-PN.
 - The Company plans to present updated data from the ongoing Phase 1 study in 2024.

Hereditary Angioedema (HAE)

- **NTLA-2002:** NTLA-2002 is a wholly owned, investigational *in vivo* CRISPR-based therapy designed to knock out the *KLKB1* gene in the liver, with the goal of lifelong control of HAE attacks after a single dose.
 - Intellia plans to initiate the global pivotal Phase 3 study, including U.S. patients, in the second half of 2024, subject to regulatory feedback.
 - As previously announced in January, Intellia completed enrollment and dosing in the Phase 2 portion of the Phase 1/2 study in adults with HAE. The Company plans to present updated data from the Phase 1 and new data from the Phase 2 portion in 2024.
 - In January, the Company announced that positive interim results from the Phase 1 portion of the Phase 1/2 study of NTLA-2002 were published in the *New England Journal of Medicine* (NEJM). 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. NTLA-2002

was well tolerated at all dose levels. The most frequent adverse events reported were mild, transient infusion-related reactions and fatigue.

- During the fourth quarter of 2023, Intellia received Priority Medicines (PRIME) designation from the European Medicines Agency and orphan drug designation from the European Commission for NTLA-2002.

***In Vivo* Targeted Gene Insertion**

- **NTLA-3001 for Alpha-1 Antitrypsin Deficiency (AATD)-Associated Lung Disease:** NTLA-3001 is a wholly owned, first-in-class CRISPR-mediated *in vivo* targeted gene insertion development candidate for the treatment of AATD-associated lung disease. It is designed to precisely insert a healthy copy of the *SERPINA1* gene, which encodes the alpha-1 antitrypsin (A1AT) protein, with the potential to restore permanent expression of functional A1AT protein to therapeutic levels after a single dose.
 - In December 2023, Intellia submitted a Clinical Trial Application (CTA) to initiate a first-in-human, Phase 1 study of NTLA-3001. The Company plans to dose the first patient in 2024.
- **Hemophilia B:** In February, Regeneron and Intellia announced the clearance by the U.S. Food and Drug Administration of its investigational new drug application to initiate a clinical trial of its investigational *in vivo* CRISPR-based *Factor 9* gene insertion program for people living with hemophilia B. A Phase 1, first-in-human study is expected to begin in mid-2024. Regeneron leads development and commercialization of hemophilia A and B programs in collaboration with Intellia.

***In Vivo* Platform Expansion Including to Tissues Outside of the Liver**

- In February, Intellia and ReCode announced a strategic collaboration to develop novel genomic medicines for the treatment of cystic fibrosis (CF). The collaboration will leverage Intellia's proprietary CRISPR-based gene editing platform, including its DNA writing technology, and ReCode's proprietary Selective Organ Targeting (SORT) lipid nanoparticle delivery platform to precisely correct one or more CF disease-causing gene mutations.
- In October 2023, Intellia and Regeneron announced an expanded research collaboration to develop additional *in vivo* CRISPR-based gene editing therapies focused on neurological and muscular diseases.
- In October 2023, Regeneron exercised its option to extend the existing technology collaboration term with Intellia for two years. The technology collaboration term now extends to April 2026, and Intellia will receive a \$30 million payment due in April 2024.

***Ex Vivo* Program Updates**

- Intellia is advancing multiple preclinical programs, wholly owned and in collaboration with partners, utilizing its allogeneic platform for the treatment of immuno-oncology and autoimmune diseases. The

Company's proprietary allogeneic cell engineering platform is designed to avoid both T cell- and NK cell-mediated rejection, a key unsolved challenge with other investigational allogeneic approaches.

Upcoming Events

The Company will participate in the following events in March:

- TD Cowen 44th Annual Health Care Conference, March 4, Boston
- Leerink Global Biopharma Conference, March 12, Miami
- Barclays Global Healthcare Conference, March 13, Miami

Fourth Quarter and Full-Year 2023 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were \$1.0 billion as of December 31, 2023, compared to \$1.3 billion as of December 31, 2022. The decrease was driven by cash used to fund operations of \$448.8 million. The decrease was offset in part by \$119.8 million of net equity proceeds from the Company's "At the Market" (ATM) program, \$49.8 million of interest income, \$18.7 million of reimbursement from its collaborators, and \$10.5 million in proceeds from employee-based stock plans. The cash position is expected to fund operations into mid-2026.
- **Collaboration Revenue:** Collaboration revenue decreased by \$15.5 million to negative \$1.9 million during the fourth quarter of 2023, compared to \$13.6 million during the fourth quarter of 2022. This decrease was mainly driven by a \$10.3 million one-time revenue recognition adjustment related to Regeneron extending the technology collaboration to April 2026. Intellia will receive a \$30.0 million payment due in April 2024 as part of the Regeneron extension.
- **R&D Expenses:** Research and development expenses increased by \$9.0 million to \$109.0 million during the fourth quarter of 2023, compared to \$100.0 million during the fourth quarter of 2022. This increase was primarily driven by the advancement of our lead programs and personnel growth to support these programs. Stock-based compensation expense included in research and development expenses was \$21.7 million for the fourth quarter of 2023.
- **G&A Expenses:** General and administrative expenses increased by \$5.4 million to \$29.0 million during the fourth quarter of 2023, compared to \$23.6 million during the fourth quarter of 2022. This increase was primarily related to an increase in stock-based compensation of \$4.3 million. Stock-based compensation expense included in general and administrative expenses was \$13.3 million for the fourth quarter of 2023.
- **Net Loss:** The Company's net loss was \$132.2 million for the fourth quarter of 2023, compared to \$113.4 million during the fourth quarter of 2022.

Conference Call to Discuss Fourth Quarter and Full Year 2023 Results

The Company will discuss these results on a conference call today, Thursday, February 22, at 8 a.m. ET.

To join the call:

- U.S. callers should dial 1-833-316-0545 and international callers should dial 1-412-317-5726, approximately five minutes before the call. All participants should ask to be connected to the Intellia Therapeutics conference call.
- Please visit this link for a simultaneous live webcast of the call.

A replay of the call will be available through the Events and Presentations page of the Investors & Media section on Intellia's website at intelliatx.com, beginning on February 22, at 12 p.m. ET.

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 concerning: the safety, efficacy, success and advancement of its clinical programs for NTLA-2001 for 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, pursuant to its clinical trial applications ("CTA") and investigational new drug ("IND") submissions, including the expected timing of data releases, regulatory feedback, regulatory filings, and the initiation, enrollment, dosing and completion of clinical trials, such as the presentation of additional data from the NTLA-2001 and NTLA-2002 clinical trials in 2024, dosing of the first patient in its global pivotal Phase 3 MAGNITUDE trial for NTLA-2001 in Q1 2024 and its ability to rapidly enroll this study, the planned initiation of a global pivotal Phase 3 study of NTLA-2002 in 2H 2024 subject to regulatory feedback, its ability to dose the first patient in its NTLA-3001 Phase 1 study in 2024, and the potential of NTLA-3001 to restore permanent expression of functional alpha-1 antitrypsin protein to therapeutic levels after a single dose; the expansion of its CRISPR/Cas9 technology and

related novel technologies, including DNA writing and related research milestones and delivery to other tissues outside of the liver; its ability to advance multiple *ex vivo* programs utilizing an allogeneic platform, which is designed to avoid both T cell- and NK cell-mediated rejection, for the treatment of immuno-oncology and autoimmune diseases; its ability to advance additional *in vivo* and *ex vivo* development candidates and timing expectations of advancing such development candidates and releasing data related to such technologies and development candidates; its ability to optimize the impact of its collaborations on its development programs, including, but not limited to, its collaboration with Regeneron Pharmaceuticals, Inc. (“Regeneron”) and their co-development programs for ATTR amyloidosis and Hemophilia B, as well as their expanded research collaboration to develop additional *in vivo* CRISPR-based gene editing therapies focused on neurological and muscular diseases and its collaboration with ReCode Therapeutics, Inc. (“ReCode”) to develop novel genomic medicines for the treatment of cystic fibrosis utilizing CRISPR-based gene editing, including DNA writing, and Selective Organ Targeting lipid nanoparticle delivery technologies; and its growth as a Company and expectations regarding its uses of capital, expenses, future accumulated deficit and financial results.

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 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 Intellia’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 potential delay of planned clinical trials due to regulatory feedback or other developments; and risks related to Intellia’s collaborations with Regeneron, ReCode, 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 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, 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 THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)
(Amounts in thousands, except per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
Collaboration revenue	\$ (1,917)	\$ 13,573	\$ 36,275	\$ 52,121
Operating expenses:				
Research and development	108,981	100,034	435,069	419,979
General and administrative	28,994	23,626	116,497	90,306
Total operating expenses	137,975	123,660	551,566	510,285
Operating loss	(139,892)	(110,087)	(515,291)	(458,164)
Other income (expense), net:				
Interest income	12,459	5,354	49,832	8,542
Loss from equity method investment	(4,728)	(3,248)	(15,633)	(11,079)
Change in fair value of contingent consideration	-	(5,426)	(100)	(13,485)
Total other income (expense), net	7,731	(3,320)	34,099	(16,022)
Net loss	\$ (132,161)	\$ (113,407)	\$ (481,192)	\$ (474,186)
Net loss per share, basic and diluted	\$ (1.46)	\$ (1.40)	\$ (5.42)	\$ (6.16)
Weighted average shares outstanding, basic and diluted	90,461	81,223	88,770	76,972

INTELLIA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEET DATA (UNAUDITED)
(Amounts in thousands)

	December 31, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	\$ 1,012,087	\$ 1,261,960
Total assets	1,300,977	1,520,114
Total liabilities	250,808	284,530
Total stockholders' equity	1,050,169	1,235,584

Intellia Contacts:

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