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): November 13, 2023

Astria Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-37467**	**26-3687168**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

75 State Street **Suite 1400** **Boston, Massachusetts**	**02109**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 349-1971

(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, $0.001 par value per share	ATXS	The Nasdaq Stock Market LLC

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 November 13, 2023, Astria Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2023. The full text of the press release issued in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 2.02, including Exhibit 99.1 attached hereto, 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 made by the Company 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibit is furnished herewith:

Exhibit Number	**Description**
99.1	Press Release issued by the Company on November 13, 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 hereunto duly authorized.

ASTRIA THERAPEUTICS, INC.

Date: November 13, 2023

By: /s/ Ben Harshbarger
Ben Harshbarger
Chief Legal Officer

Exhibit 99.1

Astria Therapeutics Reports Third Quarter Financial Results and Provides a Corporate Update

-- New Phase 1a Results Confirm Potential for STAR-0215 to Prevent HAE Attacks with Dosing 2 or 4 Times Per Year --

-- ALPHA-STAR Trial of STAR-0215 Initial Proof-of-Concept Data in Patients Now Expected Q1 2024 --

-- STAR-0310, Potential Best-in-Class OX40 Program for the Treatment of Atopic Dermatitis, Expected IND Submission by Year-End 2024 and Phase 1a Initiation in Q1 2025 --

-- Webcast Today at 8:30am ET --

BOSTON, Mass., November 13, 2023 – Astria Therapeutics, Inc. (NASDAQ:ATXS), a biopharmaceutical company focused on developing life-changing therapies for rare and niche allergic and immunological diseases, today reported financial results for the third quarter ended September 30, 2023 and provided a corporate update.

"We are realizing our vision of growing an allergy and immunology company with a pipeline of potential best-in-class therapies," said Jill C. Milne, Ph.D., Chief Executive Officer at Astria Therapeutics. "The STAR-0215 program is in a strong position to achieve our goal of becoming a first-choice preventative therapy for hereditary angioedema, and data from the Phase 1a healthy subject trial recently shared at ACAAI support the potential to provide patients with dosing options two or four times per year, without compromising on safety or efficacy. We now expect to deliver initial proof-of-concept results in Q1 2024 from the Phase 1b/2 ALPHA-STAR trial in HAE patients. With the addition of STAR-0310, an OX40 inhibitor for atopic dermatitis which we believe has the potential to be best-in-class, we are excited about the future for Astria as we work towards important milestones for STAR-0215 and STAR-0310 next year."

STAR-0215

- Additional results from the Phase 1a trial were shared at the ACAAI Annual Meeting in Anaheim, CA. STAR-0215 was well-tolerated with no serious adverse events or discontinuations due to an adverse event, and low risk of injection pain. STAR-0215 achieved potentially therapeutic levels in less than one day and showed an estimated half-life of up to 127 days. Pharmacokinetic (PK) modeling of every 3 month and every 6 month clinical dose regimens predict concentrations that will continuously maintain drug levels believed to be sufficient for HAE attack prevention. Pharmacodynamic (PD) data showed statistically significant inhibition of plasma kallikrein for 140 to 224 days after single doses greater than 100 mg. These results demonstrate early proof of concept in healthy subjects for STAR-0215 as a potential preventative HAE therapy with a favorable safety profile, long half-life, and durable PD.

- The ALPHA-STAR Phase 1b/2 trial of STAR-0215 in people with hereditary angioedema (HAE) is on track and enrolling the third and final cohort. Initial proof-of-concept results are now expected in the first quarter of 2024. ALPHA-STAR is a global, open-label, proof-of-concept trial assessing single and multiple doses of STAR-0215 in patients with HAE types I and II. The trial is evaluating safety and tolerability, changes in HAE attack rate, PK, PD, and quality-of-life assessments. For each dose cohort, efficacy will be assessed at 3 months and 6 months after the last STAR-0215 dose administered.

- A Long-Term Open-Label Trial named ALPHA-SOLAR has been initiated and is enrolling participants from ALPHA-STAR, with data now accruing in participants who have received multiple doses of STAR-0215. The trial is assessing the long-term safety, tolerability, and efficacy of STAR-0215. Participants are receiving STAR-0215 every three or six months.

- Pending proof-of-concept results from the ALPHA-STAR trial, Astria expects to progress directly to a pivotal Phase 3 trial which is anticipated to initiate in the first quarter of 2025.

- Additional preclinical results were shared in the Journal of Pharmacology and Experimental Therapeutics that support STAR-0215's potential as a best-in-class plasma kallikrein inhibitor.

- Astria presented at the Hereditary Angioedema Association (HAEA) National Summit in July, and the Hereditary Angioedema International EMEA meeting in September, sharing results from a research survey where patients prioritized attack-free status as their most important target for therapeutic efficacy in HAE clinical trials.

STAR-0310

- Astria entered into an exclusive worldwide license agreement with Ichnos Sciences for an inhibitory OX40 portfolio. Astria is developing STAR-0310, a monoclonal antibody OX40 antagonist that incorporates YTE technology, for the treatment of atopic dermatitis (AD).

- STAR-0310, a preclinical stage program, has the potential to have the best-in-class profile in AD. Astria expects to submit an Investigational New Drug (IND) application for STAR-0310 by year-end 2024 and plans to initiate a Phase 1a clinical trial in healthy subjects in the first quarter of 2025, with initial results from the trial expected in the third quarter of 2025.

Webcast Information

- The Company will host a webcast today at 8:30am ET. Interested parties may join via the Investors section of the Astria website, www.astriatx.com, or with the following link: https://lifescievents.com/event/astria-2/. The webcast will be archived for 90 days.

Third Quarter 2023 Financial Results

Cash Position: As of September 30, 2023, Astria had cash, cash equivalents and short-term investments of $188.8 million, compared to $203.0 million as of June 30, 2023. The Company expects that its cash, cash equivalents and short-term investments as of September 30, 2023, together with proceeds from a $64.0 million underwritten offering in October 2023, will be sufficient to fund its current operating plan into 2026. The Company's current operating plan includes the development of STAR-0215 and STAR-0310, including (i) for STAR-0215, support for all program activities up to the initiation of the planned Phase 3 pivotal trial and (ii) for STAR-0310, the anticipated submission of an IND and the initiation and completion of the planned Phase 1a clinical trial of healthy subjects (and any related anticipated milestone payments). Net cash used in operating activities for the three months ended September 30, 2023 was $14.3 million, compared to $10.2 million for the three months ended September 30, 2022.

R&D Expenses: Research and development expenses were $13.3 million for the three months ended September 30, 2023, compared to $7.7 million for the three months ended September 30, 2022. The increase in research and development expenses was associated with advancement of STAR-0215 clinical development.

G&A Expenses: General and administrative expenses were $6.9 million for the three months ended September 30, 2023, compared to $4.7 million for the three months ended September 30, 2022.

Operating Loss: Loss from operations was $20.2 million for the three months ended September 30, 2023, compared to $12.4 million for the three months ended September 30, 2022.

Net Loss: Net loss was $17.7 million for the three months ended September 30, 2023, compared to a net loss of $12.0 million for the three months ended September 30, 2022.

Net Loss Per Share Basic and Diluted: Net loss per share basic and diluted was $0.63 for the three months ended September 30, 2023, compared to $0.87 per share for the three months ended September 30, 2022.

About Astria Therapeutics:

Astria Therapeutics is a biopharmaceutical company, and our mission is to bring life-changing therapies to patients and families affected by allergic and immunological diseases. Our lead program, STAR-0215, is a monoclonal antibody inhibitor of plasma kallikrein in clinical development for the treatment of hereditary angioedema. Our second program, STAR-0310, is a monoclonal antibody OX40 antagonist in preclinical development for the treatment of atopic dermatitis. Learn more about our company on our website, www.astriatx.com, or follow us on Twitter and Instagram @AstriaTx and on Facebook and LinkedIn.

Forward Looking Statements:

This press release contains forward-looking statements within the meaning of applicable securities laws and regulations including, but not limited to, statements regarding: our expectations regarding the potential significance of the results from the Phase 1a clinical trial of STAR-0215; our expectations regarding the timing, nature, goals and results of our Phase 1b/2 ALPHA-STAR clinical trial of STAR-0215, including the expected timing of release of initial proof-of-concept data from such trial, and that favorable results from such trial could allow us to move directly into a Phase 3 pivotal trial of STAR-0215 as a potential treatment for HAE; the expected timing of the start of the Phase 3 pivotal trial of STAR-0215; the potential for STAR-0215 to have the best-in-class profile in HAE, the potential therapeutic benefits of STAR-0215 as a treatment for HAE and our vision and goals for the program; the potential for STAR-0310 to have the best-in-class profile in AD and the potential therapeutic benefits and potential attributes of STAR-0310 as a treatment for AD; expectations regarding the timing of regulatory filings for STAR-0310; expectations regarding the timing of initiation and planned design of clinical trials for STAR-0310; the expectations regarding the timing and nature of anticipated data for planned trials of STAR-0310; our goals and vision for STAR-0310; ; anticipated cash runway; and the goal to meet the unmet needs of patients with rare and niche allergic and immunological diseases. The use of words such as, but not limited to, “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “goals,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would,” or "vision," and similar words expressions are intended to identify forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on Astria’s current beliefs, expectations and assumptions regarding the future of its business, future plans and strategies, future financial performance, results of pre-clinical and clinical results of the Astria’s product candidates and other future conditions. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including the following risks and uncertainties: changes in applicable laws or regulations; the possibility that we may be adversely affected by other economic, business, and/or competitive factors; risks inherent in pharmaceutical research and development, such as: adverse results in our drug discovery, preclinical and clinical development activities, the risk that the results of preclinical studies may not be replicated in clinical trials, that the preliminary or interim results from clinical trials may not be indicative of the final results, that the results of early stage clinical trials, such as the results from the Phase 1a clinical trial, may not be replicated in later stage clinical trials, including the ALPHA-STAR trial, the risk that we may not be able to enroll sufficient patients in our clinical trials on a timely basis, and the risk that any of our clinical trials may not commence, continue or be completed on time, or at all; decisions made by, and feedback received from, the U.S. Food and Drug Administration and other regulatory authorities on our regulatory and clinical trial submissions and other feedback from potential clinical trial sites, including investigational review boards at such sites, and other review bodies with respect to STAR-0215, STAR-0310, and any other future development candidates; our ability to manufacture sufficient quantities of drug substance and drug product for STAR-0215, STAR-0310, and any other future product candidates on a cost-effective and timely basis, and to develop dosages and formulation for STAR-0215, STAR-0310, and any other future product candidates that are patient-friendly and competitive; our ability to develop biomarker and other assays, along with the testing protocols therefore; our ability to obtain, maintain and enforce intellectual property rights for STAR-0215, STAR-0310, and any other future product candidates; our potential dependence on collaboration partners; competition with respect to STAR-0215, STAR-0310, or any of our other future product candidates; the risk that survey results and market research may not be accurate predictors of the commercial landscape for HAE, the ability of STAR-0215 to compete in HAE and the anticipated position and attributes of STAR-0215 in HAE based on clinical data to date, its preclinical profile, pharmacokinetic modeling, market research and other data; risks that any of our clinical trials of STAR-0310 may not commence, continue or be completed on time, or at all; risks that results of preclinical studies of STAR-0310 will not be replicated in clinical trials; risks with respect to the ability of STAR-0310 to compete in AD and the anticipated position and attributes of STAR-0310 in AD based on its preclinical profile; our ability to manage our cash usage and the possibility of unexpected cash expenditures; our ability to obtain necessary financing to conduct our planned activities and to manage unplanned cash requirements; the risks and uncertainties related to our ability to recognize the benefits of any additional acquisitions, licenses or similar transactions; and general economic and market conditions; as well as the risks and uncertainties discussed in the “Risk Factors” section of our Annual Report on Form 10-K for the period ended December 31, 2022 and in other filings that we may make with the Securities and Exchange Commission.

New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Astria may not actually achieve the forecasts or expectations disclosed in our forward-looking statements, and investors and potential investors should not place undue reliance on Astria's forward-looking statements. Neither Astria, nor its affiliates, advisors or representatives, undertake any obligation to publicly update or revise any forward-looking statement, whether as result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing Astria's views as of any date subsequent to the date hereof.

###

Astria Contact:
Investor Relations and Media:
Elizabeth Higgins
investors@astriatx.com

Astria Therapeutics, Inc.
Consolidated Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 13,338	$ 7,698	$ 30,460	$ 24,673
General and administrative	6,898	4,688	18,371	14,540
Total operating expenses	20,236	12,386	48,831	39,213
Loss from operations	(20,236)	(12,386)	(48,831)	(39,213)
Other income (expense):				
Interest and investment income	2,527	437	7,404	706
Other expense, net	(18)	(48)	(54)	(64)
Total other income, net	2,509	389	7,350	642
Net loss	(17,727)	(11,997)	(41,481)	(38,571)
Net loss per share attributable to common shareholders - basic and diluted	$ (0.63)	$ (0.87)	$ (1.48)	$ (2.91)
Weighted-average common shares outstanding used in net loss per share - basic and diluted	28,040,173	13,742,385	28,002,663	13,261,422

Astria Therapeutics, Inc.
Selected Consolidated Balance Sheets Data
(In thousands)
(Unaudited)

	September 30, 2023	**December 31, 2022**
Assets		
Cash and cash equivalents	$ 119,806	$ 20,525
Short-term investments	69,000	205,912
Right-of-use asset	514	948
Other current and long-term assets	4,541	3,248
Total assets	193,861	230,633
Liabilities and stockholders' equity		
Current portion of operating lease liabilities	488	582
Long term portion of operating lease liabilities	-	357
Other current and long-term liabilities	8,894	8,478
Total liabilities	9,382	9,417
Total stockholders' equity	$ 184,479	$ 221,216

Astria Therapeutics, Inc.
Selected Consolidated Statements of Cash Flows Data
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2023	**2022**
Net cash used in operating activities	$ (38,207)	$ (32,869)
Net cash provided by (used in) by investing activities	137,068	(31,949)
Net cash provided by financing activities	420	24,324
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 99,281	$ (40,494)