UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): **March 25, 2024**

Astria Therapeutics, Inc.
(Exact Name of Registrant as Specified in 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** (Address of Principal Executive Offices)	**02109** (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 (*see* General Instruction A.2. below):

☐ 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 $0.001 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 8.01. Other Events.

On March 25, 2024, Astria Therapeutics, Inc. (the "Company") announced initial proof-of-concept data from its Phase 1b/2 ALPHA-STAR clinical trial of STAR-0215.

ALPHA-STAR is a dose-ranging proof-of-concept trial in adults with hereditary angioedema ("HAE") Type 1 or 2 designed to assess safety, tolerability, efficacy, pharmacokinetics ("PK"), pharmacodynamics ("PD"), and quality of life in patients receiving single and multiple doses of STAR-0215 delivered subcutaneously to prevent attacks in HAE. Target enrollment of 16 patients has been achieved and all doses have been administered. All cohorts began with an eight-week run-in period to measure baseline HAE attacks and safety, efficacy, PK, and PD are assessed through 6-months (Day 168) after the last dose received. The initial efficacy and safety data-cut was as of March 13, 2024.

Cohort 1 evaluated a 450 mg dose and all four patients have completed 6 months of follow-up. Efficacy observations compared to baseline through 6 months of follow-up were as follows:

- 92% reduction in monthly attack rate
- 96% reduction in moderate and severe attacks
- 91% reduction in acute rescue medication use
- 50% of patients were attack-free through 3 months of follow-up

Cohort 2 evaluated a 600 mg dose followed by a 300 mg dose three months later, on Day 84. The Company plans to evaluate this dosing regimen in Phase 3. All six patients have completed 3 months of follow-up and three patients have completed 6 months of follow-up. Efficacy observations compared to baseline through 6 months of follow-up were as follows:

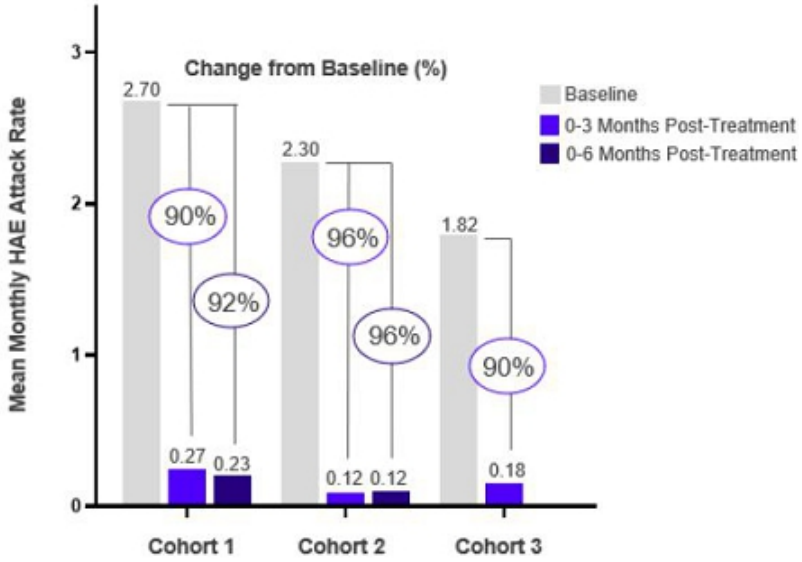
- 96% reduction in monthly attack rate
- 98% reduction in moderate and severe attacks
- 94% reduction in acute rescue medication use
- 67% of patients were attack-free
- 100% of patients were attack-free in the first month after dosing, demonstrating rapid onset of action

Cohort 3 received a 600 mg dose followed by a 600 mg dose one month later, on Day 28. Four of six patients have completed 3 months of follow-up. Efficacy observations compared to baseline through 3 months of follow-up were as follows:

- 90% reduction in monthly attack rate
- 100% reduction in moderate and severe attacks
- 95% reduction in acute rescue medication use
- 50% of patients were attack-free

The following graphic presents the observed reductions in monthly attack rates for each cohort, through 3 and 6 months of follow-up as applicable.

Mean Time-Normalized Monthly HAE Attacks



Preliminary PK and PD data are consistent with Phase 1a data in healthy subjects and consistent with observed efficacy.

STAR-0215 was generally well-tolerated with no serious treatment-emergent adverse events ("TEAEs") and no discontinuations. There were two treatment-related TEAEs (both mild), one of which was a case of dizziness and the other a transient injection site reaction (rash). There were no injection site reactions of pain.

After completion of the ALPHA-STAR trial, patients have the opportunity to continue to receive STAR-0215 every three months ("Q3M") or every six months ("Q6M") in the Company's long-term open label ALPHA-SOLAR trial. Initial safety and efficacy data from Q3M and Q6M dosing in the ALPHA-SOLAR trial are expected in mid-2025.

The observed efficacy, PK, PD, and safety and tolerability profile of STAR-0215 support advancement of STAR-0215 into Phase 3 development. To progress STAR-0215 to market as quickly as possible, the Company plans to focus the Phase 3 program on Q3M dosing initially, immediately followed by a second trial to support label expansion to Q6M. Pending regulatory feedback, the Company expects to start a pivotal Q3M Phase 3 trial in the first quarter of 2025, with top-line results expected by year-end 2026.

The Company expects that its current cash, cash equivalents, and short-term investments of $246.5 million as of December 31, 2023, plus $137.1 million from financing activity in the first quarter of 2024, will be sufficient to fund the Company into mid-2027 including all STAR-0215 program activities through the completion of a planned Q3M Phase 3 pivotal trial as well as advancing the Company's STAR-0310 OX40 program through submission of an investigational new drug application and early proof-of-concept results from a Phase 1a trial.

Cautionary Note Regarding Forward Looking Statements

This Current Report on Form 8-K 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 initial results from the Phase 1b/2 ALPHA-STAR clinical trial of STAR-0215, 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 and completion of the Phase 3 pivotal trial of STAR-0215; the expectations regarding the timing of anticipated data for planned trials of STAR-0310; and our anticipated cash runway. 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 1b/2 clinical trial, may not be replicated in later stage clinical trials, including the Phase 3 pivotal 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; 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 fiscal year ended December 31, 2023 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.

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: March 25, 2024

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