Astria Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Provides a Corporate Update

March 4, 2024

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

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

BOSTON--(BUSINESS WIRE)--Mar. 4, 2024-- Astria Therapeutics, Inc. (NASDAQ:ATXS), a biopharmaceutical company focused on developing life-changing therapies for allergic and immunological diseases, today reported financial results for the fourth quarter and full year ended December 31, 2023, and provided a corporate update.

"We have strong conviction in the potential for STAR-0215 to be the first-choice preventative therapy for HAE," said Jill C. Milne, Chief Executive Officer at Astria Therapeutics. "Our final data from the Phase 1a trial demonstrate that STAR-0215, in addition to having a trusted modality and proven mechanism, has a favorable safety profile with low risk of injection site pain and has the potential to achieve rapid and durable protection against HAE attacks. We are looking forward to sharing initial proof-of-concept data in HAE patients this quarter and believe they could support dosing as infrequently as every six months. STAR-0310 for atopic dermatitis also remains on track for expected preclinical results later this year and an IND submission by year-end."

STAR-0215

- The ALPHA-STAR Phase 1b/2 trial of STAR-0215 in people with hereditary angioedema (HAE) is on track. Initial proof-of-concept results are 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, pharmacokinetics (PK), pharmacodynamics (PD), and quality-of-life assessments. The initial proof-of-concept results are expected to inform on three and six month dosing and include efficacy results in the form of attack rate reduction, safety and tolerability, PK, and PD. Additionally, the company expects to have data from single and multiple doses in patients.
- Pending proof-of-concept results from the ALPHA-STAR trial, Astria expects to progress directly to a pivotal Phase 3 program which is anticipated to initiate in the first quarter of 2025.
- A Long-Term Open-Label Trial, ALPHA-SOLAR, has been initiated and is enrolling participants from ALPHA-STAR, with data from participants who have received multiple doses of STAR-0215 now accruing. The trial is assessing the long-term safety, tolerability, and efficacy of STAR-0215. Participants are receiving STAR-0215 every three or six months.
- Final results from the Phase 1a trial were shared at the AAAAI Annual Meeting in Washington D.C. These results confirm 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.

STAR-0310

- 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.
- Astria intends to present information on the preclinical profile of STAR-0310 at upcoming scientific conferences in 2024.

Underwritten Offering

- In February 2024, Astria closed an underwritten offering of 10,340,000 shares of common stock for gross proceeds of approximately $125.0 million before deducting underwriting fees and commissions and other offering expenses.
- The financing was led by RA Capital Management, with participation from Perceptive Advisors, Venrock Healthcare Capital Partners, TCGX, Driehaus Capital Management, and Adage Capital Partners L.P. in addition to other existing shareholders.

Fourth Quarter and Full Year 2023 Financial Results

Cash Position: As of December 31, 2023, Astria had cash, cash equivalents and short-term investments of $246.5 million, compared to $188.8 million as of September 30, 2023. The Company expects that its cash, cash equivalents and short-term investments as of December 31, 2023, together with gross proceeds from approximately $145.0 million in financing activity in Q1 2024, will be sufficient to fund its current operating plan into mid-2027. As of February 29, 2024, there were 54,903,061 shares of common stock outstanding. The Company's current operating plan centers on

the development of STAR-0215 and STAR-0310, including (i) for STAR-0215, support for all program activities up to the completion of a 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 December 31, 2023, was $30.2 million, compared to $10.7 million for the three months ended December 31, 2022. Net cash used in operating activities for the full year 2023 was $68.4 million, compared to $43.5 million for the full year 2022.

R&D Expenses: Research and development expenses were $11.7 million for the three months ended December 31, 2023, compared to $9.6 million for the three months ended December 31, 2022, and $42.1 million for the full year 2023, compared to $34.3 for the full year 2022. The increase in research and development expenses was primarily attributable to advancement of STAR-0215 from IND-enabling activities and a single-site clinical trial in healthy volunteers in 2022 into multi-site international clinical trials in patients in 2023.

G&A Expenses: General and administrative expenses were $7.3 million for the three months ended December 31, 2023, compared to $4.7 million for the three months ended December 31, 2022, and $25.7 million for the full year 2023, compared to $19.2 million for the full year 2022. The increase in general and administrative expenses was primarily attributable to an increase in employee expenses due to company growth.

Operating Loss: Loss from operations was $34.2 million for the three months ended December 31, 2023, compared to $14.3 million for the three months ended December 31, 2022, and $83.0 million for the full year 2023, compared to $53.5 million for the full year 2022. The increase in operating losses was largely attributable to the $15.2 million in acquired in-process R&D expense associated with the license agreement of the STAR-0310 candidate.

Net Loss: Net loss was $31.4 million for the three months ended December 31, 2023, compared to a net loss of $13.3 million for the three months ended December 31, 2022, and $72.9 million, or $2.42 per share for the full year 2023, compared to $51.8 million, or $3.55 per share for the full year 2022.

Net Loss Per Share Basic and Diluted: Net loss per share basic and diluted was $0.86 for the three months ended December 31, 2023, compared to $0.72 per share for the three months ended December 31, 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 X 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, 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.

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

	Year Ended December 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 42,127	$ 34,264
General and administrative	25,704	19,239
Acquired in-process research and development	15,199	-
Total operating expenses	83,030	53,503
Loss from operations	(83,030)	(53,503)
Other income (expense):		
Interest and investment income	10,201	1,724
Other expense, net	(62)	(55)
Total other income, net	10,139	1,669
Net loss	(72,891)	(51,834)
Net loss per share attributable to common shareholders - basic and diluted	$ (2.42)	$ (3.55)
Weighted-average common shares outstanding used in net loss per share - basic and diluted	30,123,316	14,620,618

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

	December 31, 2023	December 31, 2022
Assets		
Cash and cash equivalents	$ 175,530	$ 20,525
Short-term investments	71,000	205,912
Right-of-use asset	363	948
Other current and long-term assets	7,773	3,248
Total assets	254,666	230,633
Liabilities and stockholders’ equity		
Current portion of operating lease liabilities	329	582
Long term portion of operating lease liabilities	-	357
Other current and long-term liabilities	11,221	8,478
Total liabilities	11,550	9,417
Total stockholders’ equity	$ 243,116	$ 221,216

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

	Year Ended December 31,	
	2023	**2022**
Net cash used in operating activities	$ (68,445)	$ (43,533)

Net cash provided by (used in) by investing activities	135,052	(167,129)
Net cash provided by financing activities	88,398	144,721
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 155,005	$ (65,941)

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