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

May 11, 2023

-- Administration of STAR-0215 to HAE Patients is Underway in the ALPHA-STAR Phase 1b/2 Trial --

-- ALPHA-STAR on Track for Initial Proof-of-Concept Results Anticipated Mid-2024 --

-- Mechanistic Modeling Data Supports STAR-0215 Administration Once Every Three or Six Months for Robust Suppression of HAE Attacks --

BOSTON--(BUSINESS WIRE)--May 11, 2023-- Astria Therapeutics, Inc. (NASDAQ:ATXS), a biopharmaceutical company developing STAR-0215 for the treatment of hereditary angioedema (HAE) and focused on life-changing therapies for rare and niche allergic and immunological diseases, today reported financial results for the first quarter ended March 31, 2023 and provided a corporate update.

"We are excited to be administering STAR-0215 to patients in the Phase 1b/2 ALPHA-STAR clinical trial. We on track to share initial proof-of-concept results which are anticipated in mid-2024," said Jill C. Milne, Ph.D., Chief Executive Office at Astria. "We are also encouraged by human mechanistic modeling data that supports the potential for STAR-0215 to be administered once every three or six months for robust suppression of HAE attacks with low treatment burden. The modeling results, in conjunction with our clinical momentum, bring us closer to our goal of making STAR-0215 the first-choice preventative treatment for HAE to help normalize the lives of the HAE community."

STAR-0215

- The ALPHA-STAR Phase 1b/2 trial of STAR-0215 in people with HAE is underway and is enrolling and administering STAR-0215 to patients. Initial proof-of-concept results are expected in mid-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, pharmacodynamics, 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. Additionally, the company plans to initiate a long-term open label trial in the second half of this year.
- Astria is also evaluating the potential for administration of STAR-0215 every six months with additional cohorts added to the ongoing Phase 1a and ALPHA-STAR trials. In the fourth quarter of 2023, the company expects initial Phase 1a results from the additional cohorts in healthy subjects, as well as final results from cohorts 1 through 3.
- Pending proof-of-concept results from the ALPHA-STAR trial, Astria expects to progress directly to a pivotal trial informed by data from both the Phase 1a and ALPHA-STAR trials.
- Human mechanistic modeling data was presented at the C1-Inhibitor Deficiency and Angioedema Workshop in May 2023. These data support the potential for STAR-0215 to be administered once every three or six months for robust suppression of HAE attacks. Additionally, Principal Investigator Dr. Marcus Maurer presented the ALPHA-STAR trial, including design, dose selection rationale, and partnerships with the HAE community.
- Initial unblinded results from the first three cohorts of the STAR-0215 Phase 1a trial were presented at the American Academy of Allergy, Asthma, and Immunology Annual Meeting (AAAAI) in February 2023. STAR-0215 was well-tolerated at all doses studied. The results showed rapid and sustained drug levels, with an estimated half-life of up to 117 days and sustained target engagement with plasma kallikrein inhibition for at least three months. These results establish early proof of concept for STAR-0215 as a long-acting preventative therapy for HAE.

Company Highlights

- Learnings from HAE patients guide the development of STAR-0215 at Astria. On February 15, the company hosted its first STAR-0215 Day, where a panel of speakers living with HAE shared their stories. Their experiences, learnings from advocacy organizations, and company patient and physician market research all support STAR-0215's potential to make a significant impact on the lives of patients and be the leading preventative choice in a future HAE marketplace.
- The company is proud to support the upcoming hae day:-) on May 16 which raises awareness for HAE and better quality of lives for the HAE community.
- Astria named Andrea Matthews as Chief Business Officer. Ms. Matthews brings 20 years of business experience to the role. She will be responsible for leading the company's Corporate Strategy, Business Development, Investor Relations, Corporate Communications, and Patient Advocacy functions.

First Quarter 2023 Financial Results

Cash Position: As of March 31, 2023, Astria had cash, cash equivalents and short-term investments of $213.3 million, compared to $226.4 million as of December 31, 2022. The Company expects that it has sufficient cash to fund its current operating plan through the first half of 2025. Net cash used in operating activities for the three months ended March 31, 2023 was $13.3 million, compared to $12.6 million for the three months ended March 31, 2022.

R&D Expenses: Research and development expenses were $8.0 million for the three months ended March 31, 2023, compared to $10.4 million for the three months ended March 31, 2022. The decrease in year-over-year R&D expenses was primarily attributable to the significant Q1 2022 expenses related to the STAR-0215 IND. R&D expenses are expected to be higher throughout the remainder of 2023 compared to 2022 and Q1 2023 as clinical activities progress.

G&A Expenses: General and administrative expenses were $5.5 million for the three months ended March 31, 2023, compared to $5.0 million for the three months ended March 31, 2022.

Operating Loss: Loss from operations was $13.5 million for the three months ended March 31, 2023, compared to $15.4 million for the three months ended March 31, 2022.

Net Loss: Net loss was $11.2 million for the three months ended March 31, 2023, compared to a net loss of $15.3 million for the three months ended March 31, 2022.

Net Loss Per Share Basic and Diluted: Net loss per share basic and diluted was $0.40 for the three months ended March 31, 2023, compared to a net loss basic and diluted of $1.18 per share for the three months ended March 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 rare and niche 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. Learn more about our company on our website, www.astriatx.com, or follow us on Twitter and Instagram @AstriaTx and on Facebook and LinkedIn.

About STAR-0215:

STAR-0215 is a monoclonal antibody inhibitor of plasma kallikrein in development for the treatment of HAE. Our vision is for STAR-0215 to be the first-choice preventative treatment for people with HAE dosed once every three or six months and to make substantial progress towards normalizing their lives. The Phase 1b/2 ALPHA-STAR trial evaluating STAR-0215 in HAE patients is ongoing, with proof-of-concept results expected in mid-2024.

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: expectations regarding the potential significance of the results from the Phase 1a STAR-0215 trial and the anticipated nature and timing of receipt of additional data from the trial; expectations regarding the timing and nature of the anticipated proof of concept results from the ALPHA-STAR Phase 1b/2 clinical trial; the longer term development plans for STAR-0215, including the plan, pending proof-of-concept results from the ALPHA-STAR trial, to progress directly to a pivotal trial; our plans to initiate a long-term open label trial in the second half of this year; the potential attributes and differentiated profile of STAR-0215 as a treatment for HAE, including those suggested by the results from the STAR-0215 Phase 1a trial, market research, mechanistic modeling and patient feedback, and our goals and vision for STAR-0215; the potential commercial opportunity for STAR-0215 in HAE and the likelihood that it can effectively compete in HAE, assuming its approved; the need for effective treatments for HAE and the expected growth of the HAE market; the potential for three and six-month administration and suppression of HAE attacks of STAR-0215; the Company's anticipated cash runway; and the Company's 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," or "would" 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 the Company'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 Company'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 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, including the COVID-19 pandemic; 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 pre-clinical studies may not be replicated in clinical studies, that the preliminary results from the Phase 1a trial may not be indicative of the final results, that the results of early stage clinical studies, such as the preliminary and initial unblinded results from the Phase 1a trial, may not be replicated in later stage clinical studies, 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 and any other future development candidates; our ability to manufacture sufficient quantities of drug substance and drug product for STAR-0215 and any other future product candidates on a cost-effective and timely basis, and to develop dosages and formulation for STAR-0215 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 and any other future product candidates; our potential dependence on collaboration partners; competition with respect to STAR-0215 or any of our other future product candidates; the risk that the clinical results to date, 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 its clinical data to date, pre-clinical profile, mechanistic and other modeling, market research, patient feedback and other data; 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 make with the Securities and Exchange Commission ("SEC"). New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. The Company 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 the Company's forward-looking statements. Neither the Company, 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 the Company'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)
(Unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 8,033	$ 10,358
General and administrative	5,460	5,020
Total operating expenses	13,493	15,378
Loss from operations	(13,493)	(15,378)
Other income (expense):		
Interest and investment income	2,321	56
Other expense, net	(16)	(1)
Total other income, net	2,305	55
Net loss	(11,188)	(15,323)
Net loss per share attributable to common shareholders - basic and diluted	$ (0.40)	$ (1.18)
Weighted-average common shares outstanding used in net loss per share - basic and diluted	27,944,458	13,016,955

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

	March 31,	December 31,
	2023	**2022**
Assets		
Cash and cash equivalents	$ 202,301	$ 20,525
Short-term investments	11,027	205,912
Right-of-use asset	806	948
Other current and long-term assets	4,106	3,248
Total assets	218,240	230,633
Liabilities and stockholders' equity		
Current portion of operating lease liabilities	587	582
Long-term portion of operating lease liabilities	207	357
Other current and long-term liabilities	6,086	8,478
Total liabilities	6,880	9,417
Total stockholders' equity	$ 211,360	$ 221,216

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

	Three Months Ended March 31,	
	2023	**2022**
Net cash used in operating activities	$ (13,253)	$ (12,559)
Net cash provided by (used in) by investing activities	194,992	(27,099)
Net cash provided by financing activities	37	-
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 181,776	$ (39,658)

View source version on businesswire.com: https://www.businesswire.com/news/home/20230511005687/en/

Investor relations:

Andrea Matthews
investors@astriatx.com

Media:
Elizabeth Higgins
media@astriatx.com

Source: Astria Therapeutics, Inc.