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

August 7, 2023

-- STAR-0215 Granted Fast Track Designation by the U.S. FDA --

-- New Results from Healthy Subjects Informing STAR-0215 Administration Plan Expected in Q4 2023 --

-- ALPHA-STAR on Track with Initial Proof-of-Concept Results in Patients Anticipated Mid-2024 --

BOSTON--(BUSINESS WIRE)--Aug. 7, 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 second quarter ended June 30, 2023 and provided a corporate update.

“We are making excellent progress with our STAR-0215 program and are proud to have received Fast Track Designation for the treatment of HAE,” said Jill C. Milne, Ph.D., Chief Executive Officer at Astria Therapeutics. “We believe that STAR-0215 has the profile of a potential first-choice preventative therapy for HAE based on its well-established mechanism, trusted modality, long half-life, and potential for infrequent dosing. We are looking forward to sharing additional data from our Phase 1a trial in Q4. We expect these results will provide additional information on dose selection for three and six-month administration, with data on safety, tolerability, pharmacokinetics, and pharmacodynamics from a wide range of single dose levels.”

STAR-0215

- STAR-0215 was granted Fast Track Designation by the U.S. Food and Drug Administration for the treatment of HAE.
- The ALPHA-STAR Phase 1b/2 trial of STAR-0215 in people with HAE is progressing well. 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.
- In the fourth quarter of 2023, the company expects to announce final results from three single dose cohorts in healthy subjects. Initial results from the two additional dose-ranging cohorts in healthy subjects are also expected to be shared in Q4. Overall, the data are expected to provide more information around plans for future trials, dose selection for potential three and six-month administration, safety and tolerability, and PK and PD from a wide range of single dose levels.
- A Long-Term Open-Label Trial named ALPHA-SOLAR will be open to participants from ALPHA-STAR and is expected to initiate in the fourth quarter of 2023. It will assess the long-term safety, tolerability, and efficacy of STAR-0215. Participants will be assigned to a dosing regimen based on their cohort assignment in the ALPHA-STAR trial and all are expected to receive 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 trial.
- In June 2023, Astria presented at the European Academy of Allergy and Clinical Immunology Annual Meeting in Hamburg, Germany. Results included an overview of the design of the ALPHA-STAR clinical trial, a summary of the positive initial Phase 1a results of STAR-0215 in healthy subjects, and details about STAR-0215’s differentiated mode of plasma kallikrein binding.
- Human mechanistic modeling data were 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.

Company Highlights

- Astria presented at the Hereditary Angioedema Association (HAEA) National Summit in July, sharing results from a research survey where patients prioritized attack-free status as their most important target for therapeutic efficacy in HAE clinical trials.
- In July, Astria named John Ruesch as Senior Vice President, Pharmaceutical Sciences and Technical Operations. Mr. Ruesch brings to Astria more than 25 years of experience in pharmaceutical drug development.

Second Quarter 2023 Financial Results

Cash Position: As of June 30, 2023, Astria had cash, cash equivalents and short-term investments of $203.0 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 June 30, 2023 was $10.7 million, compared to $10.1 million for the three months ended June 30, 2022.

R&D Expenses: Research and development expenses were $9.1 million for the three months ended June 30, 2023, compared to $6.6 million for the three months ended June 30, 2022.

G&A Expenses: General and administrative expenses were $6.0 million for the three months ended June 30, 2023, compared to $4.8 million for the three months ended June 30, 2022.

Operating Loss: Loss from operations was $15.1 million for the three months ended June 30, 2023, compared to $11.4 million for the three months ended June 30, 2022.

Net Loss: Net loss was $12.6 million for the three months ended June 30, 2023, compared to a net loss of $11.3 million for the three months ended June 30, 2022.

Net Loss Per Share Basic and Diluted: Net loss per share basic and diluted was $0.45 for the three months ended June 30, 2023, compared to a net loss basic and diluted of $0.86 per share for the three months ended June 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 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 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; plans for, and timing of, initiation of the ALPHA-SOLAR trial; the potential for STAR-0215 to be the first choice preventative therapy for HAE and the potential differentiation, administration, dosing regimens, impact on HAE attacks and other attributes of STAR-0215, in each case, assuming its approval; 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,” 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 results of early stage clinical studies, such as the preliminary and initial unblinded results from the first three cohorts of the Phase 1a trial, may not be replicated in the final data from the first three cohorts of the Phase 1a trial, the subsequent cohorts of the Phase 1a trial, 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 9,089	$ 6,617	$ 17,122	$ 16,975
General and administrative	6,013	4,832	11,473	9,852
Total operating expenses	15,102	11,449	28,595	26,827
Loss from operations	(15,102)	(11,449)	(28,595)	(26,827)
Other income (expense):				
Interest and investment income	2,556	214	4,877	269
Other expense, net	(20)	(15)	(36)	(16)
Total other income, net	2,536	199	4,841	253
Net loss	(12,566)	(11,250)	(23,754)	(26,574)
Net loss per share attributable to common shareholders - basic and diluted	$ (0.45)	$ (0.86)	$ (0.85)	$ (2.04)
Weighted-average common shares outstanding used in net loss per share - basic and diluted	28,022,306	13,016,955	27,983,597	13,016,955

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

	June 30, 2023	December 31, 2022
Assets		
Cash and cash equivalents	$ 133,958	$ 20,525
Short-term investments	69,000	205,912
Right-of-use asset	661	948
Other current and long-term assets	3,434	3,248
Total assets	207,053	230,633
Liabilities and stockholders' equity		
Current portion of operating lease liabilities	590	582
Long-term portion of operating lease liabilities	53	357
Other current and long-term liabilities	6,008	8,478
Total liabilities	6,651	9,417
Total stockholders' equity	$ 200,402	$ 221,216

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

	Six Months Ended June 30,	
	2023	2022
Net cash used in operating activities	$ (23,949)	$ (22,620)
Net cash provided by (used in) by investing activities	137,072	(33,899)
Net cash provided by financing activities	310	-
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 113,433	$ (56,519)

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