Astria Therapeutics Reports Third Quarter 2022 Financial Results and Provides a Corporate Update

November 10, 2022

-- Preliminary Results from Phase 1a Clinical Trial of STAR-0215 in Healthy Subjects Expected by Year-End 2022 --

-- Phase 1a Results Expected to Inform on STAR-0215's Profile to Prevent Attacks in Hereditary Angioedema --

BOSTON--(BUSINESS WIRE)--Nov. 10, 2022-- Astria Therapeutics, Inc. (NASDAQ:ATXS), a biopharmaceutical company developing STAR-0215 for hereditary angioedema (HAE) and focused on life-changing therapies for rare and niche allergic and immunological diseases, today reported financial results for the third quarter ended September 30, 2022 and provided a corporate update.

"We are on track to report preliminary results from our Phase 1a trial of STAR-0215 by the end of this year. The trial is assessing safety and tolerability and will inform on dosing frequency and target engagement. We believe the results from this trial will validate STAR-0215's differentiated best-in-class profile," said Jill C. Milne, Ph.D., Chief Executive Officer of Astria. "STAR-0215 is a long-acting monoclonal antibody inhibitor of plasma kallikrein that has the potential to reduce treatment burden for patients with HAE with dosing once every three months or longer."

Phase 1a Clinical Trial of STAR-0215

- The Food and Drug Administration cleared Astria's Investigational New Drug application for STAR-0215 in July 2022.
- The Phase 1a randomized, double-blind, placebo-controlled single ascending dose trial evaluating the safety, pharmacokinetics, and pharmacodynamics of STAR-0215 at a single U.S. center was initiated in August 2022. Astria has enrolled and dosed 24 evaluable subjects who were randomized to receive single subcutaneous administrations of one of three dose levels of 100 mg, 300 mg, or 600 mg of STAR-0215 or placebo. The subjects are now in the follow-up phase.
- The trial aims to establish the prolonged half-life and demonstrate inhibition of plasma kallikrein activity, which, if favorable, would provide proof of mechanism for STAR-0215 as a potential best-in-class treatment for HAE.
- The company plans to initiate a multi-center, global, single and multiple dose Phase 1b/2 proof-of-concept trial in people living with HAE, called ALPHA-STAR, or Astria Long-Acting Prophylaxis for HAE: STAR-0215, in Q1 2023, subject to favorable Phase 1a results.

STAR-0215 Highlights

- Astria presented new preclinical data at the European Academy of Allergy and Clinical Immunology 2022 Hybrid Congress that demonstrate STAR-0215's rapid and durable inhibition of plasma kallikrein in cynomolgus monkeys, supporting the potential for once every three month or longer dosing in humans. The study demonstrated rapid inhibition of plasma kallikrein after subcutaneous administration. Inhibition of high molecular weight kininogen cleavage was rapid and sustained throughout the entire 84-day dose-free period in the extended portion of the study. These data confirm the long half-life of STAR-0215 and demonstrate prolonged pharmacological activity of STAR-0215 in circulation in cynomolgus monkeys.
- The company will share preclinical data for STAR-0215 in a presentation titled "Modeling and Simulation Predicts Robust HAE Attack Suppression with Every 3 Month Dosing of STAR-0215" at the 2022 American College of Allergy, Asthma and Immunology (ACAAI) Annual Scientific Meeting in Louisville, Kentucky on November 13, 2022 at 12:05pm ET.

Corporate Highlights

- Astria named Chris Morabito, M.D., as Chief Medical Officer. Dr. Morabito brings more than 20 years of clinical development experience in rare diseases and other indications to Astria. He has spent his career developing innovative medicines that improve the health outcomes of patients with complex and difficult to treat diseases.
- The company hosted a virtual R&D Day: Update on STAR-0215 and its Clinical Development for the Prevention of HAE Attacks on September 30, 2022. A replay of the event can be accessed on the investors section of www.astriatx.com.

Third Quarter 2022 Financial Results

Cash Position: As of September 30, 2022, Astria had cash, cash equivalents and short-term investments of $116.6 million, compared to $131.8 million as of September 30, 2021. Subsequent to September 30, 2022, Astria raised $12.7 million in net proceeds under its at-the-market offering (ATM) program. The company expects that it has sufficient cash to fund its current operating plan into mid-2024. Net cash used in operating activities for the three months ended September 30, 2022, was $10.2 million, compared to $7.7 million for the three months ended September 30, 2021.

Capital Structure: As of November 3, 2022, there were 17,051,429 shares of common stock issued and outstanding. Additionally, there were 31,455 shares of Series X Preferred Stock outstanding, which are convertible into approximately 5,242,501 million shares of common stock.

R&D Expenses: Research and development expenses were $7.7 million for the three months ended September 30, 2022, compared to $3.8 million

for the three months ended September 30, 2021.

G&A Expenses: General and administrative expenses were $4.7 million for the three months ended September 30, 2022, compared to $4.1 million for the three months ended September 30, 2021.

Operating Loss: Loss from operations was $12.4 million for the three months ended September 30, 2022, compared to $7.9 million for the three months ended September 30, 2021.

Net Loss: Net loss was $12.0 million for the three months ended September 30, 2022, compared to a net loss of $7.9 million for the three months ended September 30, 2021.

Net Loss Per Share Basic and Diluted: Net loss per share basic and diluted was $0.87 for the three months ended September 30, 2022, compared to a net loss basic and diluted of $0.61 per share for the three months ended September 30, 2021.

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.

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: the Company's projected cash runway; the expected timing, scope, goals and nature of the preliminary results from the Phase 1a clinical trial for STAR-0215, including the expectation that the results will inform on STAR-0215's profile to prevent attacks in HAE and validate STAR-0215's differentiated best-in-class profile; the planned timing of initiation of a Phase 1b/2 proof-of-concept trial of STAR-0215 in patients with HAE; the potential attributes and differentiated profile of STAR-0215 as a treatment for HAE and the potential commercial opportunity for STAR-0215 in HAE, including that STAR-0215 has the potential to reduce treatment burden for patients with HAE with dosing once every three months or longer; the need for effective treatments for HAE; and the Company's broader 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: related to changes in applicable laws or regulations; the possibility that the Company 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 and modeling data may not be replicated in clinical studies, the risk that early data from the initial cohorts in the Phase 1a trial of STAR-0215 may not be replicated in the preliminary results that the Company plans to release by year-end 2022, the Company's ability to enroll patients in our clinical trials, and the risk that any of the Company's clinical trials may not commence, continue or be completed on time, or at all; decisions made by, or feedback received from, the U.S. FDA and other regulatory authorities, investigational review boards at clinical trial sites and other review bodies with respect to STAR-0215 and any future product candidates; the Company's ability to manufacture and supply sufficient quantities of drug substance and drug product on a cost-effective and timely basis; the Company's ability to obtain, maintain and enforce intellectual property rights for STAR-0215 and any other future product candidates; competition with respect to STAR-0215 in HAE or with respect to any other future product candidates; the anticipated position and attributes of STAR-0215 in HAE based on its pre-clinical profile, pharmacokinetic modeling and other data; the Company's ability to manage its cash usage and the possibility of unexpected cash expenditures; the Company's ability to obtain necessary financing to conduct its planned activities and to manage unplanned cash requirements; general economic and market conditions; as well as the risks and uncertainties set forth under the caption "Risk Factors" in the Company's most recent Annual Report on Form 10-K filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in the Company's subsequent filings with the 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 7,698	$ 3,788	$ 24,673	$ 9,859
General and administrative	4,688	4,110	14,540	10,992
Acquired in-process research and development	-	-	-	164,617
Total operating expenses	12,386	7,898	39,213	185,468
Loss from operations	(12,386)	(7,898)	(39,213)	(185,468)

Other income (expense):				
Interest and investment income	437	35	706	89
Other expense, net	(48)	(8)	(64)	(42)
Total other income, net	389	27	642	47
Net loss	(11,997)	(7,871)	(38,571)	(185,421)
Dividend on convertible preferred stock related to beneficial conversion feature and issuance costs	-	-	-	(24,437)
Net loss attributable to common shareholders	$ (11,997)	$ (7,871)	$ (38,571)	$ (209,858)
Net loss per share - basic and diluted	$ (0.87)	$ (0.61)	$ (2.91)	$ (27.81)
Weighted-average common shares outstanding used in net loss per share - basic and diluted	13,742,385	12,830,782	13,261,422	7,546,969

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

	September 30, 2022	December 31, 2021
Assets		
Cash and cash equivalents	$ 45,972	$ 86,508
Short-term investments	70,599	39,000
Right-of-use asset	1,087	394
Other current and long-term assets	2,159	1,612
Total assets	119,817	127,514
Liabilities and stockholders' equity		
Current portion of operating lease liabilities	578	365
Long-term portion of operating lease liabilities	504	-
Other current and long-term liabilities	5,863	4,838
Total liabilities	6,945	5,203
Total stockholders' equity	$ 112,872	$ 122,311

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

	Nine Months Ended September 30, 2022	2021
Net cash used in operating activities	$ (32,869)	$ (23,865)
Net cash (used in) provided by investing activities	(31,949)	26,445
Net cash provided by financing activities	24,324	104,267
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (40,494)	$ 106,847

View source version on businesswire.com: https://www.businesswire.com/news/home/20221110006015/en/

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Source: Astria Therapeutics, Inc.