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

May 12, 2022

-- Expect to File IND Application for STAR-0215 Mid-Year --

-- Initial Phase 1a Clinical Results Anticipated by Year-End 2022 --

-- Pharmacokinetic Modeling Data Supports STAR-0215 Dosing Once Every Three Months or Longer with Effective Plasma Kallikrein Inhibition --

BOSTON--(BUSINESS WIRE)--May 12, 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 first quarter ended March 31, 2022 and provided a corporate update.

"We are looking forward to advancing STAR-0215 into the clinic this year with the Phase 1a trial, which we plan to initiate shortly after our anticipated mid-year IND filing. We expect initial results by year end," said Jill C. Milne, Ph.D., Chief Executive Officer of Astria. "Pharmacokinetic modeling suggests that STAR-0215 could be effective at inhibiting plasma kallikrein and has the potential to prevent HAE attacks with subcutaneous administration with a self-injectable device dosed once every three-months or longer. This model informs our plans for the Phase 1a trial, which aims to evaluate safety, tolerability, demonstrate inhibition of plasma kallikrein activity, and establish the prolonged half-life of STAR-0215."

STAR-0215 for the Treatment of HAE

- Lead program STAR-0215 is a monoclonal antibody inhibitor of plasma kallikrein designed to provide long-acting, effective attack prevention for HAE with dosing once every three months or longer. The goal for STAR-0215 is to provide the most patient-friendly preventative treatment option for people living with HAE.
- HAE is a rare genetic disorder characterized by severe, recurrent, unpredictable, painful, and sometimes life-threatening swelling in the face, limbs, abdomen, and airway. Targeted plasma kallikrein inhibition can prevent HAE attacks by suppressing the pathway that generates bradykinin and causes excessive swelling.
- Astria expects to file an Investigational New Drug application for STAR-0215 in the middle of this year and plans to initiate a Phase 1a clinical trial shortly thereafter with initial results anticipated by year-end. The Phase 1a clinical trial is planned to be conducted at a single center with healthy volunteers and evaluate several single ascending dose cohorts with subcutaneous administration. The goals of this initial proof of concept trial are to demonstrate safety and tolerability, establish prolonged half-life of STAR-0215, and to demonstrate inhibition of plasma kallikrein activity. We plan to initiate a multi-center, global Phase 1b/2 trial in patients with HAE in 2023.
- Astria presented preclinical data demonstrating how STAR-0215 binds to plasma kallikrein at the American Academy of Allergy, Asthma, and Immunology Annual Scientific Meeting in February.
- At the Fc Receptor and IgG Targeted Therapies Conference in April, Astria presented pharmacokinetic modeling data supporting that STAR-0215 can effectively inhibit plasma kallikrein and prevent HAE attacks with subcutaneous dosing volumes appropriate for a self-injectable device dosed once every three months or longer.

First Quarter 2022 Financial Results

Cash Position: As of March 31, 2022, Astria had cash, cash equivalents and short-term investments of $112.8 million, compared to $125.5 million as of December 31, 2021. The Company expects that it has sufficient cash to fund its current operating plan through 2023. Net cash used in operating activities for the three months ended March 31, 2022, was $12.6 million, compared to $8.7 million for the three months ended March 31, 2021.

R&D Expenses: Research and development expenses were $10.4 million for the three months ended March 31, 2022, compared to $2.6 million for the three months ended March 31, 2021.

G&A Expenses: General and administrative expenses were $5.0 million for the three months ended March 31, 2022, compared to $2.9 million for the three months ended March 31, 2021.

Operating Loss: Loss from operations was $15.4 million for the three months ended March 31, 2022, compared to $170.1 million for the three months ended March 31, 2021.

Acquired In-Process Research and Development (IPR&D) Expense: Acquired IPR&D expense was $164.6 million for the three months ended March 31, 2021. IPR&D expense resulted from the acquisition of Quellis Biosciences in January 2021. The acquisition cost allocated to acquired IPR&D with no alternative future use was recorded as expense at the acquisition date. No acquired IPR&D expenses were incurred in 2022.

Net Loss: Net loss was $15.3 million for the three months ended March 31, 2022, compared to a net loss of $170.1 million for the three months ended March 31, 2021.

Net Loss Per Share Basic and Diluted: Net loss per share basic and diluted was $1.18 for the three months ended March 31, 2022, compared to a net loss basic and diluted of $45.60 per share for the three months ended March 31, 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 preclinical 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; expectations regarding the timing for filing an IND for STAR-0215; the expected commencement and design of a Phase 1 clinical trial for STAR-0215 and the expected timing and nature of the interim results from such trial; the planned initiation of a Phase 1b/2 clinical trial of STAR-0215; the potential attributes and differentiated profile of STAR-0215 as a treatment for HAE, including those suggested by pharmacokinetic modeling data, and the potential commercial opportunity for STAR-0215 in HAE; 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 may not be replicated in clinical studies, 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 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 March 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 10,358	$ 2,593
General and administrative	5,020	2,880
Acquired in-process research and development	-	164,612
Total operating expenses	15,378	170,085
Loss from operations	(15,378)	(170,085)
Other income (expense):		
Interest and investment income	56	14
Other expense, net	(1)	(13)
Total other income, net	55	1
Net loss	(15,323)	(170,084)
Net loss per share - basic and diluted	$ (1.18)	$ (45.60)
Weighted-average common shares outstanding used in net loss per share - basic and diluted	13,016,955	3,730,029

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

	March 31, 2022	December 31, 2021
Assets		
Cash and cash equivalents	$ 46,687	$ 86,508
Short-term investments	66,129	39,000
Right-of-use asset	228	394
Other current and long-term assets	1,609	1,612
Total assets	114,653	127,514
Liabilities and stockholders' equity		
Current portion of operating lease liabilities	184	365
Long-term portion of operating lease liabilities	-	-
Other current and long-term liabilities	4,783	4,838
Total liabilities	4,967	5,203
Total stockholders' equity	$ 114,653	$ 127,514

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

	Three Months Ended March 31,	
	2022	2021
Net cash used in operating activities	$ (12,559)	$ (8,716)
Net cash (used in) provided by investing activities	(27,099)	26,445
Net cash provided by financing activities	-	104,261
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (39,658)	$ 121,990

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