Astria Therapeutics Reports Third Quarter 2021 Financial Results and Provides a Corporate Update

November 10, 2021

-- STAR-0215, in Development to Treat HAE, on Track for Initial Phase 1 Clinical Results Expected by Year End 2022 --

-- New Preclinical Data on STAR-0215 Demonstrating High Potency and Extended Plasma Half-Life --

-- Findings on Burdens of Disease and Treatment in HAE Support Substantial Need to Decrease Patient Burden --

BOSTON--(BUSINESS WIRE)--Nov. 10, 2021-- Astria Therapeutics, Inc. (NASDAQ:ATXS), a biopharmaceutical company developing STAR-0215 for the treatment of hereditary angioedema (HAE), today reported financial results for the third quarter ended September 30, 2021 and provided a corporate update.

"Our new company name, Astria, embodies our commitment to put patients first in all that we do. Astria originates from the Greek word for star, and patients are our guiding stars. Our goal is to develop the most patient-friendly preventative treatment option for HAE with dosing once every three months or longer," said Jill C. Milne, Ph.D., Chief Executive Officer of Astria Therapeutics. "With STAR-0215, we believe we can reduce treatment burden, and we are looking forward to advancing development of STAR-0215 through clinical proof of concept with initial results anticipated by year end 2022."

STAR-0215 (formerly QLS-215) 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.
- The Company presented new preclinical data at the American College of Allergy, Asthma and Immunology (ACAAI) Annual Scientific Meeting in November 2021 supporting STAR-0215's differentiated profile. STAR-0215 binds to plasma kallikrein *in vitro* with high affinity and inhibits its activity more potently than lanadelumab, a monoclonal antibody plasma kallikrein inhibitor. In addition, in competition binding experiments, STAR-0215 binds to a different site on plasma kallikrein than lanadelumab. YTE modifications in STAR-0215 are designed to enable a long duration of action. In non-human primates dosed with STAR-0215, the enhanced FcRn binding enabled by the YTE modifications translated to a more than three-fold increase in plasma half-life for STAR-0215 compared to an antibody without the YTE modifications. The plasma half-life in non-human primates was also more than three-fold longer than that of lanadelumab, supporting the potential for less frequent dosing.
- Astria is on track to file an Investigational New Drug application for STAR-0215 in mid-2022 and plans to initiate a Phase 1 clinical trial with initial results anticipated by year end 2022. Astria expects that the results of this trial, if positive, could provide clinical proof of concept for the activity and plasma half-life improvements for STAR-0215.
- The Company presented findings on the burdens of disease and treatment from interviews conducted with HAE patients at the 2021 National Organization for Rare Disorders (NORD) Rare Diseases and Orphan Products Breakthrough Summit in October 2021. These findings support that there is substantial need to address both HAE disease burden and treatment burden with effective preventative therapies that have less frequent dosing.

Corporate Highlights

- On September 8, 2021, the Company formally changed its name from Catabasis Pharmaceuticals to Astria Therapeutics. The name Astria originates from the Greek word for star, reflecting the Company's commitment to having patients serve as guiding stars, and showcasing the patient-focused mission to bring hope with life changing therapies to patients and families. Astria began trading under the ATXS ticker on the Nasdaq Global Market on September 9, 2021.

Capital Structure

- On August 19, 2021, Astria completed a 1-for-6 reverse stock split of its common stock. Split-adjusted common stock shares began trading on the Nasdaq Capital Market on August 20, 2021.
- As of September 30, 2021, there were 13,009,477 shares of common stock issued and outstanding. Additionally, there were 31,455 shares of Series X Preferred Stock outstanding, which are convertible into approximately 5.2 million shares of common stock on a post-split basis.

Third Quarter 2021 Financial Results

Cash Position: As of September 30, 2021, Astria had cash and cash equivalents of $131.8 million, compared to $139.5 million as of June 30, 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 September 30, 2021, was $7.7 million, compared to $9.9 million for the three months ended September 30, 2020.

R&D Expenses: Research and development expenses were $3.8 million for the three months ended September 30, 2021, compared to $7.8 million for the three months ended September 30, 2020.

G&A Expenses: General and administrative expenses were $4.1 million for the three months ended September 30, 2021, compared to $3.1 million for the three months ended September 30, 2020.

Operating Loss: Loss from operations was $7.9 million for the three months ended September 30, 2021, compared to $10.9 million for the three months ended September 30, 2020.

Net Loss: Net loss was $7.9 million for the three months ended September 30, 2021, compared to a net loss of $10.9 million for the three months ended September 30, 2020.

Net Loss Per Share Basic and Diluted: Net loss per share basic and diluted was $0.61 for the three months ended September 30, 2021, compared to a net loss basic and diluted of $3.36 per share for the three months ended September 30, 2020.

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 the filing of an IND and commencement of a Phase 1 clinical trial for STAR-0215, the timing of the initial results from such trial and that the results from such trial could provide clinical proof of concept for the activity and plasma half-life improvements for STAR-0215; the potential attributes and differentiated profile of STAR-0215 as a treatment for HAE, 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 the Company's ability to recognize the anticipated benefits of the Quellis acquisition; 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 risk that survey results and market research may not be accurate predictors of the commercial landscape for HAE and the anticipated position of STAR-0215 in HAE based on its pre-clinical profile; 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,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 3,788	$ 7,806	$ 9,859	$ 19,845

General and administrative	4,110	3,057	10,992	8,612
Acquired in-process research and development	-	-	164,617	-
Total operating expenses	7,898	10,863	185,468	28,457
Loss from operations	(7,898)	(10,863)	(185,468)	(28,457)
Other income (expense):				
Interest and investment income	35	4	89	231
Other expense, net	(8)	(3)	(42)	(96)
Total other income, net	27	1	47	135
Net loss	(7,871)	(10,862)	(185,421)	(28,322)
Dividend on convertible preferred stock related to beneficial conversion feature and issuance costs	-	-	(24,437)	-
Net loss attributable to common shareholders	$ (7,871)	$ (10,862)	$ (209,858)	$ (28,322)
Net loss per share - basic and diluted	$ (0.61)	$ (3.36)	$ (27.81)	$ (9.56)
Weighted-average common shares outstanding used in net loss per share - basic and diluted	12,830,782	3,237,477	7,546,969	2,961,623

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

	September 30, 2021	December 31, 2020
Assets		
Cash and cash equivalents	$ 131,777	$ 24,930
Short-term investments	-	20,000
Right-of-use asset	557	966
Other current and long-term assets	2,795	1,560
Total assets	135,129	47,456
Liabilities and stockholders' equity		
Current portion of operating lease liabilities	541	649
Long-term portion of operating lease liabilities	-	397
Other current and long-term liabilities	4,159	5,741
Total liabilities	4,700	6,787
Total stockholders' equity	$ 130,429	$ 40,669

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

	Nine Months Ended September 30,	
	2021	2020
Net cash used in operating activities	$ (23,865)	$ (24,424)
Net cash provided by investing activities	26,445	26,310
Net cash provided by financing activities	104,267	40,829
Net increase in cash, cash equivalents and restricted cash	$ 106,847	$ 42,715

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