Astria Therapeutics Reports Second Quarter 2024 Financial Results and Provides a Corporate Update

August 12, 2024

-- Navenibart (STAR-0215), the Potential Market-Leading Therapy for the Treatment of Hereditary Angioedema, on Track for Expected Phase 3 Initiation in Q1 2025 --

-- Preclinical Results Support STAR-0310 as a Potential Best-in-Class OX40 Inhibitor --

BOSTON--(BUSINESS WIRE)--Aug. 12, 2024-- Astria Therapeutics, Inc. (NASDAQ:ATXS), a biopharmaceutical company focused on developing life-changing therapies for allergic and immunological diseases, today reported financial results for the second quarter ended June 30, 2024, and provided a corporate update.

“As we prepare for Phase 3 with initiation expected in Q1 2025, our vision for navenibart is to be the market-leading treatment for HAE, a large and growing market. Based on its profile and the data to date, we believe that navenibart could be patients’ and physicians’ first choice treatment and change the way that people live with their HAE,” said Jill C. Milne, Ph.D., Chief Executive Officer at Astria Therapeutics. “We also presented preclinical data on STAR-0310 that supports our vision for the program to be a best-in-class OX40 antagonist for the treatment of AD and potentially other diseases. We believe that we are in a strong position to become a leading allergy and immunology company that aims to change the way that patients live with their disease.”

Navenibart (STAR-0215)

- The World Health Organization’s (WHO) International Nonproprietary Names (INN) Expert Committee and the United States Adopted Names (USAN) Council of the American Medical Association (AMA) have adopted navenibart (nah-VEN-eh-bart) as the nonproprietary name for STAR-0215. Based on the WHO monoclonal antibody (mAb) nomenclature scheme which took effect in November 2021, the infix “-eni-” represents enzyme inhibitor and the suffix “-bart” represents a monoclonal antibody. The prefix “nav” represents Astria’s commitment to navigate the development navenibart with patients guiding the journey.
- In March, the Company shared positive initial proof-of-concept results from the ALPHA-STAR Phase 1b/2 trial of navenibart in people with hereditary angioedema (HAE). Navenibart administered once or twice over six months reduced monthly attack rates by 90-96% and supports chronic dosing two or four times per year. Additionally, navenibart was well-tolerated with no serious adverse events and no discontinuations. The Company plans to report additional data from ALPHA-STAR in Q4 of 2024.
- All of the original 16 target enrollment patients from ALPHA-STAR have entered or consented to enter the ALPHA-SOLAR long-term open-label trial. Initial safety and efficacy data from ALPHA-SOLAR, including from Q3M and Q6M administration, are expected mid-2025.
- Based on the positive results from the ALPHA-STAR trial, Astria plans to advance navenibart to Phase 3 development. Pending regulatory feedback, the Company plans to initiate the Phase 3 program in Q1 2025 and expects top-line results by year-end 2026. The goal is to enable patients to choose what works best for them by developing both Q3M and Q6M dosing options. The company believes navenibart will be life-changing for HAE patients and has the opportunity to become the market leading HAE treatment.
- The company recently announced that it has chosen Ypsomed as its partner for the development of an autoinjector for navenibart. Astria believes that the YpsoMate autoinjector option is a great choice for navenibart due to its ease of use, needle shielding feature, and navenibart's proprietary formulation that enables a quick injection with low risk of pain.

STAR-0310

- Astria is developing STAR-0310, a high affinity monoclonal antibody OX40 antagonist that incorporates YTE technology, for the treatment of atopic dermatitis (AD). Preclinical results support the potential for STAR-0310 to have the best-in-class OX40 inhibitor profile.
- The Company presented preclinical information on STAR-0310 at the European Academy of Allergy and Clinical Immunology (EAACI) conference in Valencia, Spain. STAR-0310 exhibits a long mean half-life of 26 days in cynomolgus monkeys, compared to 10-14 days in a typical non-half-life extended IgG1 antibody and supports the extended half-life of STAR-0310.
- There was also an approximately 8-fold increase in binding affinity to human OX40 observed for STAR-0310 compared to telazorlimab, and STAR-0310 was seen to have comparable potency to rocatinlimab. Additionally, there is significantly less antibody-dependent cellular cytotoxicity (ADCC) with STAR-0310 compared to rocatinlimab. Less ADCC has the potential for a favorable safety profile for STAR-0310.

- Astria plans to submit an Investigational New Drug (IND) application for STAR-0310 by year-end 2024 and plans to initiate a Phase 1a clinical trial in healthy subjects in the first quarter of 2025, with initial results from the trial expected in the third quarter of 2025.

Second Quarter 2024 Financial Results

Cash Position: As of June 30, 2024, Astria had cash, cash equivalents and short-term investments of $354.7 million, compared to $246.5 million as of December 31, 2023. The Company expects that its cash, cash equivalents and short-term investments as of June 30, 2024 will be sufficient to fund its operations into mid-2027, including all navenibart program activities through the completion of a planned Phase 3 pivotal trial as well as advancing the STAR-0310 OX40 program through submission of an IND and early proof-of-concept results from a Phase 1a clinical trial. Net cash used in operating activities for the three months ended June 30, 2024 was $16.8 million, compared to $10.7 million for the three months ended June 30, 2023.

R&D Expenses: Research and development expenses were $20.7 million for the three months ended June 30, 2024, compared to $9.1 million for the three months ended June 30, 2023. The increase in research and development expenses was primarily associated with the STAR-0310 program's manufacturing and IND-enabling activities in addition to external research and development costs associated with the navenibart program's advancement in multi-site international clinical trials.

G&A Expenses: General and administrative expenses were $8.1 million for the three months ended June 30, 2024, compared to $6.0 million for the three months ended June 30, 2023. The increase in general and administrative expenses was primarily attributable to stock-based compensation and company growth to support the advancement of our programs.

Operating Loss: Loss from operations was $28.8 million for the three months ended June 30, 2024, compared to $15.1 million for the three months ended June 30, 2023.

Net Loss: Net loss was $24.2 million for the three months ended June 30, 2024, compared to a net loss of $12.6 million for the three months ended June 30, 2023.

Net Loss Per Share Basic and Diluted: Net loss per share basic and diluted was $0.43 for the three months ended June 30, 2024, compared to a net loss basic and diluted of $0.45 per share for the three months ended June 30, 2023.

About Astria Therapeutics:

Astria Therapeutics is a biopharmaceutical company, and our mission is to bring life-changing therapies to patients and families affected by allergic and immunological diseases. Our lead program, navenibart (STAR-0215), is a monoclonal antibody inhibitor of plasma kallikrein in clinical development for the treatment of hereditary angioedema. Our second program, STAR-0310, is a monoclonal antibody OX40 antagonist in preclinical development for the treatment of atopic dermatitis. Learn more about our company on our website, www.astriatx.com, or follow us on X 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: our expectations about the potential significance of the initial results from the Phase 1b/2 ALPHA-STAR clinical trial of navenibart, and that the results from such trial will allow us to advance navenibart into Phase 3 development as a potential treatment for HAE; the expected timing of the release of additional data from the ALPHA-STAR trial; the expected timing of initiation and receipt of topline results from the planned navenibart Phase 3 program; the expected timing of release of initial safety and efficacy data from the ALPHA-SOLAR trial; our goal of developing two dosing options for navenibart; the potential for navenibart in the HAE market, including to potential to be the market leader, the first choice therapy, and to have the best-in-class profile in HAE, the potential therapeutic benefits of navenibart as a treatment for HAE and our vision and goals for the program; our belief that the YpsoMate autoinjector option is a great choice for navenibart, along with the reasons therefore; the potential for STAR-0310 to have the best-in-class OX40 inhibitor profile for the treatment of AD and other diseases, and the potential therapeutic benefits and potential attributes of STAR-0310 as a treatment for AD; expectations regarding the timing of regulatory filings for STAR-0310; expectations regarding the timing of initiation and planned design of clinical trials for STAR-0310; expectations regarding the timing and nature of anticipated data for planned trials of STAR-0310; our goals and vision for STAR-0310, including its potential development for additional indications; anticipated cash runway; and the goal of bringing life changing therapies to patients and families affected by allergic and immunological diseases and to become a leading allergy and immunology company. 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," "would," or "vision," 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 Astria'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 Astria'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 the following 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; 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 preclinical studies, including of navenibart and STAR-0310, may not be replicated in clinical trials, that the preliminary or interim results from clinical trials may not be indicative of the final results, that the results of early stage clinical trials, such as the results from the navenibart Phase 1a clinical trial and the initial results from the ALPHA-STAR trial, may not be replicated in later stage clinical trials, including additional and final results from the ALPHA-STAR trial or the planned navenibart Phase 3 development program, 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 navenibart, STAR-0310, and any other future development candidates, and devices for such product candidates; our ability to manufacture sufficient quantities of drug substance and drug product for navenibart, STAR-0310, and any other future product candidates, and devices for such product candidates, on a cost-effective and timely basis, and to develop dosages and formulation for navenibart, STAR-0310, 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 navenibart, STAR-0310, and any other future product candidates; our potential dependence on collaboration partners; competition with respect to navenibart, STAR-0310, or any of

our other future product candidates; the risk that survey results and market research may not be accurate predictors of the commercial landscape for HAE, the ability of navenibart to compete in HAE and the anticipated position and attributes of navenibart in HAE based on clinical data to date, its preclinical profile, pharmacokinetic modeling, market research and other data; risks with respect to the ability of STAR-0310 to compete in AD and the anticipated position and attributes of STAR-0310 in AD based on its preclinical profile; 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, 2023 and in other filings that we may make with the Securities and Exchange Commission.

New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Astria 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 Astria's forward-looking statements. Neither Astria, 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 Astria'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,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 20,709	$ 9,089	$ 36,435	$ 17,122
General and administrative	8,094	6,013	16,518	11,473
Total operating expenses	28,803	15,102	52,953	28,595
Loss from operations	(28,803)	(15,102)	(52,953)	(28,595)
Other income (expense):				
Interest and investment income	4,647	2,556	8,888	4,877
Other expense, net	(16)	(20)	(35)	(36)
Total other income, net	4,631	2,536	8,853	4,841
Net loss	(24,172)	(12,566)	(44,100)	(23,754)
Net loss per share attributable to common shareholders - basic and diluted	$ (0.43)	$ (0.45)	$ (0.81)	$ (0.85)
Weighted-average common shares outstanding used in net loss per share - basic and diluted	56,485,962	28,022,306	54,390,364	27,983,597

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

	June 30, 2024	December 31, 2023
Assets		
Cash and cash equivalents	$ 87,212	$ 175,530
Short-term investments	267,491	71,000
Right-of-use asset	5,715	363
Other current and long-term assets	7,571	7,773
Total assets	367,989	254,666
Liabilities and stockholders' equity		
Current portion of operating lease liabilities	1,245	329
Long term portion of operating lease liabilities	4,544	-
Other current and long-term liabilities	15,123	11,221
Total liabilities	20,912	11,550
Total stockholders' equity	$ 347,077	$ 243,116

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

	Six Months Ended June 30,	
	2024	**2023**
Net cash used in operating activities	$ (35,885)	$ (23,949)
Net cash (used in) provided by investing activities	(194,334)	137,072
Net cash provided by financing activities	141,901	310
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (88,318)	$ 113,433

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