# Astria Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Provides a Corporate Update

March 22, 2023

*-- ALPHA-STAR Phase 1b/2 Trial in People with HAE Underway with Initial Proof-of-Concept Results Anticipated Mid-2024 --*

*-- Phase 1a Results Support STAR-0215's Target Profile as a Long-Acting Plasma Kallikrein Inhibitor with Estimated Half-Life of up to 117 Days --*

*-- Ended 4Q 2022 with Cash, Cash Equivalents, and Short-term Investments of $226M, Expected Cash Runway Through H1 2025 --*

*-- Webcast Today at 8:30am ET --*

BOSTON--(BUSINESS WIRE)--Mar. 22, 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 fourth quarter and full year ended December 31, 2022 and provided a corporate update.

"We made excellent progress with our STAR-0215 program in 2022, culminating in the promising initial Phase 1a results. These results support our vision for STAR-0215 to be the first-choice preventative therapy for HAE," said Jill C. Milne, Ph.D., Chief Executive Officer of Astria. "The recent initiation of our ALPHA-STAR Phase 1b/2 trial marked an important step towards our goal of reducing the disease and treatment burden as we work to normalize the lives of people with HAE. We look forward to the initial proof-of-concept results from ALPHA-STAR expected in mid-2024."

**STAR-0215 Clinical Development**

- Positive preliminary results from the Phase 1a clinical trial of STAR-0215 in healthy subjects were announced in December 2022 and initial unblinded results from the first three cohorts were presented at the American Academy of Allergy Asthma, and Immunology Annual Meeting (AAAAI) in February 2023. STAR-0215 was well-tolerated at all doses studied. The results showed rapid and sustained drug levels, with an estimated half-life of up to 117 days and sustained target engagement with plasma kallikrein inhibition for at least three months. These results establish early proof of concept for STAR-0215 as a long-acting preventative therapy for HAE.
- The Company initiated the ALPHA-STAR Phase 1b/2 trial of STAR-0215 in people with HAE in February 2023. Initial proof-of-concept results are expected in mid-2024. The ALPHA-STAR trial is a global, open-label, proof-of-concept trial enrolling patients with HAE types I and II that is evaluating safety and tolerability, changes in HAE attack rate, pharmacokinetics, pharmacodynamics, and quality-of-life assessments. Following an initial run-in period, qualifying participants will be enrolled in either single or multiple dose cohorts. Data from up to 18 participants will evaluate efficacy and safety, and comparisons will be made against data collected in the run-in period. Pending proof-of-concept results from the ALPHA-STAR trial, Astria expects to progress directly to a pivotal trial.
- Astria is also evaluating the potential for administration of STAR-0215 every six months in additional cohorts in the Phase 1a trial, with preliminary results expected in the fourth quarter of 2023. These data, in conjunction with the ALPHA-STAR results, are expected to inform plans for the pivotal trial.

**Webcast Information**

- The Company will host a webcast today at 8:30am ET. Interested parties may join the webcast via the Investors section of the Astria website, www.astriatx.com or with following the link https://lifescievents.com/event/astria-therapeutics-event/. The webcast will be archived for 90 days.

**Fourth Quarter and Full Year 2022 Financial Results**

**Cash Position:** In December 2022, Astria closed a $115.0 million underwritten offering of common stock. As of December 31, 2022, Astria had cash, cash equivalents, and short-term investments of $226.4 million, compared to $116.6 million as of September 30, 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 December 31, 2022, was $10.7 million, compared to $6.3 million for the three months ended December 31, 2021. Net cash used in operating activities for the full year 2022 was $43.5 million, compared to $30.2 million for the full year 2021.

**R&D Expenses:** Research and development expenses were $9.6 million for the three months ended December 31, 2022, compared to $5.7 million for the three months ended December 31, 2021, and $34.3 million for the full year 2022, compared to $15.6 million for the full year 2021. The increase in research and development expenses was associated with STAR-0215's advancement through IND-enabling activities into clinical trials.

**G&A Expenses:** General and administrative expenses were $4.7 million for the three months ended December 31, 2022, compared to $3.8 million for the three months ended December 31, 2021, and $19.2 million for the full year 2022, compared to $14.8 million for the full year 2021.

**Operating Loss:** Loss from operations was $14.3 million for the three months ended December 31, 2022, compared to $9.5 million for the three

months ended December 31, 2021, and $53.5 million for the full year 2022, compared to $195.0 million for the full year 2021. The year-over-year decrease in net loss was largely attributable to the $164.6 million in acquired in-process R&D expense associated with acquiring Quellis Biosciences in 2021.

**Net Loss:** Net loss was $13.3 million for the three months ended December 31, 2022, compared to a net loss of $9.5 million for the three months ended December 31, 2021, and $51.8 million, or $3.55 per share for the full year 2022, compared to $194.9 million, or $21.84 per share, for the full year 2021.

**Net Loss Per Share Basic and Diluted:** Net loss per share basic and diluted was $0.72 for the three months ended December 31, 2022, compared to a net loss basic and diluted of $0.73 per share for the three months ended December 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 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 preliminary results from the Phase 1a STAR-0215 trial and the anticipated nature and timing of receipt of the data from the two additional cohorts in such trial; expectations regarding the timing and nature of the anticipated proof of concept results from the ALPHA-STAR Phase 1b/2 clinical trial of STAR-0215; the longer term development plans for STAR-0215, including the plan, assuming positive results, to move directly from the ALPHA-STAR trial into a pivotal trial; the potential attributes and differentiated profile of STAR-0215 as a treatment for HAE, including those suggested by the preliminary and initial results from the STAR-0215 Phase 1a trial and market research, and our goals and vision for STAR-0215; the potential commercial opportunity for STAR-0215 in HAE and the likelihood that it can effectively compete in HAE, assuming its approved; the need for effective treatments for HAE; the potential for six-month dosing of STAR-0215; the Company's anticipated cash runway; and the Company's 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 preliminary results from the Phase 1a trial may not be indicative of the final results, that the results of early stage clinical studies, such as the preliminary results from the Phase 1a trial, may not be replicated in 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 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, pharmacokinetic modeling, market research 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, 2021 and in other filings that we make with the Securities and Exchange Commission ("SEC"), including our Current Report on Form 8-K filed on December 15, 2022. 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)
*(Audited)*

| | Three Months Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Operating expenses: | | | | |
| Research and development | $ 9,591 | $ 5,693 | $ 34,264 | $ 15,552 |
| General and administrative | 4,699 | 3,816 | 19,239 | 14,807 |
| Acquired in-process research and development | - | - | - | 164,617 |
| Total operating expenses | 14,290 | 9,509 | 53,503 | 194,976 |
| Loss from operations | (14,290) | (9,509) | (53,503) | (194,976) |
| Other income (expense): | | | | |
| Interest and investment income | 1,018 | 32 | 1,724 | 122 |
| Other expense, net | 9 | (16) | (55) | (58) |
| Total other income, net | 1,027 | 16 | 1,669 | 64 |
| Net loss | (13,263) | (9,493) | (51,834) | (194,912) |
| Dividend on convertible preferred stock related to beneficial conversion feature and issuance costs | - | - | - | (24,437) |
| Net loss attributable to common shareholders | $ (13,263) | $ (9,493) | $ (51,834) | $ (219,349) |
| Net loss per share attributable to common shareholders - basic and diluted | $ (0.72) | $ (0.74) | $ (3.55) | $ (24.58) |
| Weighted-average common shares outstanding used in net loss per share - basic and diluted | 18,417,203 | 12,830,782 | 14,620,618 | 8,925,173 |

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

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| **Assets** | | |
| Cash and cash equivalents | $ 20,525 | $ 86,508 |
| Short-term investments | 205,912 | 39,000 |
| Right-of-use asset | 948 | 394 |
| Other current and long-term assets | 3,248 | 1,612 |
| Total assets | 230,633 | 127,514 |
| **Liabilities and stockholders' equity** | | |
| Current portion of operating lease liabilities | 582 | 365 |
| Long-term portion of operating lease liabilities | 357 | - |
| Other current and long-term liabilities | 8,478 | 4,838 |
| Total liabilities | 9,417 | 5,203 |
| Total stockholders' equity | $ 221,216 | $ 122,311 |

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

| | Year Ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Net cash used in operating activities | $ (43,533) | $ (30,151) |
| Net cash used in by investing activities | (167,129) | (12,555) |
| Net cash provided by financing activities | 144,721 | 104,284 |
| Net (decrease) increase in cash, cash equivalents and restricted cash | $ (65,941) | $ 61,578 |

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Source: Astria Therapeutics, Inc.