UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 5, 2023

Astria Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	001-37467	26-3687168
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

75 State Street, Suite 1400 Boston, Massachusetts	02109
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (617) 349-1971

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	ATXS	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition

On January 5, 2023, Astria Therapeutics, Inc. (the "Company") is making publicly available on its website a corporate presentation (the "Corporate Presentation"). A copy of the Corporate Presentation is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

As disclosed in the Corporate Presentation, although it has not finalized its full financial results for the fourth quarter and fiscal year ended December 31, 2022, on a preliminary and unaudited basis, the Company had approximately $226 million of cash, cash equivalents and short-term investments as of December 31, 2022 (the "Financial Information"), which, based on the Company's current operating plan is estimated to enable the Company to fund its operating expenses and capital expenditure requirements through the first half of 2025.

The Financial Information contained in this Item 2.02 of this Current Report on Form 8-K is unaudited and preliminary, subject to the completion of the Company's financial closing procedures, and does not present all information necessary for an understanding of the Company's financial condition as of December 31, 2022, and its results of operations for the three months and year ended December 31, 2022. The audit of the Company's consolidated financial statements for the year ended December 31, 2022, is ongoing and could result in changes to the Financial Information. In addition, the Company has based its estimate regarding its cash runway on assumptions that may prove to be wrong, and the Company could use its available capital resources sooner than it currently expects.

The information in this Item 2.02 of this Current Report on Form 8-K, including the Corporate Presentation, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 7.01. Regulation FD Disclosure

On January 5, 2023, the Company is making publicly available on its website the Corporate Presentation. A copy of the Corporate Presentation is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 of this Current Report on Form 8-K, including the Corporate Presentation, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events

As disclosed in the Corporate Presentation, there were 27,501,340 shares of the Company's common stock issued and outstanding as of December 30, 2022, reflecting the issuance of shares of common stock pursuant to the previously announced underwritten offering in December 2022, including the exercise of the option granted by the Company to the underwriters to purchase additional shares of common stock.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1	Copy of the Company's corporate presentation (furnished herewith)
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Forward Looking Statements

Any statements in this Current Report on Form 8-K about future expectations, plans and prospects for the Company, including statements about the Company's estimated cash, cash equivalents and short-term investments as of December 31, 2022, and anticipated cash runway, among other things, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The words "aims," "anticipate," "believe," "estimate," "expect," "may," "could," and other words and terms of similar meaning are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. You should not place undue reliance on these statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: risks and uncertainties inherent in the initiation and completion of preclinical studies and clinical trials and clinical development of the Company's product candidates; whether interim results from a clinical trial will be predictive of the final results of the trial or the results of future trials; expectations for regulatory approvals to conduct trials or to market products; potential changes in estimated cash, cash equivalents and marketable securities based on the completion of financial closing procedures and release of complete fiscal 2022 results; availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; other matters that could affect the availability or commercial potential of the Company's product candidates; and other factors discussed in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the U.S. Securities and Exchange Commission ("SEC"), and in other filings that the Company may make with the SEC in the future. In addition, the forward-looking statements included in this Current Report on Form 8-K represent the Company's views as of the date hereof and should not be relied upon as representing the Company's views as of any date subsequent to the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ASTRIA THERAPEUTICS, INC.

Date: January 5, 2023

By: /s/ Ben Harshbarger
Ben Harshbarger
Chief Legal Officer

Exhibit 99.1

Corporate Presentation

January 2023

Forward Looking Statements

This presentation and various remarks we make during this presentation contain forward-looking statements of Astria Therapeutics, Inc. ("Astria," the "Company," "we", "our" or "us") within the meaning of applicable securities laws and regulations, including statements with respect to: the Company's projected cash runway and cash, cash equivalents and short-term investments as of 12/30/2022; expectations regarding the nature, timing and potential significance of the preliminary results from the Phase 1a STAR-0215 trial, the plans to add additional cohorts to the trial and the anticipated nature and timing of receipt of the data from such additional cohorts; expectations regarding the timing of initiation, design and timing and nature of the anticipated proof of concept results from the planned Phase 1b/2 clinical trial of STAR-0215; the longer term development plans for STAR-0215; the potential attributes and differentiated profile of STAR-0215 as a treatment for HAE, including its potential best-in-class pharmacokinetic profile, potential dosing frequency, clinical benefit and those suggested by the preliminary results from the STAR-0215 Phase 1a trial, preclinical and pharmacokinetic modeling data; the potential commercial opportunity for STAR-0215 in HAE, including its potential to be a best-in-class and most patient friendly treatment option for HAE; the need for effective treatments for HAE; the size and anticipated growth of the HAE market; the expected patent protection of patents directed at STAR-0215; potential every six-month dosing for STAR-0215; and the Company's goal to meet the unmet needs of patients with rare and niche allergic and immunological diseases, and expand its pipeline. We use words such as "aims," "anticipate," "believe," "estimate," "expect," "goals," "hope," "intend," "may," "opportunity," "plan," "predict," "project," "target," "potential," "would," "vision," "can," "could," "should," "continue," and other words and terms of similar meaning to help identify forward-looking statements, although not all forward-looking statements contain these identifying words. 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 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 be change once the final results are received and analyzed, that the results of early stage clinical studies may not be replicated in later stage clinical studies, 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. FDA ("FDA") 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 and the anticipated position and attributes of STAR-0215 in HAE based on its clinical data to date, pre-clinical profile, pharmacokinetic modeling 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 risk that our final audited cash, cash equivalents and short-term investments as of 12/30/2022 may differ materially from the preliminary and unaudited amount reported in this presentation; 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 may make with the Securities and Exchange Commission ("SEC"). These forward-looking statements should not be relied upon as representing our view as of any date subsequent to the date of this presentation, and we expressly disclaim any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

This presentation contains estimates and other statistical data made by independent parties and by us relating to market size and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data and estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

Investment Highlights

Astria (Nasdaq: ATXS) is developing differentiated therapeutics for patients with rare and niche allergic and immunological diseases

Our lead program, **STAR-0215**, is a monoclonal antibody inhibitor of plasma kallikrein for the preventative treatment of Hereditary Angioedema (HAE)

- STAR-0215 has shown early proof of concept for its target profile: long-acting preventative therapy, best-in-class PK profile, and dosing once every 3 months or less frequently
- HAE market is large and growing, expected to reach $4.5B by 2027[1,2]

Initiating Phase1b/2 ALPHA-STAR trial in HAE patients, expected in Q1 2023 with initial proof of concept results expected by mid-2024

Pursuing opportunities to expand our pipeline in allergic and immunological diseases

Cash, cash equivalents and short-term investments of $226M[3]
Expected cash runway through H1 2025 based on current operating plan

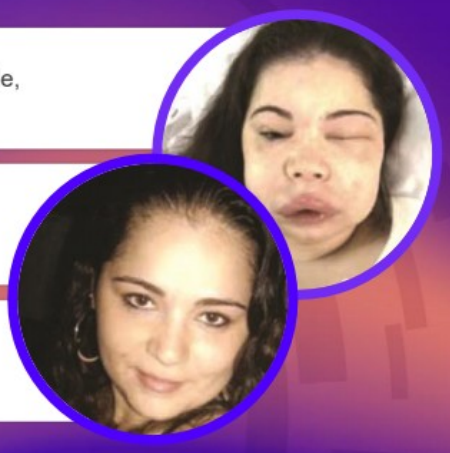
1. Analyst consensus forecasts compiled by Clarivate's Cortellis, Astria company research and analysis
2. Company-reported sales (Takeda, CSL Behring, Pharming, BioCryst)
3. As of 12/31/2022, unaudited and preliminary

Hereditary Angioedema (HAE): A Rare, Disfiguring, and Potentially Life-Threatening Disease

Rare genetic disorder charactered by severe, unpredictable, sometimes **life-threatening** swelling[1]

Affects **<8,000 in the U.S. and <15,000 in Europe,**[2, 3, 4] average age of onset is 11 years old[5]

Standard of care has evolved to both **on-demand** and **preventative treatments** with room for improvement

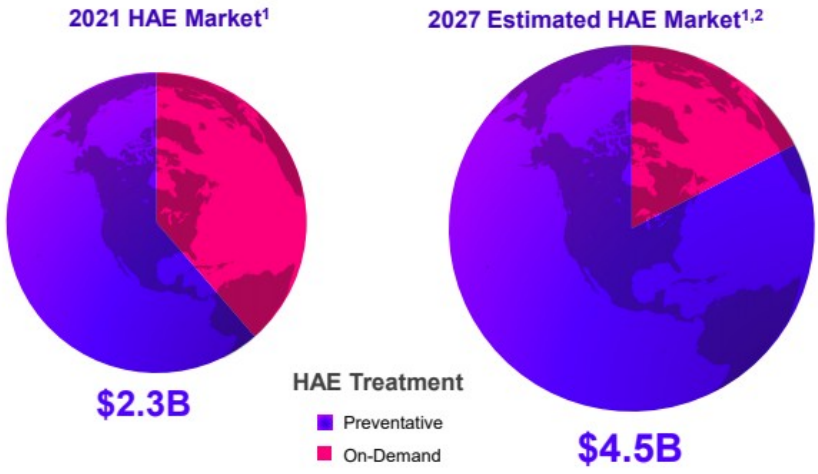


1. Zuraw BL. N Engl J Med. 2008;359:1027-36.
2. Busse, P.J. et al. N Engl J Med. 2021; 132-150.
3. Lumry, W.R. Front Med. 2018; 5, 22.
4. Aygören-Pürsün, E. et.al. Orphanet j Rare Dis. 2018; 13:73.
5. Bork K, et al. Am J Med. 2006;119:267-274.
6. Images obtained by haeimages.com

Global HAE Treatment Market is Substantial and Growing

The HAE market is expected to nearly double by 2027[1,2], driven by:

- Patients being diagnosed earlier[3]
- More patients taking preventative treatments[4]
- Geographic expansion for currently available therapies[5]



1. Company-reported sales (Takeda, CSL Behring, Pharming, BioCryst)
2. Analyst consensus forecasts compiled by Clarivate's Cortellis, Astria company research and analysis.
3. Zanichelli A. Clin Transl Allergy. 2018: doi: 10.1186/s13601-018-0229-4
4. Astria company research and analysis
5. Company-reported expectations (Takeda, CSL Behring, BioCryst)

Approved and Late-Stage Preventative HAE Treatments

Approved Therapies

Product	Mechanism of Action	Administration	Mean Attack Reduction*	% of Attack- Free Patients
CINRYZE	Plasma derived C1-INH	2x/week	52%	18% (12 weeks)[1]
HAEGARDA	Plasma derived C1-INH	2x/week	88%	40% (16 weeks)[2]
TAKHZYRO *(lanadelumab)*	Plasma kallikrein inhibitor	1-2x/month	73-87%	31-44% (26 weeks)[3]
ORLADEYO *(berotralstat)*	Plasma kallikrein inhibitor	1x/day	30-44%	2-8% (24 weeks)[4]

Late-Stage Development Programs

Program	Mechanism of Action	Administration	Development Phase	Efficacy
garadacimab	Factor XIIa inhibitor	1x/month	3	TBD[5]
donidalorsen	Prekallikrein inhibitor	1x/1-2 months	3	TBD[6]

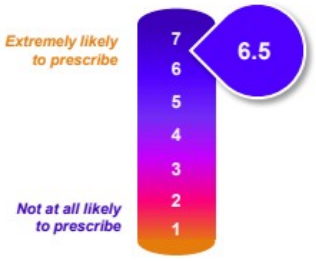
There remains a need for an effective, infrequent treatment that can help normalize the lives of people with HAE

*Efficacy quoted as reduction in mean attack rate vs placebo; data from respective products' Prescribing Information[1,3,3,7].

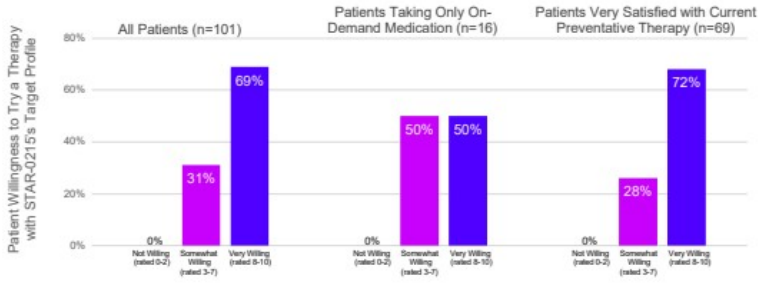
1. CINRYZE Prescribing Information, 2021.
2. HAEGARDA Prescribing Information, 2020.
3. TAKHZYRO Prescribing Information, 2018.
4. Center for Drug Evaluation and Research. NDA/BLA Multidisciplinary Review and Evaluation NDA 214094. Washington DC: CDER (US); 2020.
5. CSL Behring, 2022 Aug 17, Press release. https://www.cslbehring.com/newsroom/2022/positive-top-line-phase-3-results-for-garadacimab
6. IONIS 2021 Nov 18, Press Release. https://ir.ionispharma.com/news-releases/news-release-details/ionis-initiates-phase-3-clinical-program-donidalorsen-patients
7. ORLADEYO Prescribing Information 2020.

STAR-0215's Target Efficacy and Dosing is Compelling to Surveyed HAE Treatment Providers and Patients

Surveyed Prescribers Were Highly Motivated to Prescribe a Product with STAR-0215's Target Profile[1]



All Surveyed Patients Were Willing to Try a Product with STAR-0215's Target Profile[2]



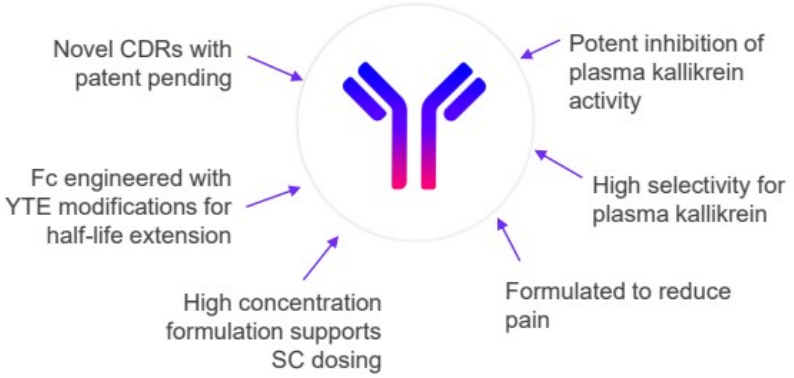
Willingness rated on a scale where "0" indicates "Not at all willing," and "10" indicates "Extremely willing." Satisfaction with current treatment rated on a scale where "0" indicates "Not at all satisfied," and "10" indicates "Extremely satisfied." Ratings of 8-10 grouped as "Very Satisfied."

Survey respondents were shown a blinded product profile that included: a monoclonal antibody inhibitor of plasma kallikrein that helps prevent HAE attacks by suppressing the pathway that generates bradykinin and causes excessive swelling, efficacy on par with current subcutaneous therapies, dosing once every 3 months or longer

1. Astria proprietary blinded qualitative market research study (2021) with 20 HAE treatment providers (screened for those treating at least 5 Type 1 & 2 HAE patients per year). 2. Astria proprietary blinded quantitative market research study (2022) with 101 HAE patients recruited by HAEA patient organization. Patients were screened for those currently taking preventative HAE therapy or having at least 1 attack every 3 months.

STAR-0215
Potential for Best-in-Class Profile in HAE

Preclinical Profile of STAR-0215



Encouraging preliminary clinical results
Demonstrated high potency for plasma kallikrein and long plasma half-life

Differentiated profile
Potential benefits include long duration without breakthrough attacks and infrequent SC dosing- once every 3 months or longer

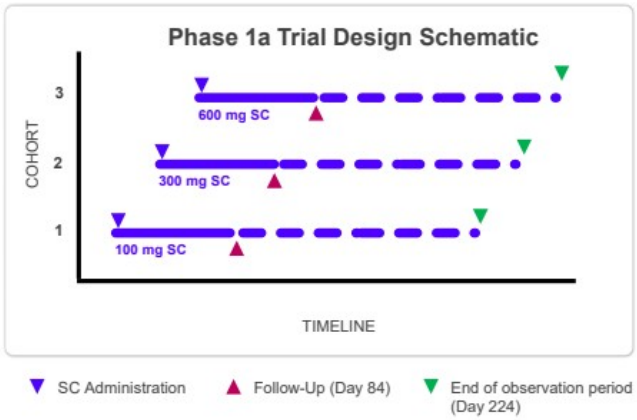
Trusted modality
To provide patients with improved quality of life

Astria wholly owns an international patent application directed to STAR-0215. If nationalized in the U.S. and granted, the patent would expire in 2042, excluding any potential patent term extension[1]

1. If this application is nationalized in PCT member states ex-U.S., the term of any resulting patents would also be to 2042, exclusive of any available term extensions.

STAR-0215 Phase 1a Trial

- **Randomized, double-blind[1], placebo-controlled**
  - Healthy adult subjects
  - 3 single ascending doses, delivered SC
  - 6 active to 2 placebo randomization
- **Preliminary data include safety (84 days for 3 cohorts), PK and PD (84 days for cohorts 1 and 2; 56 days for cohort 3)**



Preliminary, blinded data, cut-off Dec 5, 2022

1. As of this data cut-off, treatment assignments remain blinded. Presented PK, PD, and safety data are delinked from individual subject identifier.

SC = subcutaneous; PK = pharmacokinetic; PD = pharmacodynamic

Results Suggest that STAR-0215 is Well-Tolerated and has a Favorable Safety Profile

3-Month Timepoint Blinded Adverse Event Results

STAR-0215[1]:

- 8 (32%) subjects (STAR-0215 or placebo) had related TEAEs
- No SAEs and all related TEAEs were mild (Grade 1) and resolved. No Grade 2, 3, or 4 TEAEs.
- 6 subjects had ISRs (all mild), most commonly site redness; no reports of pain

Lanadelumab[2]:

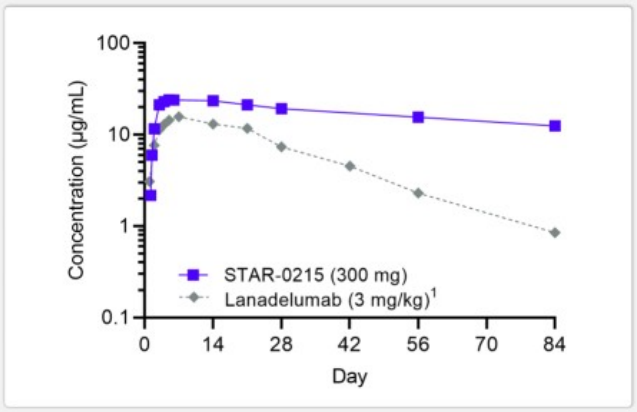
The most common adverse reactions associated with lanadelumab are:

- Injection site reactions, most commonly pain (52%)
- Upper respiratory tract infection (29%)
- Headache (21%)

TEAE= Treatment-emergent adverse event; ISR = injection site reaction; SAE = serious adverse events

1. Other related TEAEs were headache (1 subject) and unexplained weight gain (1 subject), both in Cohort 1 (100 mg). There were no clinically relevant changes in vital signs, ECG parameters, or laboratory values.
15 Grade 1 (mild) ISRs occurred in 6 subjects, including erythema (site redness), pruritus, swelling and inflammation.
No clinically relevant changes in liver enzymes or coagulation parameters. No deaths, or adverse events leading to study discontinuation.
Results will be finalized after the end of the observation period
2. TAKHZYRO US Prescribing Information, Feb 2022.
The comparison presented between STAR-0215 and lanadelumab represents a cross-trial comparison and does not involve data from a head-to-head clinical trial

Results Show STAR-0215 has a Potential Best-In-Class PK Profile



STAR-0215:

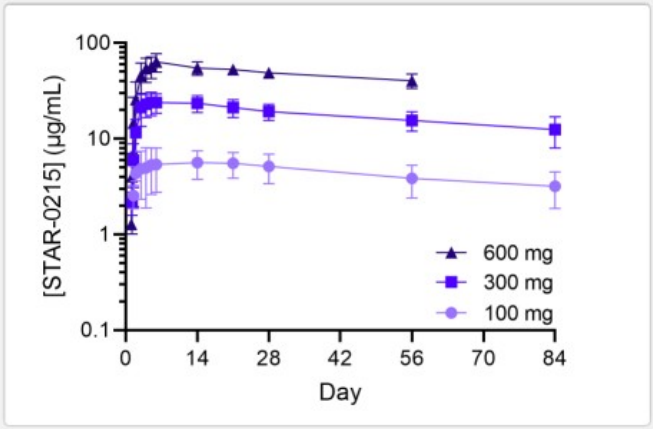
- **Estimated half-life is up to 110 days, >5 times longer than lanadelumab**
- **Rapid achievement of maximum concentration**
- **Sustained concentrations at levels consistent with clinical benefit**

Results will be finalized after the end of the observation period

1. Chyung et al 2014. Weight (SD) in this dose cohort = 83.08 (9.459) kg. Mean dose is 249.2 mg SC.

The comparison presented between STAR-0215 and lanadelumab represents a cross-trial comparison and does not involve data from a head-to-head clinical trial.

Results Show Rapid and Sustained STAR-0215 Concentrations After Single Subcutaneous Doses

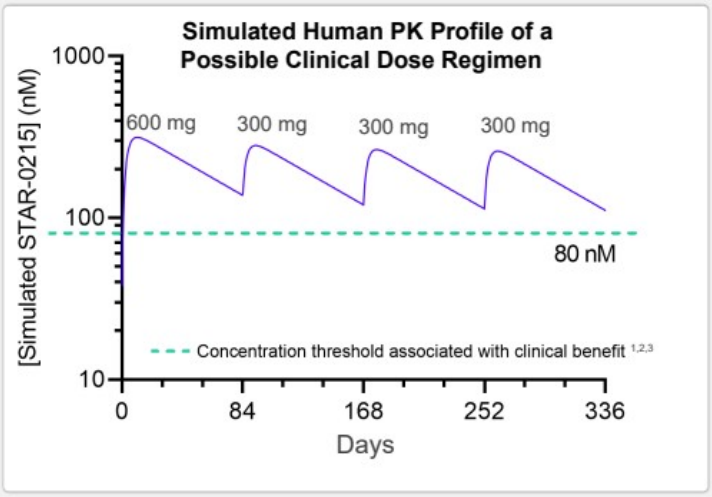


STAR-0215:

- **Concentrations are proportional to dose**
- **Long elimination phase consistent with YTE-modification**
- **Estimated half-life of up to 110 days**

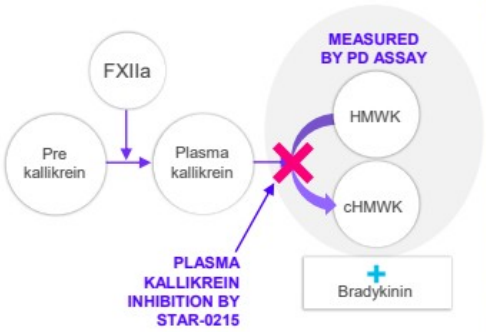
Mean (SD) concentrations over time
Results will be finalized after the end of the observation period

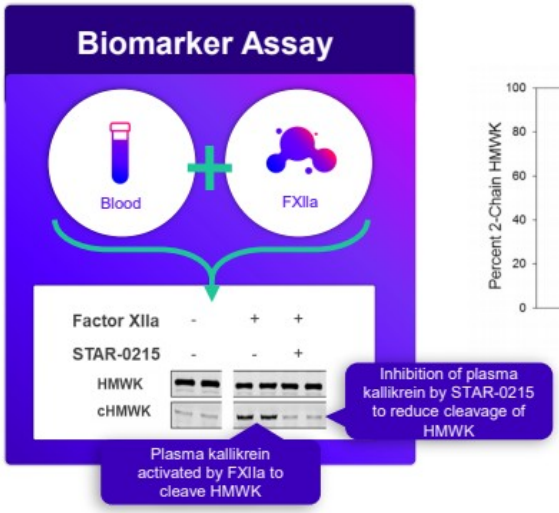
Modeling Supports Potential for Clinical Benefit with Infrequent Dosing

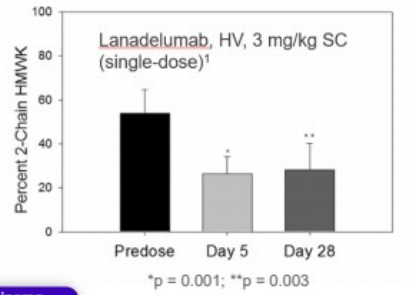


1. Kaufman 1991 June 15. Blood 77(12): 2660-2667
2. Wang et al. Clin Transl Sci. 2020 Nov, 13(6): 1208-1216. doi 10-1111/cts. 12806 Epub 2020 May 26.
3. Ecallantide EMA Assessment Report. 2011 June 23. EMA/CHMP/476618/2011

Target Engagement is Assessed by Change in FXIIa-Activated cHMWK



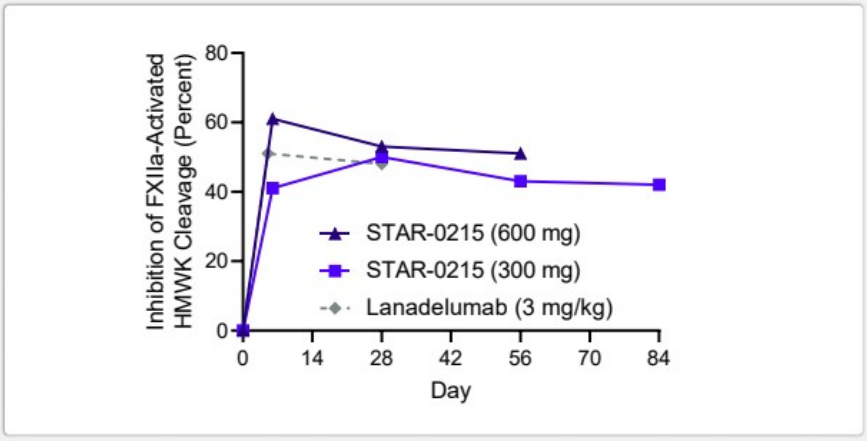




HMWK = high molecular weight kininogen
cHMWK = cleaved high molecular weight kininogen
FXIIa = activated Factor XII

1. Chyung et al, 2014
HV = healthy volunteer

Results Show STAR-0215 Achieves Sustained Inhibition of Plasma Kallikrein



- Levels of inhibition achieved (40-60% decreases in FXIIa-activated cHMWK) are consistent with the levels shown to prevent attacks in patients[1]
- Single dose of 300 mg leads to significant durable inhibition of plasma kallikrein observed through 3 months

No significant changes at any timepoints with placebo or 100 mg STAR-0215
Results will be finalized after the end of the observation period
1. Wang et al. Clin Transl Sci. 2020 Nov, 13(6): 1208-1216. doi 10-1111/cts. 12806 Epub 2020 May 26.
The comparison presented between STAR-0215 and lanadelumab represents a cross-trial comparison and does not involve data from a head-to-head clinical trial

Proposed ALPHA-STAR Trial Design

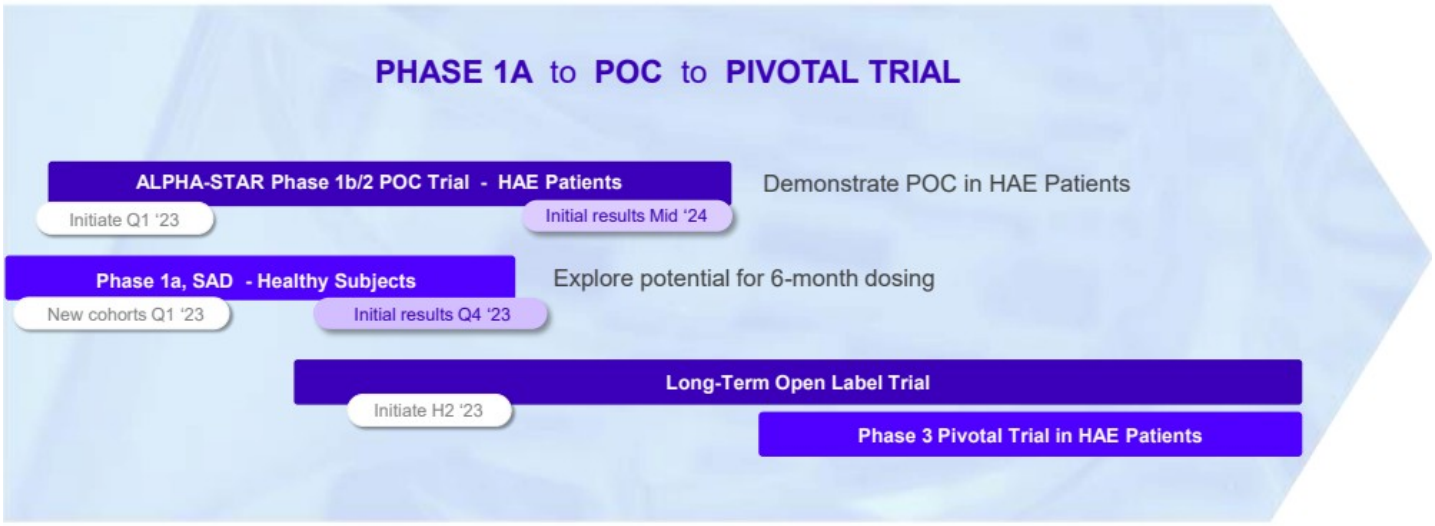
Open-Label Single and Multiple Dose Phase 1b/2 POC Clinical Trial in HAE

PROOF OF CONCEPT ENDPOINTS:

PRIMARY:	Safety and tolerability
SECONDARY:	Change from baseline in HAE attacks, PK, and PD
EXPLORATORY:	Angioedema Quality of Life Patient Reported Outcome Assessment

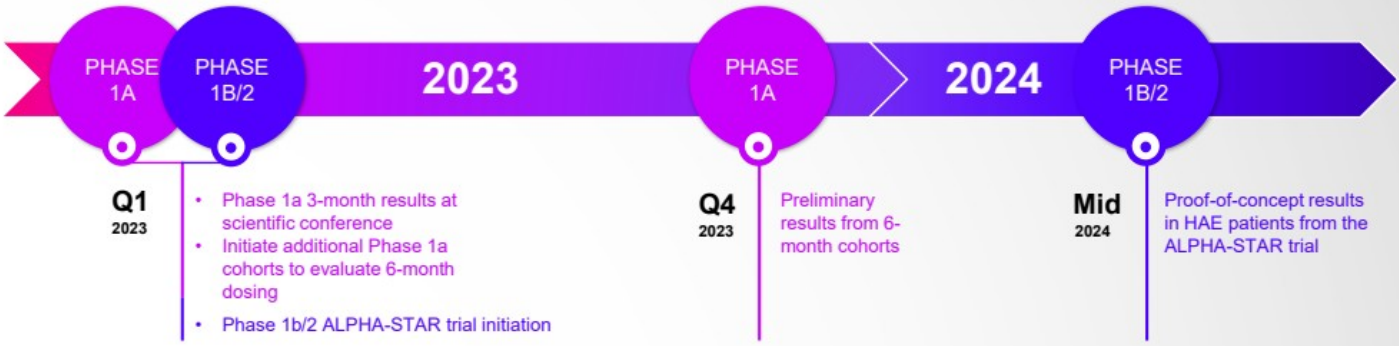
1. This cohort is expected to commence after a safety assessment of Cohort 1

Overview of the Expected Clinical Development Plan



Astria (Nasdaq ATXS) Well-Positioned for the Future

Expected Upcoming Milestones



- Cash, cash equivalents and short-term investments of $226M[1]
- Expected cash runway through H1 2025 based on current operating plan
- Common stock outstanding on an as-converted basis[2]: 32.7M
  - 27.5M common stock outstanding and 5.2M series X preferred

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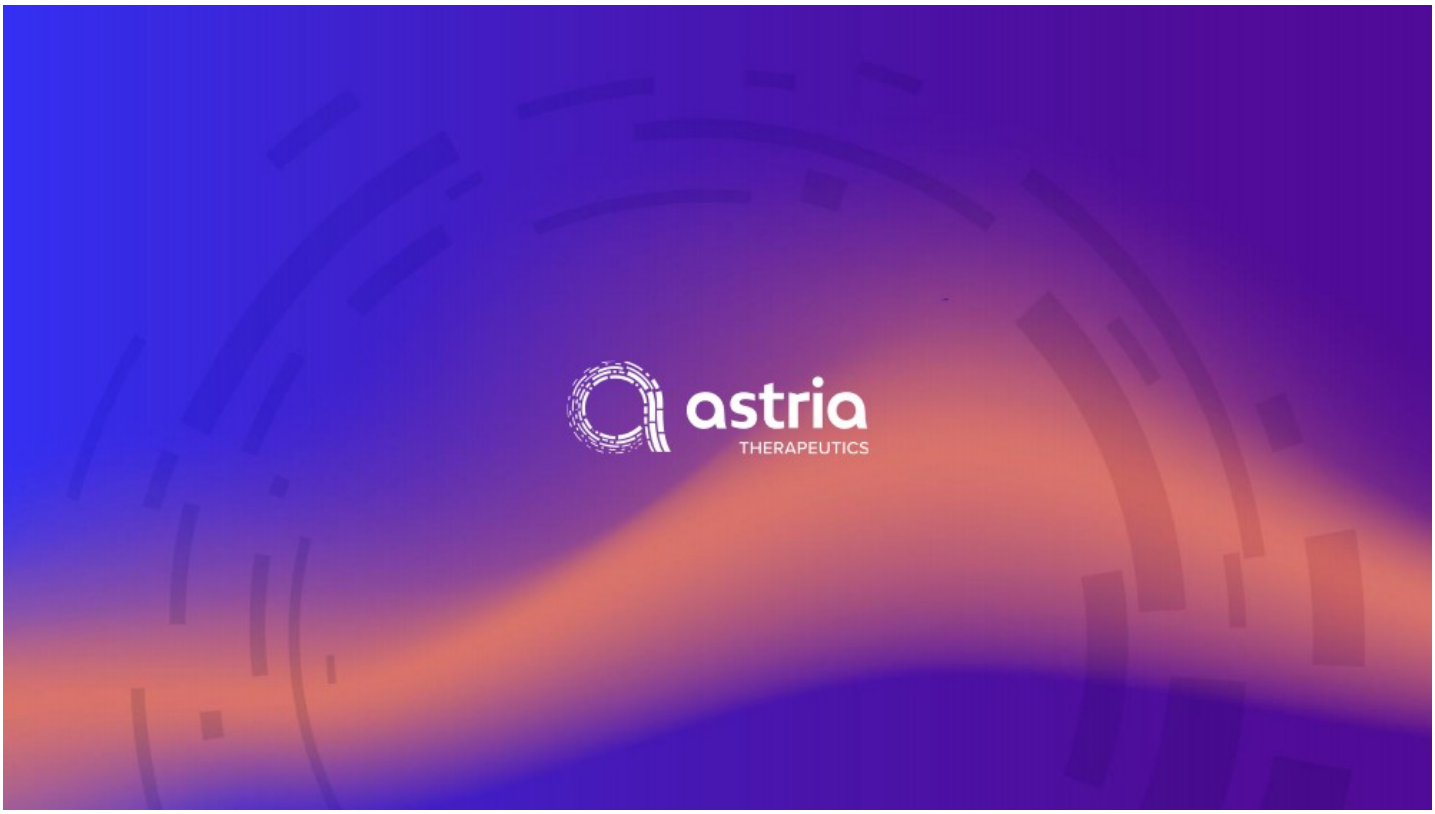
1. As of 12/31/2022, unaudited and preliminary
2. As of 12/30/2022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