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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 001-37467

Astria Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**26-3687168**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
75 State Street Suite 1400 Boston, Massachusetts	**02109**
(Address of Principal Executive Offices)	(Zip Code)

(617) 349-1971
(Registrant's Telephone Number, Including Area Code)

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, $0.001 par value per share	**ATXS**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. **Yes** ☒ **No** ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). **Yes** ☒ **No** ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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 accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). **Yes** ☐ **No** ☒

As of April 28, 2023, there were 28,025,844 shares of the registrant's common stock, par value $0.001 per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Quarterly Report on Form 10-Q contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance, strategy, future financial condition and clinical development programs. Such forward-looking statements are subject to various risks and uncertainties. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, clinical development programs, regulatory filings and expected market growth are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- our expectations regarding the potential significance of the preliminary results from the Phase 1a STAR-0215 clinical trial and the anticipated nature and timing of receipt of the data from additional cohorts in such trial;
- our expectations regarding the timing, nature, goals and results of our Phase 1b/2 clinical trial of STAR-0215 and that favorable results from such trial could allow us to move directly into a pivotal trial of STAR-0215 as a potential treatment for hereditary angioedema, or HAE;
- our expectations about the design of a pivotal clinical trial for STAR-0215 as a potential treatment for HAE, assuming positive data from the Phase 1b/2 trial;
- our expectations about the unmet medical need for HAE, the potential differentiating attributes of STAR-0215 as a potential treatment for HAE, along with the potential market impact of such differentiation, the potential of STAR-0215 to be a best-in-class monoclonal antibody inhibitor of plasma kallikrein able to provide long-acting, effective attack prevention for HAE, and our vision for STAR-0215 to become the first-choice preventative treatment for HAE with administration every three or six months with the goal of normalizing the lives of people living with HAE;
- the nature and anticipated growth of the global HAE market and HAE therapies;
- our plans to improve the formulation of STAR-0215 and corresponding work to develop a drug-device combination for STAR-0215 for potential use in late-stage clinical trials and commercially, if approved;
- our expectations that we have scaled the manufacturing process for STAR-0215 cell line in a manner to generate sufficient material for our planned STAR-0215 nonclinical and clinical studies;
- our expectations regarding our ability to expand our pipeline;
- the potential benefits of any future acquisition, in-license, collaboration or preclinical development activities;
- our manufacturing plans, capabilities and strategy;
- our intellectual property position and strategy;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing, including additional financing to fund our long-term operations;
- developments relating to our competitors and our industry; and
- the impact of government laws and regulations.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, particularly in the sections entitled “Summary of the Material Risks Associated with Our Business” and “Risk Factors”, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

PART I- FINANCIAL INFORMATION

Item 1. Financial Statements

Astria Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)

(Unaudited)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 202,301	$ 20,525
Short-term investments	11,027	205,912
Prepaid expenses and other current assets	2,117	1,253
Total current assets	215,445	227,690
Right-of-use asset	806	948
Other assets	1,989	1,995
Total assets	$ 218,240	$ 230,633
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 930	$ 788
Accrued expenses	5,156	7,690
Current portion of operating lease liabilities	587	582
Total current liabilities	6,673	9,060
Long term portion of operating lease liabilities	207	357
Total liabilities	6,880	9,417
Commitments (Note 6)		
Stockholders' equity:		
Preferred stock, $0.001 par value per share, 4,908,620 shares authorized and no shares issued and outstanding	—	—
Series X redeemable convertible preferred stock, $0.001 par value per share, 91,380 shares authorized; 31,107 and 31,455 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	95,324	96,398
Common stock, $0.001 par value per share, 150,000,000 shares authorized; 27,986,718 and 27,501,340 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	28	28
Additional paid-in capital	634,843	632,512
Accumulated other comprehensive loss	(4)	(79)
Accumulated deficit	(518,831)	(507,643)
Total stockholders' equity	211,360	221,216
Total liabilities and stockholders' equity	$ 218,240	$ 230,633

The accompanying notes are an integral part of these condensed consolidated financial statements.

Astria Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share data)

(Unaudited)

	Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development	$ 8,033	$ 10,358
General and administrative	5,460	5,020
Total operating expenses	13,493	15,378
Loss from operations	(13,493)	(15,378)
Other income (expense):		
Interest and investment income	2,321	56
Other expense, net	(16)	(1)
Total other income, net	2,305	55
Net loss	(11,188)	(15,323)
Net loss per share attributable to common shareholders - basic and diluted	$ (0.40)	$ (1.18)
Weighted-average common shares outstanding used in net loss per share - basic and diluted	27,944,458	13,016,955

The accompanying notes are an integral part of these condensed consolidated financial statements.

Astria Therapeutics, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2023	2022
Net loss	$ (11,188)	$ (15,323)
Other comprehensive gain (loss):		
Unrealized gain (loss) on short-term investments, net of tax of $0	75	(53)
Total other comprehensive gain (loss):	75	(53)
Comprehensive loss	$ (11,113)	$ (15,376)

The accompanying notes are an integral part of these condensed consolidated financial statements.

Astria Therapeutics, Inc.
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity
(In thousands, except shares)

(Unaudited)

	Series X redeemable convertible preferred stock, shares	Series X redeemable convertible preferred stock, value	Common stock, shares	Common stock, par value	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total stockholders' equity (deficit)
Balance at December 31, 2022	31,455	$ 96,398	27,501,340	$ 28	$632,512	$(507,643)	$ (79)	$ 221,216
Issuance of common stock upon the conversion of preferred stock	(348)	(1,074)	57,910	—	1,074	—	—	—
Issuance of common stock upon exericse of options and warrants	—	—	427,468	—	37	—	—	37
Stock-based compensation expense	—	—	—	—	1,220	—	—	1,220
Unealized gain on short-term investments	—	—	—	—	—	—	75	75
Net loss	—	—	—	—	—	(11,188)	—	(11,188
Balance at March 31, 2023	31,107	$ 95,324	27,986,718	$ 28	$634,843	$(518,831)	$ (4)	$ 211,360

The accompanying notes are an integral part of these condensed consolidated financial statements.

Astria Therapeutics, Inc.
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity
(In thousands, except shares)

(Unaudited)

	Series X redeemable convertible preferred stock, shares	Series X redeemable convertible preferred stock, value	Common stock, shares	Common stock, par value	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total stockholders' equity (deficit)
Balance at December 31, 2021	31,455	$ 96,398	13,016,955	$ 13	$ 481,709	$ (455,809)	$ —	$ 122,311
Expense related to warrants inherited in acquisiton of Quellis	—	—	—	—	1,542	—	—	1,542
Stock-based compensation expense	—	—	—	—	1,209	—	—	1,209
Unrealized loss on short-term investments	—	—	—	—	—	—	(53)	(53)
Net loss	—	—	—	—	—	(15,323)	—	(15,323)
Balance at March 31, 2022	31,455	$ 96,398	13,016,955	$ 13	$ 484,460	$ (471,132)	$ (53)	$ 109,686

The accompanying notes are an integral part of these condensed consolidated financial statements.

Astria Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2023	2022
Operating activities		
Net loss	$ (11,188)	$ (15,323)
Reconciliation of net loss to net cash used in operating activities:		
Stock-based compensation expense	1,220	1,209
Net gain on warrants inherited in acquisition of Quellis	—	1,542
Right-of-use asset - operating lease	142	—
Other non-cash items	(26)	(79)
Changes in assets and liabilities:		
Prepaid expenses and other assets	(864)	163
Lease liability - operating lease	(145)	(15)
Accounts payable	140	(627)
Accrued expenses	(2,532)	571
Net cash used in operating activities	(13,253)	(12,559)
Investing activities		
Purchases of short-term investments	(95,923)	(81,702)
Sales and maturities of short-term investments	290,920	54,603
Purchases of property and equipment	(5)	—
Net cash provided by (used in) investing activities	194,992	(27,099)
Financing activities		
Proceeds from exercise of stock options	37	—
Net cash provided by financing activities	37	—
Net increase (decrease) in cash, cash equivalents and restricted cash	181,776	(39,658)
Cash, cash equivalents and restricted cash, beginning of period	20,688	86,629
Cash, cash equivalents and restricted cash, end of period	$ 202,464	$ 46,971
Supplemental disclosure of non-cash transactions:		
Conversion of Series X Preferred Stock into common stock	$ 1,074	$ —

The accompanying notes are an integral part of these condensed consolidated financial statements.

Astria Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Organization and Operations

The Company

Astria Therapeutics, Inc. (the "Company"), formerly known as Catabasis Pharmaceuticals, Inc., is a biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics. Its mission is to bring hope with life-changing therapies to patients and families that are affected by rare and niche allergic and immunological diseases. On October 26, 2020, the Company announced that the Phase 3 PolarisDMD trial of the Company's previous lead product candidate, edasalonexent, for the treatment of Duchenne Muscular Dystrophy did not meet its primary and secondary endpoints. Based on these results, the Company announced that it was stopping activities related to the development of edasalonexent, including the Company's ongoing open-label extension trial. On January 28, 2021, the Company acquired Quellis Biosciences, Inc. ("Quellis"). The Company's lead product candidate, which was acquired in the Quellis acquisition, is STAR-0215, a monoclonal antibody inhibitor of plasma kallikrein in clinical development for the treatment of hereditary angioedema ("HAE"), a rare, debilitating and potentially life-threatening disease. The Company was incorporated in the State of Delaware on June 26, 2008.

Liquidity

On June 30, 2021, the Company entered into an Open Market Sale Agreement℠ with Jefferies LLC ("Jefferies"), pursuant to which the Company can issue and sell shares of common stock of up to $25.0 million under an at-the-market offering program (the "Jefferies ATM Program"). The Company pays Jefferies sales agent commissions of 3% of the gross proceeds from any common stock sold through the Jefferies ATM Program. On September 15, 2022, the Jefferies ATM Program was modified to increase the amount of the Company's common stock that may be offered thereunder to an aggregate offering price of up to $50.0 million, with $30.5 million of such amount then being available for future issuance. In November 2022, the Jefferies ATM Program was once again modified to increase the amount of the Company's common stock that may be offered thereunder to an aggregate offering price of up to $88.1 million, with $50.0 million of such amount then being available for future issuance. As of March 31, 2023, $50.0 million of common stock remains available for sale under the Jefferies ATM Program. There was no activity from the Jefferies ATM Program during the three months ended March 31, 2023 or 2022.

As of March 31, 2023, the Company had an accumulated deficit of $518.8 million and had available cash, cash equivalents and short-term investments $213.3 million. The Company estimates its existing cash, cash equivalents, and short-term investments are sufficient to sustain operations for at least twelve months from the issuance of these unaudited condensed consolidated financial statements. The Company has been primarily involved with research and development activities and has incurred operating losses and negative cash flows from operations since its inception. The Company has not generated any product revenues and has financed its operations primarily through public offerings and private placements of its equity securities. There can be no assurance that the Company will be able to obtain additional debt, equity or other financing or generate product revenues or revenues from collaborative partners, on terms acceptable to the Company, on a timely basis or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations, and financial condition.

The Company is subject to a number of risks similar to other life science companies, including, but not limited to, successful discovery and development of its drug candidates, raising additional capital, development by its competitors of new technological innovations, protection of proprietary technology and regulatory approval and market acceptance of the Company's products. The Company has been primarily involved with research and development activities and has incurred operating losses and negative cash flows from operations since its inception. The Company anticipates that it will continue to incur significant operating losses for the next several years as it continues to develop its product candidates.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying financial statements and the related disclosures are unaudited and have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP"). Additionally, certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted from this report. Accordingly, these unaudited condensed consolidated financial statements should be read in conjunction with the financial statements as of and for the year ended December 31, 2022 and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 (the "2022 Annual Report on Form 10-K").

The unaudited condensed consolidated financial statements have been prepared on the same basis as the audited financial statements. In the opinion of the Company's management, the accompanying unaudited condensed consolidated financial statements contain all adjustments, including those adjustments that are of a normal and recurring nature, which are necessary to fairly present the Company's results for the interim periods presented. The results for the three months ended March 31, 2023 are not necessarily indicative of the results for the year ending December 31, 2023 or for any future period.

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Astria Securities Corporation and Quellis Biosciences, LLC, successor in interest to Quellis. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the Company's unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the unaudited condensed consolidated financial statements and accompanying notes. Actual results could differ from such estimates.

The Company utilizes certain estimates to record expenses relating to research and development contracts. These contract estimates, which are primarily related to the length of service of each contract and the amount of service provided as of each measurement date, are determined by the Company based on input from internal project management, as well as from the Company's service providers.

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss attributable by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the Company's dilutive net loss per share calculation, preferred stock, stock options and warrants to purchase common stock and preferred stock were considered to be common stock equivalents but were excluded from the calculation of diluted net loss per share as their effect would be anti-dilutive; therefore, basic and diluted net loss per share were the same for all periods presented.

The following common stock equivalents, including Series X Preferred Stock shown as common stock equivalents, were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	Three Months Ended March 31,	
	2023	2022
Series X Preferred Stock	5,184,591	5,242,501
Stock options	2,562,234	1,962,650
Common stock warrants	1,031,820	1,530,176
	8,778,645	8,735,327

Cash, Cash Equivalents and Restricted Cash

Cash equivalents are short-term, highly liquid investments that are readily convertible into cash, with original maturities of three months or less. Cash equivalents are mainly comprised of money market accounts invested in U.S. Treasury securities, corporate debt securities, commercial paper and reverse repurchase agreements.

Restricted cash is comprised of deposits with a financial institution used to collateralize letters of credit related to the Company's lease arrangements. Restricted cash is presented as a component of other long-term assets at March 31, 2023 and prepaid expenses and other current assets and other long-term assets at March 31, 2022.

The reconciliation of cash, cash equivalents and restricted cash reported within the applicable condensed consolidated balance sheet that sum to the total of the same such amount shown in the condensed consolidated statement of cash flows is as follows (in thousands):

	March 31,	
	2023	2022
Cash and cash equivalents	$ 202,301	$ 46,687
Restricted cash	163	284
Total	$ 202,464	$ 46,971

Preferred Stock Discount

In February 2021, the Company issued Series X Preferred Stock in a private placement transaction. It was determined that this transaction resulted in recognition of a beneficial conversion feature, which was valued based on the difference between the price of the shares of common stock on the date of commitment and the conversion price on the closing date, resulting in a total value of $19.6 million. Additionally, the Company incurred total issuance costs of $5.7 million related to the private placement. Both of these features were recorded as a discount on Series X Preferred Stock recognized at the close of the transaction. These features are analogous to preferred dividends and are recorded as a non-cash return to holders of Series X Preferred Stock through additional paid in capital. The discount related to the beneficial conversion feature was recognized through the earliest possible date of conversion, which occurred in June 2021. The issuance costs are recognized as a dividend at the time of conversion to common shares. As of March 31, 2022, $24.4 million of the above amounts were accounted for as a non-cash dividend related to shares of Series X Preferred Stock, and $0.9 million remained to be recognized upon future conversion.

Recent Accounting Pronouncements - Adopted

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies and adopted by the Company as of the specified effective date.

In June 2016, the FASB issued Accounting Standards Update 2016-13, *Financial Instruments-Credit Losses* (Topic 326). This standard requires a financial asset to be presented at amortized cost basis at the net amount expected to be collected. It also requires that credit losses relating to available-for-sale debt securities should be recorded through an allowance for credit losses. In November 2019, the FASB issued an amendment making this standard effective for annual reporting periods beginning after December 15, 2022 for smaller reporting companies. Early adoption is permitted. The Company adopted this standard on January 1, 2023 with no material impact on the condensed consolidated financial statements.

Recent Accounting Pronouncements – Not Yet Adopted

In August 2020, the FASB issued Accounting Standards Update 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging Contracts in Entity's Own Equity (Subtopic 815-40)* ("ASU 2020-06"), which reduces the number of accounting models for convertible debt instruments and convertible preferred stock as well as amends the derivatives scope exception for contracts in an entity's own equity. ASU 2020-06 is effective for the Company on January 1, 2024, with early adoption permitted.

Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2, "*Summary of Significant Accounting Policies*" in the 2022 Annual Report on Form 10-K, and there were no significant changes to such policies in the three months ended March 31, 2023 that had a material impact on the Company's results of operations or financial position.

3. Financial Instruments

The tables below present information about the Company's assets and liabilities that are measured at fair value on a recurring basis as of March 31, 2023 and December 31, 2022, and indicate the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize observable inputs such as quoted prices in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are either directly or indirectly observable, such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points for which there is little or no market data, which require the Company to develop its own assumptions for the asset or liability. There were no transfers between fair value measurement levels during the three months ended March 31, 2023 and 2022.

The Company's investment portfolio may include fixed income securities that do not always trade on a daily basis. As a result, the pricing services used by the Company apply other available information as applicable through processes such as benchmark yields, benchmarking of like securities, sector groupings and matrix pricing to prepare valuations. The Company validates the prices provided by its third party pricing services by obtaining market values from other pricing sources and analyzing pricing data in certain instances. The Company also invests in certain reverse repurchase agreements which are collateralized by deposits in the form of U.S. Government Securities and Obligations for an amount no less than 102% of their value. The Company does not record an asset or liability for the collateral as the Company is not permitted to sell or re-pledge the collateral. The collateral has at least the prevailing credit rating of U.S. Government Treasuries and Agencies. The Company utilized a third-party custodian to manage the exchange of funds and ensure that collateral received is maintained at 102% of the value of the reverse repurchase agreements on a daily basis.

The Company accounted for warrants to purchase its stock pursuant to Accounting Standards Codification ("ASC") Topic 470, *Debt*, and ASC Topic 480, *Distinguishing Liabilities from Equity*, and classifies warrants for common stock and preferred stock as liabilities or equity. The warrants classified as liabilities are reported at their estimated fair value and any changes in fair value are reflected in research and development expense. The warrants classified as equity are reported at their estimated fair value with no subsequent remeasurement.

Below is a summary of assets and liabilities measured at fair value on a recurring basis (in thousands):

	As of March 31, 2023			
	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash equivalents:				
Money market funds	$ 1,715	$ —	$ —	$ 1,715
Reverse repurchase agreements	—	69,000	—	69,000
Treasury bills	6,973	—	—	6,973
Short-term investments:				
Corporate debt securities	—	6,075	—	6,075
Treasury bills	4,952	—	—	4,952
Total	$ 13,640	$ 75,075	$ —	$ 88,715

	As of December 31, 2022			
	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash and cash equivalents:				
Money market funds	$ 1,944	$ —	$ —	$ 1,944
Short term investments				
Corporate debt securities	—	16,445	—	16,445
Yankee securities	—	1,999	—	1,999
Bonds	—	2,988	—	2,988
Treasury bills	5,980	—	—	5,980
Reverse repurchase agreements	—	178,500	—	178,500
Total	$ 7,924	$ 199,932	$ —	$ 207,856

The carrying amounts reflected in the unaudited condensed consolidated balance sheets for cash, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities. Items measured at fair value on a recurring basis include cash equivalents and short-term investments as of March 31, 2023 and December 31, 2022.

4. Short-Term Investments

The following table summarizes the short-term investments held at March 31, 2023 and December 31, 2022 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
March 31, 2023				
Corporate debt securities	$ 6,082	$ —	$ (7)	$ 6,075
Treasury bills	4,949	3	—	4,952
Total	$ 11,031	$ 3	$ (7)	$ 11,027

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2022				
Corporate debt securities	$ 16,508	$ —	$ (63)	$ 16,445
Treasury bills	5,983	—	(3)	5,980
Yankee securities	2,000	—	(1)	1,999
U.S. agency bonds	3,000	—	(12)	2,988
Reverse repurchase agreements	178,500	—	—	178,500
Total	$ 205,991	$ —	$ (79)	$ 205,912

The contractual maturities of all short-term investments held at March 31, 2023 and December 31, 2022 were one year or less. There were 3 and 16 short-term investments in an unrealized loss position with aggregate values of $6.2 million and $25.6 million as of March 31, 2023 and December 31, 2022, respectively. These investments were in a loss position for less than 12 months and the Company considered the loss to be temporary in nature. The Company considered the decline in market value for these securities to be primarily attributable to economic and market conditions. As of March 31, 2023, the Company did not intend to sell, and it was not likely that the Company would be required to sell, the investments that were in an unrealized loss position before recovery of their amortized cost basis. Accordingly, the Company did not recognize any other-than-temporary impairments related to its short-term investments in an unrealized loss position.

Gross realized gains and losses on the sales of short-term investments are included in other income, net. Unrealized holding gains or losses for the period that have been included in accumulated other comprehensive income, as well as gains and losses reclassified out of accumulated other comprehensive income into other income, net, were not material to the Company's condensed consolidated results of operations. The cost of investments sold or the amount reclassified out of the accumulated other comprehensive income into other income, net is based on the specific identification method for purposes of recording realized gains and losses. All proceeds in the three-month periods ended March 31, 2023 and 2022 related to maturities of underlying investments. The gains on proceeds from maturities of short-term investments were not material to the Company's condensed consolidated results of operations for the three months ended March 31, 2023 and 2022.

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Accrued contracted costs	$ 2,818	$ 2,822
Accrued compensation	974	3,373
Accrued professional fees	955	588
Accrued other	409	407
Accrued milestones	—	500
Total	$ 5,156	$ 7,690

6. Commitments

On January 28, 2022, the Company entered into a sublease agreement (the "Sublease") with Grant Thornton LLP for new office space to replace its existing office space. The Sublease commenced on May 1, 2022 and will end on July 31, 2024 (or on such earlier date as the term may cease or expire as set forth in the Sublease).

Future minimum payments required under the Company's Sublease as of March 31, 2023 are summarized as follows (in thousands):

Period Ending December 31,	Amount
2023	446
2024	395
Total lease payments	$ 841
Less: imputed interest	(47)
Total operating lease liabilities	$ 794

Rent expense was $0.2 million for each of the three months ended March 31, 2023 and 2022. Lease payments were $0.2 million for each of the three months ended March 31, 2023 and 2022.

7. Stockholders' Equity

Preferred Stock

Under the Company's Restated Certificate of Incorporation, the Company has 5,000,000 shares of preferred stock authorized for issuance, with a $0.001 par value per share. Preferred stock may be issued from time to time in one or more series, each series to have such terms as stated or expressed in the resolutions providing for the issue of such series adopted by the Board of Directors of the Company. Preferred stock which may be redeemed, purchased or acquired by the Company may be reissued except as otherwise provided by law.

In January, 2021 the Company into a Stock Purchase Agreement (the "Purchase Agreement") with certain institutional and accredited investors. Pursuant to the Purchase Agreement, the Company sold an aggregate of 35,573 shares of Series X Preferred Stock for gross proceeds of approximately $110.0 million, and net proceeds of $104.3 million. Each share of Series X Preferred Stock is convertible into 166.67 shares of common stock. On January 3, 2023, a holder of Series X Preferred Stock elected to convert 348 shares of Series X Preferred Stock into 57,910 shares of common stock. As of March 31, 2023, the Company had 31,107 shares of Series X Preferred Stock outstanding and the number of shares of underlying common stock issuable upon conversion of the Series X Preferred Stock was 5,184,591.

Outstanding Warrants

The following table presents information about warrants that are issued and outstanding at March 31, 2023:

Year Issued	Equity Instrument	Warrants Outstanding	Exercise Price	Date of Expiration
2018	Common Stock	699,962	$ 72.00	6/21/2023
2019	Common Stock	331,858	$ 37.50	2/7/2024
Total		1,031,820		
Weighted average exercise price			$ 60.90	
Weighted average life in years				0.43

8. Reserved for Future Issuance

The Company has reserved for future issuance the following shares of common stock:

	March 31, 2023	December 31, 2022
Series X Preferred Stock	5,184,591	5,242,501
Options outstanding to purchase common stock	2,562,234	2,253,431
Reserve under the 2015 Stock Incentive Plan and the 2022 Inducement Stock Incentive Plan	1,082,245	1,013,520
Warrants for the purchase of common stock	1,031,820	1,530,176
Shares reserved for the employee stock purchase plan	43,060	36,982
Total	9,903,950	10,076,610

9. Stock Incentive Plans

A summary of the Company's stock option activity and related information follows:

	Shares	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	2,253,431	$ 15.43	8.57	$ 9,733
Granted	474,250	$ 13.35		
Exercised	(22,472)	$ 1.65		
Cancelled or forfeited	(142,975)	$ 13.52		
Outstanding at March 31, 2023	2,562,234	$ 15.27	8.57	$ 7,370
Vested and exercisable at March 31, 2023	835,970	$ 23.94	7.87	$ 1,468
Vested and expected to vest at March 31, 2023	2,562,234	$ 15.27	8.57	$ 7,370

The intrinsic value of stock options exercised in the three months ended March 31, 2023 was $0.3 million. There were no stock options exercised in the three months ended March 31, 2022. The total grant date fair value of stock options vested for the three months ended March 31, 2023 and 2022 was $1.5 million and $0.6 million, respectively. The weighted-average grant date fair value of options granted to employees and non-employees for the three months ended March 31, 2023 and 2022 was $8.49 and $4.05, respectively.

At March 31, 2023, the total unrecognized compensation expense related to unvested stock option awards was $11.2 million. The Company expects to recognize that cost over a weighted-average period of approximately 2.6 years.

On February 1, 2023, the Company issued stock options exercisable for 855,000 shares of common stock to certain officers of the Company. Subsequently one officer of the Company left and consequently of these stock options only options exercisable for 755,000 shares remain outstanding. The stock options issued on February 1, 2023 were issued subject to stockholder approval of the authorization of additional shares of common stock for issuance under the Company's 2015 Amended and Restated Stock Incentive Plan on or before January 31, 2024. Due to this stockholder approval requirement, these stock options are not considered granted as of March 31, 2023. The Company is seeking stockholder approval of an additional 4,300,000 shares for this plan at the Company's 2023 Annual Meeting of Stockholders, which is scheduled for June 2, 2023. Stockholder approval of this proposal would result in the officer stock option grants discussed above being considered granted.

On February 17, 2022, the Company's Board of Directors adopted the 2022 Inducement Stock Incentive Plan (the "Inducement Plan"). The Inducement Plan provides for the grant of nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards with respect to an aggregate of 300,000 shares of the Company's common stock. On January 31, 2023, the Company's Board of Directors approved an amendment to the Inducement Plan to increase the number of shares of common stock authorized for issuance thereunder from 300,000 shares of common stock to 700,000 shares of common stock. Awards under the Inducement Plan may only be granted to persons who (a) were not previously an employee or director of the Company or (b) are commencing employment with the Company following a bona fide period of non-employment, in either case as an inducement material to the individual's entering into employment with the Company and in accordance with the requirements of Nasdaq Stock Market Rule 5635(c)(4). As of March 31, 2023, options to purchase 232,800 shares of common stock have been granted under the Inducement Plan, which are included in the table above.

10. Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence for certain estimates and to identify matters that require additional disclosure. Subsequent events have been evaluated as required.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2022, or the 2022 Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the sections entitled "Risk Factors" and "Summary of the Material Risks Associated with Our Business" in our 2022 Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. This section provides additional information regarding our business, current developments, results of operations, cash flows, financial condition, contractual commitments and critical accounting policies and estimates that require significant judgement and have the most potential impact on our unaudited condensed consolidated financial statements. This discussion and analysis is intended to better allow investors to view the Company from management's perspective.

Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics. Our mission is to bring hope with life-changing therapies to patients and families that are affected by rare and niche allergic and immunological diseases. Our lead product candidate is STAR-0215, a potential best-in-class monoclonal antibody inhibitor of plasma kallikrein in clinical development for the treatment of hereditary angioedema, or HAE, a rare, debilitating and potentially life-threatening disease. STAR-0215 has the potential to be the most patient-friendly chronic treatment option for HAE, based on the data generated to date and the existing HAE treatment landscape.

The treatment options for patients with HAE have improved in recent years, however, there is remaining unmet medical need and the global market for HAE therapy is strong and growing. The goal for STAR-0215 is to develop a best-in-class monoclonal antibody inhibitor of plasma kallikrein able to provide long-acting, effective attack prevention for HAE. Our vision for STAR-0215 is to become the first-choice preventative treatment for HAE with administration every three or six months with the goal of normalizing the lives of people living with HAE. Targeted plasma kallikrein inhibition can prevent HAE attacks by suppressing the pathway that generates bradykinin and causes excessive swelling. STAR-0215 is currently in clinical development. We submitted an investigational new drug application, or IND, for STAR-0215 in June 2022 and the FDA cleared our IND for STAR-0215 in July 2022.

We initiated a Phase 1a clinical trial in August 2022 and we announced preliminary results in December 2022. We presented additional initial results from the trial through the first 84 days of follow up at the American Academy of Allergy, Asthma, and Immunology conference in February 2023. This Phase 1a randomized, double-blind, placebo-controlled single ascending dose clinical trial evaluated the safety, pharmacokinetics, or PK, and pharmacodynamics, or PD, of STAR-0215 at a single U.S. center. Healthy subjects received a single dose of STAR-0215 or placebo in three cohorts of 100mg, 300mg, and 600mg administered subcutaneously. STAR-0215 was well-tolerated at all dose levels. Additionally, there were no clinically significant changes in laboratory assessments and there were no treatment-emergent anti-drug antibodies detected. STAR-0215 demonstrated rapid and sustained drug levels with dose-dependent PK and an estimated half-life of up to 117 days. Sustained target engagement was seen with inhibition of plasma kallikrein consistent with levels associated with clinical benefit for at least three months. The initial results from the Phase 1a trial support investigating STAR-0215 in HAE patients and also suggest that there could be an opportunity to dose STAR-0215 less frequently than every three months. As a result, we are evaluating the potential for 6-month dosing with additional healthy subject cohorts in the Phase 1a trial with initial results expected in the fourth quarter of 2023. The final results from the first three cohorts in the Phase 1a trial are also expected in the fourth quarter of 2023.

The initial Phase 1a results support STAR-0215's target profile as a long-acting plasma kallikrein inhibitor and support advancing STAR-0215 to a Phase 1b/2 trial called ALPHA-STAR, or **A**stria **L**ong-acting **P**rophylaxis for **H**ereditary **A**ngioedema: STAR-0215, which we initiated in February 2023. This global, multi-center, open-label, single and multiple dose proof-of-concept clinical trial in people with HAE, is evaluating safety, tolerability, HAE attack rate, PK, PD, and quality of life in patients three and six months after STAR-0215 administration. We are currently enrolling patients in the trial and have initiated administration of STAR-0215 to enrolled patients. We expect to report initial data from single and multiple dose cohorts in the trial in mid-2024.

In May 2023, we presented new human mechanistic modeling data at the 13th C1-Inhibitor Deficiency & Angioedema Workshop. These data support the potential for STAR-0215 to be administered once every three or six months for robust suppression of HAE attacks.

In January 2021, we acquired Quellis Biosciences, Inc., or Quellis, including the STAR-0215 program, and announced a private placement that, upon closing in February 2021, resulted in gross proceeds to us of approximately $110.0 million before deducting placement agent and other offering expenses, which we refer to as the February 2021 Financing.

On December 19, 2022, we closed an underwritten public offering of 10,445,050 shares of our common stock, including the full exercise of the underwriters' option to purchase 1,362,397 shares of our common stock, at a price of $11.01 per share, which we refer to as the December 2022 Financing. The gross proceeds of the December 2022 Financing were approximately $115.0 million, before deducting underwriting discounts and commissions and other offering expenses.

Financial Overview

Our business is almost entirely dependent on the success of STAR-0215, which is in the early clinical stages of development, and has only produced results in a Phase 1a clinical trial, preclinical and nonclinical settings. Our losses from operations were $13.5 million and $15.4 million for the three months ended March 31, 2023 and 2022, respectively. As of March 31, 2023, we had an accumulated deficit of $518.8 million. We have financed our operations to date primarily through private placements of preferred stock before we became a public company, our private placement of preferred stock in the February 2021 Financing and registered offerings of our common stock, including our at-the-market offering programs, and have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical development programs. As of March 31, 2023, we had $213.3 million in cash, cash equivalents and short-term investments. Based on our current operating plan, we expect that our cash, cash equivalents and short-term investments as of March 31, 2023 are sufficient to fund our operating expenses and capital expenditure requirements through the first half of 2025. Advancing the development of STAR-0215 or any future product candidates will require a significant amount of capital. Our existing cash, cash equivalents and short-term investments will not be sufficient to fund STAR-0215 or any future product candidates through regulatory approval. We will need to obtain substantial additional funding to complete the development and commercialization of STAR-0215 or any future product candidates and support our continuing operations, future clinical trials and expansion of our pipeline. Furthermore, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional financing to fund our long-term operations sooner than planned. See the section titled "Liquidity and Capital Resources" below for additional information.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts, and the development of our product candidates, which include:

- employee-related expenses including salaries, benefits and stock-based compensation expense;
- expenses incurred under agreements with third parties, including contract research organizations that conduct clinical trials and research and development and preclinical activities on our behalf;
- the cost of consultants;
- the cost of lab supplies and acquiring, developing and manufacturing study materials; and
- facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies.

Research and development costs are expensed as incurred. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

We typically use our employee, consultant and infrastructure resources across our development programs. We track outsourced development costs by product candidate or development program, but we do not allocate personnel costs, other internal costs or external consultant costs to specific product candidates or development programs. We record our research and development expenses net of any research and development tax incentives we are entitled to receive from government authorities.

The following table summarizes our research and development expenses by program (in thousands):

	Three Months Ended March 31,	
	2023	2022
STAR-0215	$ 4,140	$ 6,269
Other programs	710	365
Costs not directly allocated to programs:		
Employee expenses including cash compensation, benefits and stock-based compensation	2,746	1,375
Consultants and professional expenses, including stock-based compensation	308	2,226
Facilities	67	80
Other	62	43
Total costs not directly allocated to programs	3,183	3,724
Total research and development expenses	$ 8,033	$ 10,358

We expect to incur significant research and development expenses in the year ending December 31, 2023, and in future periods in connection with the clinical trials and other activities related to the development of STAR-0215. Because of this, we expect that our research and development expenses over the next several quarters will be higher than the prior year periods. Development of STAR-0215 and any future product candidates is highly uncertain and we cannot reasonably estimate at this time the nature, timing and costs of the efforts that would be necessary to complete the development of any such product candidates. We are also unable to predict when, if ever, material net cash inflows would commence from STAR-0215 or any other future product candidates. This is due to the fact that we would need to raise substantial additional capital to fund the clinical development of any such product candidates and the numerous risks and uncertainties associated with developing and commercializing product candidates, including the uncertainties of:

- establishing an appropriate safety profile with IND-enabling toxicology studies;
- successful design of, enrollment in, and completion of clinical trials;
- feedback from the FDA and foreign regulatory authorities on planned trial designs, pre-clinical studies and manufacturing capabilities and plans;
- changes in the FDA and foreign regulatory approval processes or perspectives that may delay or prevent the approval of new products;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity;
- launching commercial sales, if we are able to obtain marketing approval, whether alone or in collaboration with others, and our ability to compete successfully with other products; and
- a continued acceptable safety profile following approval.

A change in the outcome of any of these variables with respect to the development of STAR-0215 or any future product candidate would significantly change the costs and timing associated with the development of that product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance, accounting, pre-commercial, business development, information technology, legal and human resources functions. Other significant costs include facility costs not otherwise included in research and development expenses, legal fees relating to patent and corporate matters, and fees for accounting and consulting services.

We anticipate that our general and administrative expenses will increase from their current levels as we continue to grow our company, develop STAR-0215 and potentially expand our pipeline to include other product candidates.

Other Income, Net

Other income, net consists of interest income earned on our cash, cash equivalents and short-term investments and net amortization expense on short-term investments, and gains and losses related to foreign currency fluctuations.

Critical Accounting Estimates

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with United States generally accepted accounting principles. We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as critical because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates—which also would have been reasonable—could have been used. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

During the three months ended March 31, 2023, there were no material changes to our critical accounting policies as reported in our 2022 Annual Report on Form 10-K.

Results of Operations

Comparison of the Three Months Ended March 31, 2023 and 2022

The following table summarizes our results of operations for the three months ended March 31, 2023 and 2022, together with the dollar change in those items (in thousands):

	Three Months Ended March 31,		Period-to-Period Change
	2023	2022	
Operating expenses:			
Research and development	$ 8,033	$ 10,358	$ (2,325)
General and administrative	5,460	5,020	440
Total operating expenses	13,493	15,378	(1,885)
Loss from operations	(13,493)	(15,378)	1,885
Other income, net	2,305	55	2,250
Net loss	$ (11,188)	$ (15,323)	$ 4,135

Research and Development Expenses

Research and development expenses decreased by $2.3 million to $8.0 million for the three months ended March 31, 2023 from $10.4 million for the three months ended March 31, 2022, a decrease of 22%. The decrease in research and development expenses was primarily attributable to a $2.1 million decrease in direct costs to support development of the STAR-0215 program, and a $1.9 million decrease in professional service expenses primarily due to expense recognized on vested warrants in 2022. The decrease in costs to support development of the STAR-0215 program is due to timing of the work performed to submit our IND in the first quarter of 2022, with costs to support clinical operations in the first quarter of 2023 not yet being significant enough to result in an increase in costs to support development of the STAR-0215 program as compared to the first quarter of 2022. These decreases were partially offset by a $1.3 million increase in employee expenses and a $0.4 million increase in costs for other research programs. As noted above, we expect that our research and development expenses over the next several quarters will be higher than prior periods.

General and Administrative Expenses

General and administrative expenses increased by $0.4 million to $5.5 million for the three months ended March 31, 2023 from $5.0 million for the three months ended March 31, 2022, an increase of 9%. The increase was attributable to a $0.3 million increase in employee-related costs and a $0.3 million increase in professional services expense. These costs were partially offset by a $0.1 million decrease in insurance expense and a $0.1 million decrease in general office expenses.

Other Income, Net

Other income, net increased by $2.3 million to $2.3 million for the three months ended March 31, 2023 from $55 thousand for the three months ended March 31, 2022. The increase was primarily attributable to an increase in interest and investment income due to higher yields on our interest-earning assets.

Liquidity and Capital Resources

From our inception through March 31, 2023, we raised an aggregate of $579.3 million through equity financings including private placements of preferred stock before we became a public company, our private placement of preferred stock in the February 2021 Financing and registered offerings of our common stock, including our at-the-market offering programs. As of March 31, 2023, we had $213.3 million in cash, cash equivalents and short-term investments. Based on our current operating plan, we expect that our cash, cash equivalents and short-term investments as of March 31, 2023 are sufficient to fund our operating expenses and capital expenditure requirements through the first half of 2025. Advancing the development of STAR-0215 and other product candidates will require a significant amount of capital. Our existing cash and cash equivalents will not be sufficient to fund any of our product candidates through regulatory approval. Furthermore, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional financing to fund our long-term operations sooner than planned.

We will need to obtain substantial additional funding to complete the development and commercialization of STAR-0215 or any future product candidates, support our continuing operations, future clinical trials and the expansion of our pipeline. In addition, STAR-0215 or any future product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of product candidates that we do not expect to be commercially available for years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. The terms of any financing may adversely affect the holdings or the rights of our stockholders. General economic conditions, both inside and outside the United States, including heightened inflation, capital market instability and volatility, interest rate and currency rate fluctuations and economic slowdown or recession as well as the COVID-19 pandemic and geopolitical events, including civil or political unrest (such as the Ukraine-Russian war), may have a significant impact on the availability of funding sources and the terms on which any funding may be available. In addition, market instability and volatility, high levels of inflation and interest rate fluctuations may increase our cost of financing or restrict our access to potential sources of future liquidity. If we fail to raise capital as, and when, needed, we may be unable to continue our operations at planned levels and be forced to modify our business strategies and reduce or terminate our operations. Although we will continue to pursue these plans, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations when needed or at all.

December 2022 Financing

On December 19, 2022, we closed an underwritten public offering of 10,445,050 shares of our common stock for gross proceeds of approximately $115 million, and net proceeds of $107.6 million.

At-the-Market Offerings

On June 30, 2021, we entered into an Open Market Sale Agreement[SM] with Jefferies LLC, or Jefferies, pursuant to which we can issue and sell shares of common stock of up to $25.0 million under an at-the-market offering program, or the Jefferies ATM Program. We pay Jefferies sales agent commissions of 3% of the gross proceeds from any common stock sold through the Jefferies ATM Program. On September 15, 2022, the Jefferies ATM Program was modified to increase the amount of our common stock that may be offered thereunder to an aggregate offering price of up to $50.0 million, with $30.5 million of such amount then being available for future issuance. In November 2022, the Jefferies ATM Program was once again modified to increase the amount of our common stock that may be offered thereunder to an aggregate offering price of up to $88.1 million, with $50.0 million of such amount then being available for future issuance. As of March 31, 2023, $50.0 million of common stock remains available for sale under the Jefferies ATM Program. There was no activity from the Jefferies ATM Program during the three months ended March 31, 2023 and 2022, respectively.

Cash Flows

Comparison of the Three Months Ended March 31, 2023 and 2022

The following table provides information regarding our cash flows for the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,	
	2023	2022
Net cash used in operating activities	$ (13,253)	$ (12,559)
Net cash provided by (used in) by investing activities	194,992	(27,099)
Net cash provided by financing activities	37	—
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 181,776	$ (39,658)

Net Cash Used in Operating Activities

Net cash used in operating activities was $13.3 million for the three months ended March 31, 2023 and consisted primarily of a net loss of $11.2 million adjusted for stock-based compensation expense of $1.2 million, an adjustment to our right of use asset of $0.1 million, and a net increase in net assets of $3.4 million, which resulted primarily from a decrease in accrued expenses of $2.5 million, an increase prepaid expenses of $0.9 million and a decrease in the lease liability of $0.1 million, partially offset by an increase in accounts payable of $0.1 million.

Net cash used in operating activities was $12.6 million for the three months ended March 31, 2022 and consisted primarily of a net loss of $15.3 million adjusted for stock-based compensation expense of $1.2 million and expense recognized for warrants of $1.5 million.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $195.0 million for the three months ended March 31, 2023 and consisted primarily of maturities of short-term investments of $290.9 million, partially offset by purchases of short-term investments of $95.9 million. Net cash used in investing activities was $27.1 million for the three months ended March 31, 2022 and consisted primarily of proceeds from purchases of short-term investments of $81.7 million, partially offset by maturities of short-term investments of $54.6 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $37 thousand for the three months ended March 31, 2023, which was attributable to proceeds from exercises of stock options. There was no cash provided by financing activities for the three months ended March 31, 2022.

Funding Requirements

Our primary uses of capital are for compensation and related expenses, manufacturing costs for preclinical and clinical materials, third party preclinical and clinical research and development services, clinical costs, legal and other regulatory expenses, and general overhead.

As of March 31, 2023, we had an accumulated deficit of $518.8 million. We have been primarily involved with research and development activities and have incurred operating losses and negative cash flows from operations since our inception.

As of March 31, 2023, we had available cash, cash equivalents and short-term investments of $213.3 million. Based on our current operating plan, we expect that our cash, cash equivalents and short-term investments as of March 31, 2023 are sufficient to fund our operating expenses and capital expenditures requirements through the first half of 2025.

Our estimate as to how long we expect our cash, cash equivalents and short-term investments to be able to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of biotechnology products, we are unable to estimate the exact amount of our operating capital requirements. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including:

- the progress, timing, costs and results of clinical trials of, and research and preclinical development efforts for, STAR-0215 and any future product candidates, including potential future clinical trials;
- our ability to enter into and the terms and timing of any collaborations, licensing or other arrangements that we may establish;
- the number and characteristics of future product candidates that we pursue and their development requirements;
- the outcome, timing and costs of seeking regulatory approvals;
- the costs of commercialization activities for any of our product candidates that receive marketing approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, market access, distribution, supply chain and manufacturing capabilities, and scaling up the manufacturing of drug substance and drug product to clinical and commercial scale and developing a drug device combination, if applicable, securing all raw materials necessary to conduct such scale-up and successfully completing all other activities related thereto;
- if we obtain marketing approval of any of our product candidates, revenue, if any, received from commercial sales of our product candidates;
- if we obtain marketing approval of any of our product candidates, our ability to successfully compete against other approved products that are approved or used as treatments for the indications for which our products are approved, including with respect to STAR-0215 in HAE;
- our headcount growth and associated costs;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims;
- the impact of the COVID-19 pandemic on our operations, business and prospects; and
- the costs of operating as a public company.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, STAR-0215 or any future product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of medicines that we do not expect to be commercially available for years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Debt financing, if available, would result in periodic payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business.

If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act) that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized, and reported within the time periods specified in the U.S. Securities and Exchange Commission's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of March 31, 2023, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the three months ended March 31, 2023, there were no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1A. Risk Factors

Careful consideration should be given to the factors discussed in Part I, Item 1A, Risk Factors, in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, which could materially affect our business, financial condition or future results, in addition to the information set forth in this Quarterly Report on Form 10-Q.

Item 6. Exhibits

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibits Index below:

Exhibit Number	Exhibit
10.1	2022 Inducement Stock Incentive Plan, as amended (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K (File No. 001-37467) filed with the SEC on February 2, 2023)
31.1*	Certification of principal executive officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of principal financial officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002, by the Registrant's principal executive officer and principal financial officer
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document
104	Cover Page Data File (the cover page XBRL tags are embedded within the iXBRL document).

* Filed herewith.

** Furnished herewith.

SIGNATURES

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, thereunto duly authorized.

Astria Therapeutics, Inc.

Date: May 11, 2023

By: /s/ NOAH C. CLAUSER
Noah C. Clauser
Chief Financial Officer (Principal Financial Officer)

Exhibit 31.1

CERTIFICATION

I, Jill C. Milne, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Astria Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and
   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2023

/s/ JILL C. MILNE, PH.D.
Jill C. Milne, Ph.D.
President and Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Noah C. Clauser, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Astria Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and
   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2023

/s/ NOAH C. CLAUSER
Noah C. Clauser
Chief Financial Officer (Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Astria Therapeutics, Inc. (the "Company") for the period ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officers of the Company hereby certify, pursuant to 18 U.S.C. Section 1350, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 11, 2023

/s/ JILL C. MILNE, PH.D.
Jill C. Milne, Ph.D.
President and Chief Executive Officer (Principal Executive Officer)

Date: May 11, 2023

/s/ NOAH C. CLAUSER
Noah C. Clauser
Chief Financial Officer (Principal Financial Officer)