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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 September 30, 2024

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.)
22 Boston Wharf Road 10th Floor Boston, Massachusetts	**02210**
(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 October 31, 2024, there were 56,434,219 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 and preclinical 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 and preclinical 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 results from the Phase 1a clinical trial of navenibart, formerly known as STAR-0215;
- our expectations regarding the potential significance of the initial results from the ALPHA-STAR Phase 1b/2 clinical trial of navenibart, including our expectation that the results will support advancement of navenibart into Phase 3 development as a potential treatment for hereditary angioedema, or HAE;
- our expectations regarding the timing of reporting additional data from the ALPHA-STAR trial and reporting initial safety and efficacy data from the ALPHA-SOLAR long-term open-label trial of navenibart;
- our expectations about the design and anticipated timing of a Phase 3 pivotal trial for navenibart as a potential treatment for HAE;
- our expectations about the unmet medical need for HAE, the size and potential growth of the overall HAE market, the potential differentiating attributes of navenibart as a potential treatment for HAE, along with the potential market impact of such differentiation, the potential of navenibart 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 navenibart to become the market leading and first-choice preventative treatment for HAE with administration every three and six months;
- our plans to optimize the formulation of navenibart and corresponding work to develop a drug-device combination for navenibart for potential use in late-stage clinical trials and commercially, if approved;
- our expectations that we have scaled the manufacturing process for navenibart in a manner to generate sufficient material for our planned navenibart nonclinical and clinical studies;
- the potential therapeutic benefits and potential attributes of STAR-0310, a preclinical stage product candidate which we licensed in October 2023, and our plans to develop STAR-0310 as a treatment for atopic dermatitis, or AD;
- our expectations regarding the timing of regulatory submissions for STAR-0310;
- our expectations about the design and anticipated timing of planned clinical trials of STAR-0310;
- our expectations regarding the timing and nature of anticipated data for planned clinical trials of STAR-0310;
- the potential commercial opportunity for STAR-0310 in AD and the likelihood that it can effectively compete in AD, assuming it is approved;
- the estimated size and anticipated growth of the AD market and the need for treatments for AD;

- the potential to pursue the development of STAR-0310 in additional indications;
- our goals and visions for the STAR-0310 program;
- 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 our cash runway, 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, 2023, 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)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 80,899	$ 175,530
Short-term investments	263,384	71,000
Prepaid expenses and other current assets	7,580	4,412
Total current assets	351,863	250,942
Right-of-use asset	5,390	363
Other assets	4,386	3,361
Total assets	$ 361,639	$ 254,666
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,278	$ 1,513
Accrued expenses	13,069	9,708
Current portion of operating lease liabilities	1,377	329
Total current liabilities	15,724	11,550
Long term portion of operating lease liabilities	4,261	—
Total liabilities	19,985	11,550
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 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	95,324	95,324
Common stock, $0.001 par value per share, 150,000,000 shares authorized; 56,434,219 and 41,034,797 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	57	41
Additional paid-in capital	895,110	728,285
Accumulated other comprehensive gain	331	—
Accumulated deficit	(649,168)	(580,534)
Total stockholders' equity	341,654	243,116
Total liabilities and stockholders' equity	$ 361,639	$ 254,666

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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 20,510	$ 13,338	$ 56,945	$ 30,460
General and administrative	8,504	6,898	25,022	18,371
Total operating expenses	29,014	20,236	81,967	48,831
Loss from operations	(29,014)	(20,236)	(81,967)	(48,831)
Other income (expense):				
Interest and investment income	4,517	2,527	13,405	7,404
Other expense, net	(37)	(18)	(72)	(54)
Total other income, net	4,480	2,509	13,333	7,350
Net loss	(24,534)	(17,727)	(68,634)	(41,481)
Net loss per share attributable to common shareholders - basic and diluted	$ (0.42)	$ (0.63)	$ (1.24)	$ (1.48)
Weighted-average common shares outstanding used in net loss per share - basic and diluted	57,820,458	28,040,173	55,542,074	28,002,663

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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net loss	$ (24,534)	$ (17,727)	$ (68,634)	$ (41,481)
Other comprehensive gain:				
Unrealized gain on short-term investments, net of tax of $ 0	376	—	331	79
Total other comprehensive gain:	376	—	331	79
Comprehensive loss	$ (24,158)	$ (17,727)	$ (68,303)	$ (41,402)

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 gain (loss)	Total stockholders equity
Balance at December 31, 2023	31,107	$ 95,324	41,034,797	$ 41	$728,285	$ (580,534)	$ —	$ 243,116
Issuance of common stock pursuant to an underwriting agreement, net of underwriter's discount and issuance costs	—	—	10,340,000	10	117,162	—	—	117,172
Issuance of common stock for at-the-market offerings, net of issuance costs	—	—	2,945,806	3	19,999	—	—	20,002
Issuance of common stock upon exercise of options and warrants	—	—	582,458	1	4,632	—	—	4,633
Stock-based compensation expense	—	—	—	—	2,754	—	—	2,754
Unrealized loss on short-term investments	—	—	—	—	—	—	(14)	(14
Net loss	—	—	—	—	—	(19,928)	—	(19,928
Balance at March 31, 2024	31,107	95,324	54,903,061	55	872,832	(600,462)	(14)	367,735
Issuance of common stock upon exercise of options	—	—	17,602	—	94	—	—	94
Stock-based compensation expense	—	—	—	—	3,451	—	—	3,451
Unrealized loss on short-term investments	—	—	—	—	—	—	(31)	(31
Net loss	—	—	—	—	—	(24,172)	—	(24,172
Balance at June 30, 2024	31,107	95,324	54,920,663	55	876,377	(624,634)	(45)	347,077
Issuance of common stock for at-the-market offerings, net of issuance costs	—	—	1,504,619	2	15,241	—	—	15,243
Issuance of common stock upon exercise of options	—	—	8,937	—	58	—	—	58
Stock-based compensation expense	—	—	—	—	3,434	—	—	3,434
Unealized gain on short-term investments	—	—	—	—	—	—	376	376
Net loss	—	—	—	—	—	(24,534)	—	(24,534
Balance September 30, 2024	31,107	$ 95,324	56,434,219	$ 57	$895,110	$ (649,168)	$ 331	$ 341,654

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
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 exercise of options and warrants	—	—	427,468	—	37	—	—	37
Stock-based compensation expense	—	—	—	—	1,220	—	—	1,220
Unrealized 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
Issuance of common stock upon exercise of options	—	—	39,126	—	273	—	—	273
Stock-based compensation expense	—	—	—	—	1,331	—	—	1,331
Unrealized gain on short-term investments	—	—	—	—	—	—	4	4
Net loss	—	—	—	—	—	(12,566)	—	(12,566)
Balance at June 30, 2023	31,107	95,324	28,025,844	28	636,447	(531,397)	—	200,402
Issuance of common stock upon exericse of options	—	—	16,452	—	110	—	—	110
Stock-based compensation expense	—	—	—	—	1,694	—	—	1,694
Unealized gain on short-term investments	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	(17,727)	—	(17,727)
Balance September 30, 2023	31,107	$ 95,324	28,042,296	$ 28	$638,251	$ (549,124)	$ —	$ 184,479

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)

	Nine Months Ended September 30,	
	2024	2023
Operating activities		
Net loss	$ (68,634)	$ (41,481)
Reconciliation of net loss to net cash used in operating activities:		
Stock-based compensation expense	9,639	4,245
Right-of-use asset - operating lease	726	434
Accretion of discount/premium on investment securities	(4,232)	(86)
Other non-cash items	50	34
Changes in assets and liabilities:		
Prepaid expenses and other assets	(4,081)	(1,318)
Lease liability - operating lease	(444)	(451)
Accounts payable	(235)	350
Accrued expenses	3,361	66
Net cash used in operating activities	(63,850)	(38,207)
Investing activities		
Purchases of short-term investments	(3,495,821)	(1,216,423)
Sales and maturities of short-term investments	3,308,000	1,353,500
Purchases of property and equipment	(325)	(9)
Net cash (used in) provided by investing activities	(188,146)	137,068
Financing activities		
Proceeds from public offering, net of underwriting discounts and issuance costs	117,172	—
Proceeds from at-the-market offering, net of issuance costs	35,245	—
Proceeds from exercise of stock options and warrants	4,785	420
Net cash provided by financing activities	157,202	420
Net (decrease) increase in cash, cash equivalents and restricted cash	(94,794)	99,281
Cash, cash equivalents and restricted cash, beginning of period	175,693	20,688
Cash, cash equivalents and restricted cash, end of period	$ 80,899	$ 119,969
Supplemental disclosure of non-cash transactions:		
Operating lease right-of-use assets obtained in exchange for operating lease liabilities	$ 5,753	$ —
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") is a biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics for allergic and immunological diseases. The Company's lead product candidate is navenibart, a potential best-in-class monoclonal antibody inhibitor of plasma kallikrein in clinical development for the treatment of hereditary angioedema, a rare, debilitating and potentially life-threatening disease. The Company's second product candidate is STAR-0310, a monoclonal antibody OX40 antagonist that is in preclinical development for the treatment of atopic dermatitis, an immune disorder associated with loss of skin barrier function and itching. The Company was incorporated in the State of Delaware on June 26, 2008.

Liquidity

In June 2021, the Company entered into an Open Market Sale Agreement SM with Jefferies LLC ("Jefferies"), pursuant to which the Company could issue and sell shares of common stock under an at-the-market offering program (the "2021 ATM Program") which was completed in the first quarter of 2024. On March 4, 2024, the Company entered into a new Open Market Sale Agreement SM with Jefferies, pursuant to which the Company is able to issue and sell up to $150.0 million of shares of common stock under an at-the-market offering program (the "2024 ATM Program" and collectively with the 2021 ATM Program, the "ATM Programs"). The Company pays Jefferies commissions of up to 3% of the gross proceeds from any common stock sold through the ATM Programs. In the three months ended September 30, 2024, the Company sold an aggregate of 1,504,619 shares of common stock under the 2024 ATM Program for gross proceeds of $15.6 million and net proceeds of $15.2 million. In the nine months ended September 30, 2024, the Company sold an aggregate of 4,450,425 shares of common stock under the ATM programs for gross proceeds of $ 36.2 million and net proceeds of $35.2 million. There was no activity in the ATM Programs during the three and nine months ended September 30, 2023.

As of September 30, 2024, the Company had an accumulated deficit of $ 649.2 million and had available cash, cash equivalents and short-term investments of $344.3 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 anticipates that it will continue to incur significant operating losses for the next several years as it continues to develop its product candidates. 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 equity, debt or other financing or generate product revenue 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.

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, 2023 and the notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (the "2023 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 and nine months ended September 30, 2024 are not necessarily indicative of the results for the year ending December 31, 2024 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 Biosciences, Inc. 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 service providers.

Net Loss Per Share

Basic net loss per share attributable to common stockholders is calculated by dividing net loss attributable to common stockholders by the weighted average shares outstanding during the period, without consideration for common stock equivalents. The Company has included pre-funded warrants to purchase 1,571,093 shares of common stock at an exercise price of $ 0.001 per share in its computation of weighted average shares outstanding during the period. Diluted net loss per share attributable to common stockholders 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 attributable to common stockholders calculation, stock options and warrants to purchase the Company's common stock were considered to be common stock equivalents but were excluded from the calculation of diluted net loss per share attributable to common stockholders, as their effect would be anti-dilutive; therefore, basic and diluted net loss per share attributable to common stockholders 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 and Nine Months Ended September 30,	
	2024	2023
Common stock warrants	6,796,280	331,858
Stock options	6,564,686	3,321,448
Series X Preferred Stock	5,184,591	5,184,591
	18,545,557	8,837,897

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 with a maturity period of one business day at the time of purchase.

Restricted cash is comprised of deposits with a financial institution used to collateralize letters of credit related to the Company's lease arrangements. The Company does not hold any restricted cash as of September 30, 2024. Restricted cash is presented as a component of prepaid expenses and other current assets at September 30, 2023.

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):

	September 30,	
	2024	2023
Cash and cash equivalents	$ 80,899	$ 119,806
Restricted cash	—	163
Total	$ 80,899	$ 119,969

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 upon the stockholder approval of the conversion in June 2021. The issuance costs are recognized as a dividend at the time of conversion to common shares. As of September 30, 2024, $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 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)*, 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. The Company adopted this standard on January 1, 2024 with no material impact on the unaudited condensed consolidated financial statements.

In November 2023, the FASB issued Accounting Standards Update 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. The amendments in this update improve reportable segment disclosure requirements through enhanced disclosures about significant segment expenses. The Company adopted this standard on January 1, 2024 with no material impact on the unaudited condensed consolidated financial statements.

Summary of Significant Accounting Policies

The Company’s significant accounting policies are described in Note 2, “ *Summary of Significant Accounting Policies* ” in the 2023 Annual Report on Form 10-K, and there were no significant changes to such policies in the three and nine months ended September 30, 2024 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 September 30, 2024 and December 31, 2023, 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 and nine months ended September 30, 2024 and 2023.

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 September 30, 2024			
	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	$ 32,468	$ —	$ —	$ 32,468
Short-term investments:				
Treasury notes	104,073	—	—	104,073
Reverse repurchase agreements	—	100,000	—	100,000
Treasury bills	59,311	—	—	59,311
Total	$ 195,852	$ 100,000	$ —	$ 295,852

	As of December 31, 2023			
	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	$ 7,709	$ —	$ —	$ 7,709
Short-term investments:				
Reverse repurchase agreements	—	71,000	—	71,000
Total	$ 7,709	$ 71,000	$ —	$ 78,709

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 September 30, 2024 and December 31, 2023.

4. Short-Term Investments

The following table summarizes the short-term investments held at September 30, 2024 and December 31, 2023 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
September 30, 2024				
Treasury notes	$ 103,813	260	—	$ 104,073
Reverse repurchase agreements	100,000	—	—	100,000
Treasury bills	59,240	71	—	59,311
Total	$ 263,053	$ 331	$ —	$ 263,384

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2023				
Reverse repurchase agreements	$ 71,000	$ —	$ —	$ 71,000
Total	$ 71,000	$ —	$ —	$ 71,000

The contractual maturities of all short-term investments held at September 30, 2024 and December 31, 2023 were one year or less. There were no short-term investments in an unrealized loss position as of September 30, 2024 and December 31, 2023.

The Company is required to determine whether a decline in the fair value below the amortized cost basis of short-term investments is due to credit-related factors. At each reporting date, the Company performs an evaluation of impairment to determine if any unrealized losses are the result of credit losses. Impairment is assessed at the individual security level. Factors considered in determining whether a loss resulted from a credit loss or other factors include the Company's intent and ability to hold the investment until the recovery of its amortized cost basis, the extent to which the fair value is less than the amortized cost basis, the length of time and extent to which fair value has been less than the amortized cost basis, the financial condition of the issuer, any historical failure of the issuer to make scheduled interest or principal payments, any changes to the rating of the security by a rating agency, any adverse legal or regulatory events affecting the issuer or issuer's industry, and any significant deterioration in economic conditions.

Unrealized losses on short-term investments presented in the previous table have not been recognized in the condensed consolidated statements of operations because the securities are high credit quality, investment grade securities that the Company does not intend to sell and will not be required to sell prior to their anticipated recovery, and the decline in fair value is attributable to factors other than credit losses. Based on its evaluation, the Company determined it does not have any credit losses related to its short-term investments as of September 30, 2024 and December 31, 2023.

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 statements 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- and nine-month periods ended September 30, 2024 and 2023 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 statements of operations for the three and nine months ended September 30, 2024 and 2023.

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Accrued contracted costs	$ 7,159	$ 3,861
Accrued compensation	3,617	4,047
Accrued professional fees	2,126	1,485
Accrued other	167	315
Total	$ 13,069	$ 9,708

6. Commitments

On January 3, 2024, the Company entered into a sublease agreement (the "Sublease") with Duck Creek Technologies LLC to occupy 30,110 square feet of office space in Boston, Massachusetts to replace its existing office space. The Sublease commenced on June 1, 2024 and will end on November 30, 2028 (or on such earlier date as the term may cease or expire as set forth in the Sublease). The Company concluded that the Sublease was an operating lease and recognized a lease liability and right-of-use ("ROU") asset of approximately $5.8 million at the inception of the Sublease. The lease liability represents the present value of the remaining lease payments, discounted using the Company's estimated incremental borrowing rate of 7.49%. The ROU asset represents the lease liability adjusted for any prepaid and accrued rent payments. The Sublease is secured by a security deposit of $0.4 million. As of September 30, 2024, the remaining lease term of the Sublease was 4.2 years.

The Sublease is scheduled to expire in 2028. Future minimum payments required under the Sublease as of September 30, 2024 are summarized as follows (in thousands):

Period Ending September 30,	Amount
2024	$ 261
2025	1,576
2026	1,608
2027	1,640
2028	1,531
Total lease payments	$ 6,616
Less: imputed interest	(978)
Total operating lease liabilities	$ 5,638

Rent expense was $0.4 million and $0.2 million for the three months ended September 30, 2024 and 2023, respectively. Rent expense was $ 0.9 million and $0.5 million for the nine months ended September 30, 2024 and 2023, respectively. Lease payments were $ 0.4 million and $0.2 million for the three months ended September 30, 2024 and 2023, respectively. Lease payments were $0.9 million and $0.5 million for the nine months ended September 30, 2024 and 2023, respectively.

7. Stockholders' Equity

Preferred Stock

Under the Company's restated certificate of incorporation, as amended, 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. As of September 30, 2024, the Company had 31,107 shares of Series X Preferred Stock outstanding. Each share of Series X Preferred Stock is convertible into 166.67 shares of common stock and therefore the number of shares of underlying common stock issuable upon conversion of the Series X Preferred Stock is 5,184,591.

Outstanding Warrants

The following table presents information about warrants that are issued and outstanding at September 30, 2024:

Year Issued	Equity Instrument	Warrants Outstanding	Exercise Price	Date of Expiration
2023 (1)	Common Stock	6,796,280	$ 8.03	10/16/2028
Total		6,796,280		
Weighted average exercise price			$ 8.03	
Weighted average life in years				4.05

(1) 1,571,093 pre-funded warrants were issued in 2023 with an exercise price of $ 0.001 per share and are exercisable until all pre-funded warrants are exercised in full. 1,571,093 pre-funded warrants were outstanding as of September 30, 2024 and are not included in the table above.

8. Reserved for Future Issuance

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

	September 30, 2024	December 31, 2023
Warrants for the purchase of common stock	8,367,373	9,271,689
Reserve under the 2015 Second Amended and Restated Stock Incentive Plan and the 2022 Inducement Stock Incentive Plan	8,035,373	5,334,301
Options outstanding to purchase common stock	6,564,686	3,553,969
Series X Preferred Stock	5,184,591	5,184,591
Shares reserved for the employee stock purchase plan	49,139	43,060
Total	28,201,162	23,387,610

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, 2023	3,553,969	$ 13.59	8.39	$ 1,912
Granted	3,340,175	$ 14.14		
Exercised	(36,539)	$ 5.21		
Cancelled or forfeited	(291,247)	$ 12.43		
Expired	(1,672)	$ 414.04		
Outstanding at September 30, 2024	6,564,686	$ 13.87	8.50	$ 6,021
Vested and exercisable at September 30, 2024	2,001,026	$ 15.57	7.25	$ 2,808
Vested and expected to vest at September 30, 2024	6,564,686	$ 13.87	8.50	$ 6,021

The intrinsic value of stock options exercised was less than $ 0.1 million in the three months ended September 30, 2024 and 2023. The intrinsic value of stock options exercised in the nine months ended September 30, 2024 and 2023 was $0.2 million and $0.5 million, respectively. The total grant date fair value of stock options vested for the three months ended September 30, 2024 and 2023 was $1.6 million and $0.9 million, respectively. The total grant date fair value of stock options vested for the nine months ended September 30, 2024 and 2023 was $7.2 million and $3.6 million, respectively. The weighted-average grant date fair value of options granted to employees and non-employees for the three months ended September 30, 2024 and 2023 was $7.32 and $5.89, respectively. The weighted-average grant date fair value of options granted to employees and non-employees for the nine months ended September 30, 2024 and 2023 was $9.66 and $7.48, respectively.

At September 30, 2024, the total unrecognized compensation expense related to unvested stock option awards was $ 34.4 million. The Company expects to recognize that cost over a weighted-average period of approximately 3.0 years.

On February 17, 2022, the Company's board of directors adopted the 2022 Inducement Stock Incentive Plan (the "Inducement Plan"). The Inducement Plan, as amended, 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 1,700,000 shares of the Company's 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 September 30, 2024, options to purchase 1,179,550 shares of common stock are outstanding 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, 2023, or the 2023 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 the 2023 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 our company from management's perspective.

Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics for allergic and immunological diseases. Our focus is to develop first-choice therapies that improve the health and outcomes of patients with allergic and immunological diseases. Our lead product candidate is navenibart, formerly known as 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. Navenibart has the potential to be the most patient-friendly chronic treatment option for HAE, based on initial proof-of-concept data in HAE patients and the existing HAE treatment landscape. We believe that navenibart has the potential to become the market-leading HAE treatment if approved. Our second product candidate is STAR-0310, a monoclonal antibody OX40 antagonist that is in preclinical development for the treatment of atopic dermatitis, or AD, an immune disorder associated with loss of skin barrier function and itching. We believe that with both of these programs, we are advancing a pipeline of products with meaningfully differentiated profiles based on validated mechanisms.

Navenibart

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 navenibart 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 navenibart is to lead the HAE market and become the first-choice preventative treatment for HAE with administration every three and 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. Navenibart is currently in clinical development and the U.S. Food and Drug Administration, or FDA, has granted Fast Track and Orphan Drug designations to navenibart for the treatment of HAE. The European Commission has granted Orphan Medicinal Product Designation to navenibart for the treatment of HAE.

In February 2023, we advanced navenibart to a Phase 1b/2 trial called ALPHA-STAR, or Astria Long-acting Prophylaxis for Hereditary Angioedema: STAR-0215. 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, pharmacokinetics, or PK, pharmacodynamics, or PD, and quality of life in patients three and six months after subcutaneous navenibart administration. We reported initial proof-of-concept data in HAE patients in March 2024, as described below. Target enrollment of 16 patients was achieved with all doses administered. The initial efficacy and safety data-cut was as of March 13, 2024. We expect to report final data from ALPHA - STAR target enrollment in the fourth quarter of 2024.

Cohort 1 evaluated a 450 mg dose and all four patients had completed 6 months of follow-up. Efficacy observations compared to baseline through 6 months of follow-up were as follows:

- 92% reduction in monthly attack rate
- 96% reduction in moderate and severe attacks
- 91% reduction in acute rescue medication use
- 50% of patients were attack-free through 3 months of follow-up

Cohort 2 evaluated a 600 mg dose followed by a 300 mg dose three months later, on Day 84. We plan to evaluate this dosing regimen in our planned Phase 3 trial. All six patients had completed 3 months of follow-up and three patients had completed 6 months of follow-up as of the data cut-off date. Efficacy observations compared to baseline through 6 months of follow-up were as follows:

- 96% reduction in monthly attack rate
- 98% reduction in moderate and severe attacks
- 94% reduction in acute rescue medication use
- 67% of patients were attack-free
- 100% of patients were attack-free in the first month after dosing, demonstrating rapid onset of action

Cohort 3 received a 600 mg dose followed by a 600 mg dose one month later, on Day 28. Four of six patients had completed 3 months of follow-up as of the data cut-off date. Efficacy observations compared to baseline through 3 months of follow-up were as follows:

- 90% reduction in monthly attack rate
- 100% reduction in moderate and severe attacks
- 95% reduction in acute rescue medication use
- 50% of patients were attack-free

Navenibart was generally well-tolerated with no serious treatment-emergent adverse events, or TEAEs, and no discontinuations. There were two treatment-related TEAEs (both mild), one of which was a case of dizziness and the other a transient injection site reaction (rash). There were no injection site reactions of pain.

In October 2024, we presented new quality of life data from initial results from ALPHA-STAR at the American College of Allergy Asthma and Immunology (ACAAI) demonstrating that navenibart induced rapid improvements in quality of life in HAE patients. By Day 28 after navenibart administration, 80% of participants achieved clinically meaningful improvements.

Enrollment in ALPHA-STAR was expanded and a total of 29 patients were enrolled in the trial.

The observed efficacy, PK, PD, and safety and tolerability profile of navenibart support advancement of navenibart into Phase 3 development. We are in discussions with global regulatory authorities and are finalizing the design for the Phase 3 pivotal trial. Pending regulatory feedback, we expect to start a Phase 3 pivotal trial in the first quarter of 2025 and expect top-line results by year-end 2026. Our goal for navenibart is to enable patients to choose what works best for them by developing both every 3-month, or Q3M, and every 6-month, or Q6M, administration options.

We have initiated and are enrolling subjects in ALPHA-SOLAR, a long-term open-label trial assessing the long-term safety and efficacy of navenibart. All of the original 16 target enrollment patients from ALPHA-STAR have entered ALPHA-SOLAR. Participants are being assigned to receive navenibart in one of two dosing regimens: either 300mg Q3M or 600mg Q6M. We expect to report initial safety and efficacy data from ALPHA-SOLAR in mid-2025.

STAR-0310

We believe that OX40 inhibition has the potential to treat AD and other diseases. The current treatment options in AD are insufficient to address the needs of many patients, and standard of care treatments include steroids and topical medications which can treat symptoms but do not address the underlying disease. Our goal for STAR-0310 is to reduce disease activity, relapse rate, and treatment burden for patients with moderate-to-severe AD. STAR-0310 was engineered with YTE half-life extension technology to enable infrequent dosing. As a potential long-acting OX40 inhibitor, STAR-0310 aims to address the need for a safe, effective, and infrequently administered AD treatment.

In May 2024, we shared preclinical results for STAR-0310 at the European Academy of Allergy and Clinical Immunology (EAACI) conference. STAR-0310 exhibited a long mean half-life of 26 days in cynomolgus monkeys compared to a half-life of 10-14 days for a typical non-half-life extended IgG antibody. There was also an approximately 8-fold increase in binding affinity to human OX40 observed for STAR-0310 compared to telazorlimab, an earlier generation antibody prior to affinity maturation without half-life extension. Preclinical results demonstrated significantly less antibody-dependent cellular cytotoxicity, or ADCC, potential with STAR-

0310 compared to rocatinlimab, an anti-OX40 monoclonal antibody in Phase 3 development by Amgen, Inc., with comparable potency. Having less ADCC in the context of robust potency could potentially result in a favorable safety profile and potentially wider therapeutic window for STAR-0310. We believe these preclinical results support the potential for STAR-0310 to have the best-in-class OX40 inhibitor profile.

We are on track with the FDA investigational new drug application, or IND, for STAR-0310 for the treatment of AD by year-end. Assuming the IND clears, we anticipate initiating a Phase 1a clinical trial of STAR-0310 in healthy subjects in the first quarter of 2025 and reporting initial results from the Phase 1a clinical trial in the third quarter of 2025, including PK and PD data and early signals on safety and tolerability. Assuming positive results from the Phase 1a clinical trial, we plan to initiate a Phase 1b clinical trial of STAR-0310 in patients with AD in the second half of 2025 and would expect to report results from such trial in the second quarter of 2026. The goals of the Phase 1b trial would be to demonstrate initial efficacy in AD as well as show differentiation in safety and tolerability and the potential for a reduced treatment burden as a result of extended half-life as compared to existing therapies.

Underwritten Offerings

On October 16, 2023, we closed an underwritten offering of (i) 8,253,895 shares of our common stock and accompanying common stock warrants to purchase an aggregate of 6,190,418 shares of common stock and (ii), in lieu of common stock to certain investors, pre-funded warrants to purchase up to an aggregate of 1,571,093 shares of common stock and accompanying common stock warrants to purchase up to an aggregate of 1,178,320 shares of common stock, which we refer to as the October 2023 Financing. The gross proceeds of the October 2023 Financing were $64.0 million and net proceeds were $59.5 million.

On February 1, 2024, we closed an underwritten offering of 10,340,000 shares of our common stock, which we refer to as the February 2024 Financing. The gross proceeds of the February 2024 Financing were $125.0 million and net proceeds were $117.2 million.

Financial Overview

Our business is almost entirely dependent on the success of navenibart and STAR-0310. Navenibart is in clinical development and has only produced results in Phase 1a and Phase 1b/2 clinical testing and in preclinical and nonclinical settings. STAR-0310 is in the preclinical stage of development. Our net losses were $68.6 million and $41.5 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of $649.2 million. We have not generated any product revenues and have financed our operations primarily through public offerings and private placements of our equity securities and have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical development programs.

As of September 30, 2024, we had $344.3 million in cash, cash equivalents and short-term investments which we expect will enable us to fund our operating expenses and capital expenditure requirements into mid-2027, including all navenibart program activities through the completion of a planned Phase 3 pivotal trial as well as advancing our STAR-0310 OX40 program through submission of an IND and early proof-of-concept results from a Phase 1a clinical trial. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Advancing the development of navenibart, STAR-0310, 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 enable us to fund the completion of development of any of our product candidates, including navenibart, STAR-0310 or any future product candidate. We will need to obtain substantial additional funding to complete the development and commercialization of navenibart, STAR-0310 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, or CROs, 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 and clinical trial 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):

	Nine Months Ended September 30,	
	2024	2023
Navenibart	$ 23,868	$ 18,278
STAR-0310	12,224	—
Other programs	655	2,836
Costs not directly allocated to programs:		
Employee expenses including cash compensation, benefits and stock-based compensation	12,996	7,920
Consultants and professional expenses, including stock-based compensation	5,964	957
Facilities	570	234
Other	668	235
Total costs not directly allocated to programs	20,198	9,346
Total research and development expenses	$ 56,945	$ 30,460

We expect to incur significant research and development expenses in the year ending December 31, 2024, and in future periods in connection with the clinical trials and other activities related to the development of navenibart and the preclinical studies, planned clinical trials and other activities related to the development of STAR-0310. 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 navenibart, STAR-0310 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 navenibart, STAR-0310 or any other future product candidates. This is due to the fact that we would need to raise substantial additional capital to fund the completion of 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, preclinical 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
- maintaining a continued acceptable safety profile following approval.

A change in the outcome of any of these variables with respect to the development of navenibart, STAR-0310 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, information technology, new product planning, business development, 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 navenibart and STAR-0310, 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 nine months ended September 30, 2024, there were no material changes to our critical accounting policies as reported in our 2023 Annual Report on Form 10-K.

Results of Operations

Comparison of the Three Months Ended September 30, 2024 and 2023

The following table summarizes our results of operations for the three months ended September 30, 2024 and 2023, together with the dollar change in those items (in thousands):

	Three Months Ended September 30,		Period-to-Period Change
	2024	2023	
Operating expenses:			
Research and development	$ 20,510	$ 13,338	$ 7,172
General and administrative	8,504	6,898	1,606
Total operating expenses	29,014	20,236	8,778
Loss from operations	(29,014)	(20,236)	(8,778)
Other income, net	4,480	2,509	1,971
Net loss	$ (24,534)	$ (17,727)	$ (6,807)

Research and Development Expenses

Research and development expenses increased by $7.2 million to $20.5 million for the three months ended September 30, 2024 from $13.3 million for the three months ended September 30, 2023, an increase of 54%. The increase in research and development expenses was primarily associated with the STAR-0310 program's manufacturing and IND-enabling activities in addition to an increase

in external expenses to support a planned Phase 3 pivotal trial for navenibart. These research and development activities resulted in a $3.5 million increase in expenses related to external research, manufacturing, and IND-enabling activities related to the STAR-0310 program, a $2.4 million increase in consulting expenses primarily to support the planned Phase 3 pivotal trial for navenibart, a $1.9 million increase in employee expenses due to a $0.7 million increase in employee stock-based compensation expenses and additional costs related to company growth, and a $0.3 million increase in facilities and other costs, partially offset by a $0.6 million decrease in expenses attributable to other research programs and a $0.3 million decrease in external research and development costs associated with the navenibart program.

We expect that our research and development expenses over the next several quarters will be higher than prior periods. We anticipate initiating a Phase 3 pivotal trial for navenibart in the first quarter of 2025 in addition to initiating a Phase 1a clinical trial of STAR-0310 in the first quarter of 2025.

General and Administrative Expenses

General and administrative expenses increased by $1.6 million to $8.5 million for the three months ended September 30, 2024 from $6.9 million for the three months ended September 30, 2023, an increase of 23%. The increase in general and administrative expenses was attributable to a $1.5 million increase in employee expenses primarily due to a $0.9 million increase in employee stock-based compensation expenses and additional costs related to company growth, a $0.1 million increase in facilities costs and a $0.1 million increase in general office expenses, partially offset by a $0.1 million decrease in other costs such as insurance and professional service expenses.

Other Income, Net

Other income, net increased by $2.0 million to $4.5 million for the three months ended September 30, 2024 from $2.5 million for the three months ended September 30, 2023, an increase of 79%. The increase was primarily attributable to an increase in interest and investment income due to an increase in interest-earning assets from the proceeds of financing activities.

Comparison of the Nine Months Ended September 30, 2024 and 2023

The following table summarizes our results of operations for the nine months ended September 30, 2024 and 2023, together with the dollar change in those items (in thousands):

	Nine Months Ended September 30,		Period-to-Period Change
	2024	2023	
Operating expenses:			
Research and development	$ 56,945	$ 30,460	$ 26,485
General and administrative	25,022	18,371	6,651
Total operating expenses	81,967	48,831	33,136
Loss from operations	(81,967)	(48,831)	(33,136)
Other income, net	13,333	7,350	5,983
Net loss	$ (68,634)	$ (41,481)	$ (27,153)

Research and Development Expenses

Research and development expenses increased by $26.5 million to $57.0 million for the nine months ended September 30, 2024 from $30.5 million for the nine months ended September 30, 2023, an increase of 87%. The increase in research and development expenses was associated with the STAR-0310 program's manufacturing and IND-enabling activities in addition to external research and development costs associated with the navenibart program's advancement in our multi-site international clinical trials and start-up activities to support a planned Phase 3 pivotal trial. These research and development activities resulted in a $12.2 million increase in expenses related to external research, manufacturing, and IND-enabling activities related to the STAR-0310 program, a $5.6 million increase in CRO and manufacturing expenses to support the ALPHA-STAR and ALPHA-SOLAR clinical trials in addition to start-up activities to support a planned Phase 3 pivotal trial for navenibart, a $5.1 million increase in employee expenses due to a $1.8 million increase in employee stock-based compensation expenses and additional costs related to company growth, a $5.0 million increase in consulting expenses, and a $0.8 million increase in facilities and other costs, partially offset by a $2.2 million decrease in expenses attributable to other research programs.

General and Administrative Expenses

General and administrative expenses increased by $6.6 million to $25.0 million for the nine months ended September 30, 2024 from $18.4 million for the nine months ended September 30, 2023, an increase of 36%. The increase in general and administrative expenses was attributable to a $5.2 million increase in employee expenses primarily due to a $3.1 million increase in employee stock-based compensation expenses and additional costs related to company growth, a $1.0 million increase in professional services due to increased legal fees and consulting expenses, and a $0.4 million increase in other costs, including general office, facilities, and insurance expenses.

Other Income, Net

Other income, net increased by $6.0 million to $13.3 million for the nine months ended September 30, 2024 from $7.3 million for the nine months ended September 30, 2023. The increase was primarily attributable to an increase in interest and investment income due to an increase in interest-earning assets from the proceeds of financing activities.

Liquidity and Capital Resources

From our inception through September 30, 2024, we raised an aggregate of $839.2 million through equity financings including private placements of preferred stock before we became a public company, our private placement of preferred stock in February 2021 and registered offerings of our common stock, including our at-the-market offering programs.

As of September 30, 2024, we had $344.3 million in cash, cash equivalents and short-term investments which we expect will enable us to fund our operating expenses and capital expenditure requirements into mid-2027, including all navenibart program activities through the completion of a planned Phase 3 pivotal trial, as well as advancing our STAR-0310 OX40 program through submission of an IND and early proof-of-concept results from a Phase 1a trial. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. 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.

Advancing the development of navenibart, STAR-0310, or any future product candidates will require a significant amount of capital and our existing cash, cash equivalents and short-term investments will not be sufficient to enable us to fund the completion of development of any of our product candidates, including navenibart, STAR-0310 or any future product candidate. In addition, navenibart, STAR-0310, 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 obtain substantial additional funding to complete the development and commercialization of navenibart, STAR-0310 or any future product candidates, support our continuing operations, future clinical trials and the expansion of our pipeline. 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 pandemics, epidemics and geopolitical events, including civil or political unrest (such as the Ukraine-Russian war and the conflict in the Middle East), 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.

October 2023 Financing

On October 16, 2023, we closed the October 2023 Financing, in which we sold (i) 8,253,895 shares of our common stock and accompanying common stock warrants to purchase an aggregate of 6,190,418 shares of common stock and (ii), in lieu of common stock to certain investors, pre-funded warrants to purchase up to an aggregate of 1,571,093 shares of common stock and accompanying common stock warrants to purchase up to an aggregate of 1,178,320 shares of common stock for aggregate gross proceeds of $64.0 million and net proceeds of $59.5 million.

February 2024 Financing

On February 1, 2024, we closed the February 2024 Financing, in which we sold 10,340,000 shares of our common stock for gross proceeds of $125.0 million and net proceeds of $117.2 million.

At-the-Market Offerings

In June 2021, we entered into an Open Market Sale Agreement℠ with Jefferies LLC, or Jefferies, pursuant to which we could issue and sell shares of common stock under an at-the-market offering program, or the 2021 ATM Program, which was completed in the first quarter of 2024. On March 4, 2024, we entered into a new Open Market Sale Agreement℠ with Jefferies, pursuant to which we are able to issue and sell up to $150.0 million of shares of common stock under an at-the-market offering program, or the 2024 ATM Program, and collectively with the 2021 ATM Program, the ATM Programs. We pay Jefferies commissions of up to 3% of the gross proceeds from any common stock sold through the ATM Programs. In the three months ended September 30, 2024, we sold an aggregate of 1,504,619 shares of common stock under the 2024 ATM Program for gross proceeds of $15.6 million and net proceeds of $15.2 million. In the nine months ended September 30, 2024, we sold an aggregate of 4,450,425 shares of common stock under the ATM programs for gross proceeds of $36.2 million and net proceeds of $35.2 million. There was no activity in the ATM Programs during the three and nine months ended September 30, 2023.

Cash Flows

Comparison of the Nine Months Ended September 30, 2024 and 2023

The following table provides information regarding our cash flows for the nine months ended September 30, 2024 and 2023 (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Net cash used in operating activities	$ (63,850)	$ (38,207)
Net cash (used in) provided by investing activities	(188,146)	137,068
Net cash provided by financing activities	157,202	420
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (94,794)	$ 99,281

Net Cash Used in Operating Activities

Net cash used in operating activities was $63.9 million for the nine months ended September 30, 2024 and consisted primarily of a net loss of $68.6 million adjusted for stock-based compensation expense of $9.6 million, partially offset by accretion of the discount/premium on investment securities of $4.2 million, a decrease to our right of use asset of $0.7 million, and a decrease in net assets of $1.4 million, which resulted primarily from an increase in prepaid expenses and other assets of $4.1 million, a decrease in the lease liability of $0.4 million and a decrease in accounts payable of $0.2 million, partially offset by an increase in accrued expenses of $3.3 million.

Net cash used in operating activities was $38.2 million for the nine months ended September 30, 2023 and consisted primarily of a net loss of $41.5 million adjusted for stock-based compensation expense of $4.2 million, a decrease to our right of use asset of $0.4 million, and offset by a net decrease in net assets of $1.3 million, which resulted primarily from an increase in prepaid expenses of $1.3 million.

Net Cash (Used in) Provided by Investing Activities

Net cash used in investing activities was $188.1 million for the nine months ended September 30, 2024 and consisted primarily of purchases of short-term investments of $3.5 billion, partially offset by maturities of short-term investments of $3.3 billion as the proceeds from maturities of short-term investments, primarily repurchase agreements with maturities due within five days or less, were purchased and reinvested during the nine months ended September 30, 2024. Net cash provided by investing activities was $137.1 million for the nine months ended September 30, 2023 and consisted primarily of maturities of short-term investments of $1.4 billion, partially offset by purchases of short-term investments of $1.2 billion.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $157.2 million for the nine months ended September 30, 2024, which was attributable to net proceeds of $117.2 million from the February 2024 Financing, net proceeds of $35.2 million from the ATM Programs and proceeds from exercises of stock options and warrants of $4.8 million. Net cash provided by financing activities was $0.4 million for the nine months ended September 30, 2023, which was attributable to proceeds from exercises of stock options of $0.4 million.

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 September 30, 2024, we had an accumulated deficit of $649.2 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.

Based on our current operating plan, we expect that our existing cash, cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditure requirements into mid-2027, including all navenibart program activities through the completion of a planned Phase 3 pivotal trial, as well as advancing our STAR-0310 OX40 program through submission of an IND and early proof-of-concept results from a Phase 1a trial. 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 navenibart, STAR-0310 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 navenibart in HAE and STAR-0310 in AD;
- our headcount growth and associated costs;
- the amount and timing of future milestone and royalty payments potentially payable to Ichnos Sciences SA and Ichnos Sciences Inc., or collectively Ichnos, pursuant to our October 2023 license agreement covering STAR-0310;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims; 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, navenibart, STAR-0310 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.

Material Cash Requirements from Known Contractual Obligations

Our material cash requirements from known contractual and other obligations as of September 30, 2024 are primarily related to our sublease agreements for office space. For information related to our future commitments relating to our sublease agreement, see Note 6, "Commitments", of our condensed consolidated financial statements.

We enter into agreements in the normal course of business with CROs for clinical trials, with third party manufacturers for clinical supplies and with vendors for preclinical research studies and other services and products for operating purposes. The contracts are cancelable at any time by us, generally upon 30 to 90 days' prior written notice to the counterparty, and we believe that our non-cancelable obligations under these agreements are not material.

Our license agreement with Ichnos which covers STAR-0310 includes potential milestone payments, tiered royalties and other obligations that are dependent upon the development of products using the intellectual property licensed under the agreement and contingent upon the achievement of development or regulatory approval milestones, as well as commercial milestones. These potential obligations are contingent upon future events and the timing and likelihood of such potential obligations are not known with certainty. For further information regarding this agreement, please see Note 1, "*Organization and Operations*" in our 2023 Annual Report on Form 10-K.

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 September 30, 2024, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the nine months ended September 30, 2024, 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, 2023, 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 5. Other Information

During the third quarter of 2024, Chris Morabito, our Chief Medical Officer, adopted a Rule 10b5-1 trading arrangement for the sale of our common stock that is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Securities Exchange Act of 1934, as amended. This plan was adopted on September 25, 2024. Sales under the plan may begin on February 18, 2025 and no sales may be made after November 19, 2025. Pursuant to the plan, the aggregate number of options to be exercised, and the aggregate number of shares of common stock to be sold upon exercise of those options, is not to exceed 20,000.

None of our other directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (each as defined in Item 408 of Regulation S-K) during the third quarter of 2024.

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
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: November 13, 2024

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: November 13, 2024

/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: November 13, 2024

/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 September 30, 2024 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: November 13, 2024

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

Date: November 13, 2024

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