

**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 **June 30, 2022**

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
(State or Other Jurisdiction of
Incorporation or Organization)
75 State Street
Suite 1400
Boston, Massachusetts
(Address of Principal Executive Offices)

26-3687168
(IRS Employer
Identification No.)

02109
(Zip Code)

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

100 High Street, Floor 28
Boston, Massachusetts 02110
(Former name, former address and former fiscal year, if changed since last report)

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 July 29, 2022, there were 13,016,955 shares of the registrant's common stock, par value \$0.001 per share, outstanding.

TABLE OF CONTENTS

	<u>Page</u>
<u>PART I. FINANCIAL INFORMATION</u>	2
<u>Item 1. Financial Statements (unaudited)</u>	2
<u>Condensed Consolidated Balance Sheets as of June 30, 2022 and December 31, 2021</u>	2
<u>Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2022 and 2021</u>	3
<u>Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2022 and 2021 the three months ended June 30, 2022 and 2021</u>	4
<u>Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity for the three months ended March 31, 2022 and 2021 and the three months ended June 30, 2022 and 2021</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2022 and 2021</u>	7
<u>Notes to Condensed Consolidated Financial Statements</u>	8
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	18
<u>Item 4. Controls and Procedures</u>	27
<u>PART II. OTHER INFORMATION</u>	28
<u>Item 1A. Risk Factors</u>	28
<u>Item 6. Exhibits</u>	28
<u>SIGNATURES</u>	29

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

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

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

- our expectations regarding the timing, plans, goals and results of our Phase 1a clinical trial and our planned Phase 1b/2 clinical trials of STAR-0215, including that favorable results from such trials could establish proof of concept for the differentiation of STAR-0215 as a potential treatment for hereditary angioedema (“HAE”);
- our expectations about the unmet medical need for HAE, the potential differentiating attributes of STAR-0215 as a potential treatment for HAE, along with the potential market impact of such differentiation, the potential of STAR-0215 to be a best-in-class and the most patient friendly treatment for HAE, and the nature and anticipated growth of the global HAE market and HAE therapies;
- our expectations that we have identified a stable cell line for STAR-0215 and the ability of such cell line to generate sufficient material of suitable and appropriate quality for our Phase 1a clinical trial of STAR-0215 and our planned STAR-0215 preclinical and clinical studies in a timely manner;
- 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 revenues, 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, 2021, 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)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 29,826	\$ 86,508
Short-term investments	72,652	39,000
Prepaid expenses and other current assets	1,343	1,567
Total current assets	103,821	127,075
Right-of-use asset	1,282	394
Other assets	190	45
Total assets	<u>\$ 105,293</u>	<u>\$ 127,514</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 995	\$ 1,557
Accrued expenses	3,657	3,281
Current portion of operating lease liabilities	573	365
Total current liabilities	5,225	5,203
Long term portion of operating lease liabilities	649	—
Total liabilities	5,874	5,203
Commitments (Note 7)		
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; 31,455 shares issued and outstanding as of June 30, 2022 and December 31, 2021	96,398	96,398
Common stock, \$0.001 par value per share, 150,000,000 shares authorized; 13,016,955 shares issued and outstanding at June 30, 2022 and December 31, 2021	13	13
Additional paid-in capital	485,577	481,709
Accumulated other comprehensive loss	(186)	—
Accumulated deficit	(482,383)	(455,809)
Total stockholders' equity	99,419	122,311
Total liabilities and stockholders' equity	<u>\$ 105,293</u>	<u>\$ 127,514</u>

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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 6,617	\$ 3,478	\$ 16,975	\$ 6,071
General and administrative	4,832	4,008	9,852	6,881
Acquired in-process research and development	—	—	—	164,617
Total operating expenses	<u>11,449</u>	<u>7,486</u>	<u>26,827</u>	<u>177,569</u>
Loss from operations	(11,449)	(7,486)	(26,827)	(177,569)
Other income (expense):				
Interest and investment income	214	40	269	53
Other expense, net	(15)	(20)	(16)	(34)
Total other income, net	<u>199</u>	<u>20</u>	<u>253</u>	<u>19</u>
Net loss	(11,250)	(7,466)	(26,574)	(177,550)
Dividend on convertible preferred stock related to beneficial conversion feature and issuance costs	—	(24,437)	—	(24,437)
Net loss attributable to common shareholders	<u>\$ (11,250)</u>	<u>\$ (31,903)</u>	<u>\$ (26,574)</u>	<u>\$ (201,987)</u>
Net loss per share - basic and diluted	<u>\$ (0.86)</u>	<u>\$ (5.33)</u>	<u>\$ (2.04)</u>	<u>\$ (41.55)</u>
Weighted-average common shares outstanding used in net loss per share - basic and diluted	<u>13,016,955</u>	<u>5,980,097</u>	<u>13,016,955</u>	<u>4,861,279</u>

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)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Net loss	\$ (11,250)	\$ (7,466)	\$ (26,574)	\$ (177,550)
Other comprehensive loss:				
Unrealized loss on short-term investments, net of tax of \$0	(133)	—	(186)	—
Total other comprehensive loss:	(133)	—	(186)	—
Comprehensive loss	<u>\$ (11,383)</u>	<u>\$ (7,466)</u>	<u>\$ (26,760)</u>	<u>\$ (177,550)</u>

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 Preferred Stock		Series X Preferred Stock		Common Stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total stockholders' equity (deficit)
	Series X redeemable convertible preferred stock, shares	Series X redeemable convertible preferred stock, value	Series X redeemable convertible preferred stock, shares	Series X redeemable convertible preferred stock, value	Common stock, shares	Common stock, par value				
Balance at December 31, 2020	—	\$ —	—	\$ —	3,347,386	\$ 4	\$ 301,562	\$ (260,897)	\$ —	\$ 40,669
Issuance of preferred stock in a private offering of public equity, net of issuance costs	35,573	84,696	—	—	—	—	19,565	—	—	19,565
Issuance of preferred stock and common stock upon acquisition of Quellis	50,504	156,185	—	—	555,444	—	8,098	—	—	8,098
Expense related to warrants inherited in acquisition of Quellis	—	—	—	—	—	—	241	—	—	241
Stock-based compensation expense	—	—	—	—	—	—	366	—	—	366
Net loss	—	—	—	—	—	—	—	(170,084)	—	(170,084)
Balance at March 31, 2021	86,077	240,881	—	—	3,902,830	4	329,832	(430,981)	—	(101,145)
Reclassification of preferred stock to permanent equity	(86,077)	(240,881)	86,077	240,881	—	—	—	—	—	(101,145)
Issuance of common stock upon the conversion of preferred stock	—	—	(53,532)	(165,548)	8,921,966	9	165,540	—	—	1
Expense related to warrants inherited in acquisition of Quellis	—	—	—	—	—	—	146	—	—	146
Accretion of preferred stock discount	—	—	—	24,437	—	—	(24,437)	—	—	—
Reclassification of equity classified warrants	—	—	—	—	—	—	3,468	—	—	3,468
Stock-based compensation expense	—	—	—	—	—	—	1,014	—	—	1,014
Net loss	—	—	—	—	—	—	—	(7,466)	—	(7,466)
Balance at June 30, 2021	—	\$ —	32,545	\$ 99,770	12,824,796	\$ 13	\$ 475,563	\$ (438,447)	\$ —	\$ 136,899

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 Preferred Stock		Series X Preferred Stock		Common Stock			Accumulated deficit	Accumulated other comprehensive loss	Total stockholders' equity (deficit)
	Series X redeemable convertible preferred stock, shares	Series X redeemable convertible preferred stock, value	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			
Balance at December 31, 2021	—	\$ —	31,455	\$ 96,398	13,016,955	\$ 13	\$ 481,709	\$ (455,809)	\$ —	\$ 122,311
Expense related to warrants inherited in acquisition of Quellis	—	—	—	—	—	—	1,542	—	—	1,542
Stock-based compensation expense	—	—	—	—	—	—	1,209	—	—	1,209
Unrealized loss on short-term investments	—	—	—	—	—	—	—	—	(53)	(53)
Net loss	—	—	—	—	—	—	—	(15,324)	—	(15,324)
Balance at March 31, 2022	—	—	31,455	96,398	13,016,955	13	484,460	(471,133)	(53)	109,685
Expense related to warrants inherited in acquisition of Quellis	—	—	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	1,117	—	—	1,117
Unrealized loss on short-term investments	—	—	—	—	—	—	—	—	(133)	(133)
Net loss	—	—	—	—	—	—	—	(11,250)	—	(11,250)
Balance at June 30, 2022	—	\$ —	31,455	\$ 96,398	13,016,955	\$ 13	\$ 485,577	\$ (482,383)	\$ (186)	\$ 99,419

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

(Unaudited)

	Six Months Ended June 30,	
	2022	2021
Operating activities		
Net loss	\$ (26,574)	\$ (177,550)
Reconciliation of net loss to net cash used in operating activities:		
Non-cash portion of acquired in-process research and development	—	164,612
Stock-based compensation expense	2,326	1,380
Expense (gain) on warrants inherited in acquisition of Quellis	1,542	(700)
Other non-cash items	79	10
Changes in assets and liabilities:		
Prepaid expenses and other assets	224	999
Right-of-use asset- operating lease	(31)	(85)
Accounts payable	(562)	(2,900)
Accrued expenses	376	(1,882)
Net cash used in operating activities	<u>(22,620)</u>	<u>(16,116)</u>
Investing activities		
Purchases of short-term investments	(164,889)	—
Sales and maturities of short-term investments	130,992	20,000
Cash acquired in acquisition of Quellis	—	6,466
Purchases of property and equipment	(2)	(21)
Net cash (used in) provided by investing activities	<u>(33,899)</u>	<u>26,445</u>
Financing activities		
Proceeds from private offering of public equity, net of issuance costs	—	104,261
Net cash provided by financing activities	—	104,261
Net (decrease) increase in cash, cash equivalents and restricted cash	(56,519)	114,590
Cash, cash equivalents and restricted cash, beginning of period	86,629	25,051
Cash, cash equivalents and restricted cash, end of period	<u>\$ 30,110</u>	<u>\$ 139,641</u>
Supplemental disclosure of non-cash transactions:		
Conversion of Series X Preferred Stock into common stock	\$ —	\$ 165,549
Non-cash dividend on convertible preferred stock	\$ —	\$ 24,437
Reclassification of warrant liability to additional paid-in capital	\$ —	\$ 3,468

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

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

1. Organization and Operations

The Company

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

Reverse Stock Split

On August 19, 2021, the Company effected a reverse stock split of its outstanding shares of common stock at a ratio of one-for-six (1:6) pursuant to a Certificate of Amendment to its Restated Certificate of Incorporation filed with the Secretary of State of the State of Delaware. Pursuant to the reverse stock split, every six shares of the Company’s issued and outstanding shares of common stock were automatically combined into one issued and outstanding share of common stock, without any change in the par value per share of the common stock. Amounts of common stock resulting from the reverse stock split were rounded down to the nearest whole share and any resulting fractional shares were cancelled for cash. The number of authorized shares of the Company’s common stock remained unchanged. The reverse stock split affected all issued and outstanding shares of the Company’s common stock, and the respective numbers of shares of common stock underlying the Company’s outstanding Series X Preferred Stock (as defined below), outstanding stock options, outstanding warrants and the Company’s equity incentive plans were proportionately adjusted. All share and per share amounts of the common stock included in the accompanying unaudited condensed consolidated financial statements have been retrospectively adjusted to give effect to the reverse stock split for all periods presented, including reclassifying an amount equal to the reduction in par value to additional paid-in capital.

Agreement and Plan of Merger

On January 28, 2021, the Company acquired Quellis (the “Quellis Acquisition”). Under the terms of that certain agreement and plan of merger, dated January 28, 2021 (the “Merger Agreement”), the Company issued to the stockholders of Quellis 555,444 shares of the Company’s common stock, par value \$0.001 per share, and 50,504 shares of newly designated Series X redeemable convertible preferred stock (“Series X Preferred Stock”) (as described below). The Series X Preferred Stock had a conversion value on the closing date of \$122.7 million. In addition, the Company assumed options granted under the Quellis 2019 Stock Incentive Plan, which became options to purchase 55,414 shares of the Company’s common stock, a warrant to purchase 2,805 shares of Series X Preferred Stock at an exercise price of \$341.70 per share, and a warrant to purchase 30,856 shares of the Company’s common stock at an exercise price of \$2.10 per share. Upon stockholder approval of the Conversion Proposal (as defined below) on June 2, 2021, the warrant to purchase Series X Preferred Stock was converted into the right to purchase 467,500 shares of the Company’s common stock at a per share exercise price of \$2.10 per share.

Stock Purchase Agreement and Series X Preferred Stock

Concurrent with the Quellis Acquisition, the Company entered into a Stock Purchase Agreement (the “Purchase Agreement”) with certain institutional and accredited investors. Pursuant to the Purchase Agreement, the Company sold an aggregate of 35,573 shares of Series X Preferred Stock for gross proceeds of approximately \$110.0 million, and net proceeds of \$104.3 million (the “February 2021 Financing”). Each share of Series X Preferred Stock is convertible into 166.67 shares of common stock. In accounting for the Purchase Agreement, the Company recorded a beneficial conversion feature of \$19.6 million and issuance costs of \$5.7 million. The combined total was treated as a discount to the value of Series X Preferred Stock, see Note 2, “*Summary of Significant Accounting Policies*” for further discussion.

As a result of the Quellis Acquisition and the February 2021 Financing, the Company issued the following Series X Preferred Stock and assumed the following warrant:

	Series X Preferred Stock at Transaction Date	Common Stock Issuable Upon Conversion at Transaction Date
Shares issued in merger	50,504	8,417,502
Shares issued in February 2021 Financing	35,573	5,928,952
Warrant assumed in merger	2,805	467,500
Total	<u>88,882</u>	<u>14,813,954</u>

At its Annual Meeting of Stockholders on June 2, 2021, the Company’s stockholders approved the conversion of the Company’s Series X Preferred Stock into shares of the Company’s common stock in accordance with Nasdaq Listing Rule 5635(a) (the “Conversion Proposal”). Following stockholder approval of the Conversion Proposal, each share of Series X Preferred Stock then outstanding automatically converted into 166.67 shares of the Company’s common stock, subject to certain beneficial ownership limitations, including that a holder of Series X Preferred Stock is prohibited from converting shares of Series X Preferred Stock into shares of the Company’s common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than a specified percentage (as of June 30, 2022, these percentages are set at 4.99% to 9.99% and can be adjusted by the holder to a number between 4.99% and 19.99)% of the total number of shares of the Company’s common stock issued and outstanding immediately after giving effect to such conversion. As of June 30, 2022, 54,622 shares of Series X Preferred Stock have been converted into 9,103,664 shares of common stock and 31,455 shares of Series X Preferred Stock remained outstanding. Each share of Series X Preferred Stock is convertible into 166.67 shares of common stock. At June 30, 2022, the number of shares of common stock issuable upon conversion of the remaining outstanding shares of Series X Preferred Stock is 5,242,501. Outstanding shares of Series X Preferred Stock are subject to conversion at the option of the holder.

Holders of Series X Preferred Stock are entitled to receive dividends, subject to certain beneficial ownership limitations, on shares of Series X Preferred Stock equal, on an as-if-converted-to-common-stock basis, and in the same form as dividends actually paid on shares of the Company’s common stock. Except as otherwise required by law, the Series X Preferred Stock does not have voting rights. However, as long as any shares of Series X Preferred Stock are outstanding, the Company may not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series X Preferred Stock, (i) alter or change adversely the powers, preferences or rights given to the Series X Preferred Stock or alter or amend the Certificate of Designation that authorized the Series X Preferred Stock, amend or repeal any provision of, or add any provision to, the Company’s Restated Certificate of Incorporation or bylaws, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of preferred stock, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the Series X Preferred Stock, (ii) issue further shares of Series X Preferred Stock or increase or decrease (other than by conversion) the number of authorized shares of Series X Preferred Stock, or (iii) enter into any agreement with respect to any of the foregoing.

Liquidity

The Company had entered into various sales agreements with Cowen and Company LLC (“Cowen”) pursuant to which the Company could issue and sell shares of common stock under at-the-market offering programs. On May 20, 2021, the Company terminated its sales agreement with Cowen. On June 30, 2021, the Company entered into an Open Market Sale AgreementSM with Jefferies LLC (the “Jefferies Sale Agreement”) pursuant to which the Company can issue and sell shares of common stock of up to \$25.0 million under at-the-market offering programs (collectively, with the Cowen at-the-market offering program, the “ATM Programs”). The Company pays the sales agent commissions of 3% of the gross proceeds from any common stock sold through the ATM Programs. As of June 30, 2022, the Company has not sold any shares of common stock pursuant to the Jefferies Sale Agreement. There was also no activity from the ATM Programs during the six months ended June 30, 2021.

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

As of June 30, 2022, the Company had an accumulated deficit of \$482.4 million and had available cash, cash equivalents and short-term investments of \$102.5 million. The Company has determined that its existing cash, cash equivalents and short-term investments will be sufficient to meet its projected operating expenses and capital expenditure requirements for at least 12 months from the date of issuance of these unaudited condensed consolidated financial statements. The Company has not generated any product revenues and has financed its operations primarily through public offerings and private placements of its equity securities. There can be no assurance that the Company will be able to obtain additional debt, equity or other financing or generate product revenues or revenues from collaborative partners on terms acceptable to the Company, on a timely basis or at all. Management’s conclusion with respect to its ability to fund its operations is based on estimates that are subject to risks and uncertainties that may prove to be incorrect. If actual results differ from management’s estimates, the Company may be required to seek additional funding or curtail planned activities to reduce operating expenses, which may have an adverse impact on the Company’s ability to achieve its business objectives.

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, 2021 and notes thereto included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (the “2021 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 six months ended June 30, 2022 are not necessarily indicative of the results for the year ending December 31, 2022 or for any future period.

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

Use of Estimates

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

[Table of Contents](#)

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

Net Loss Per Share

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

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

	Three and Six Months Ended June 30,	
	2022	2021
Series X Preferred Stock	5,242,501	5,424,201
Stock options	2,106,150	1,321,722
Common stock warrants	1,530,176	1,530,648
	<u>8,878,827</u>	<u>8,276,570</u>

Cash, Cash Equivalents and Restricted Cash

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

Restricted cash is comprised of deposits with a financial institution used to collateralize letters of credit related to the Company's lease arrangements. Restricted cash is presented as a component of prepaid expenses and other current assets and other long-term assets at June 30, 2022 and other long-term assets at June 30, 2021.

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):

	June 30,	
	2022	2021
Cash and cash equivalents	\$ 29,826	\$ 139,520
Restricted cash	284	121
Total	<u>\$ 30,110</u>	<u>\$ 139,641</u>

Acquired In-Process Research and Development

The Company measures and recognizes asset acquisitions that are not deemed to be business combinations based on the cost to acquire the assets, which includes transaction costs. Goodwill is not recognized in asset acquisitions. In an asset acquisition, the cost allocated to acquire in-process research and development ("IPR&D") with no alternative future use is charged to expense at the acquisition date. Refer to Note 3, "Acquisition of Quellis" for a more detailed description of the accounting policy utilized for the recent asset acquisition.

Preferred Stock Discount

As discussed above, 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 is recognized through the earliest possible date of conversion, which occurred upon stockholder approval of the Conversion Proposal in June 2021. The issuance costs are recognized as a dividend at the time of conversion to common shares. As of June 30, 2022, \$24.4 million of the above amounts were accounted for as a non-cash dividend related to shares of Series X Preferred Stock, and \$0.9 million remained to be recognized upon future conversion.

Recent Accounting Pronouncements - Not Yet Adopted

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

In June 2016, the FASB issued Accounting Standards Update 2016-13, *Financial Instruments-Credit Losses* (Topic 326). This standard requires a financial asset to be presented at amortized cost basis at the net amount expected to be collected. It also requires that credit losses relating to available-for-sale debt securities should be recorded through an allowance for credit losses. In November 2019, the FASB issued an amendment making this standard effective for annual reporting periods beginning after December 15, 2022 for smaller reporting companies. Early adoption is permitted. The Company is currently evaluating the impact that this standard will have on its consolidated financial statements as well as the timing of when this standard will be adopted.

Summary of Significant Accounting Policies

The Company’s significant accounting policies are described in Note 2, “*Summary of Significant Accounting Policies*” in the 2021 Annual Report on Form 10-K, and there were no significant changes to such policies in the three and six months ended June 30, 2022 that had a material impact on the Company’s results of operations or financial position.

3. Acquisition of Quellis

On January 28, 2021, the Company completed the Quellis Acquisition in accordance with the terms of the Merger Agreement as discussed in Note 1, “*Organization and Operations*”. Under the terms of the Merger Agreement, the Company issued 555,444 shares of common stock and 50,504 shares of Series X Preferred Stock. Each share of Series X Preferred Stock is convertible into 166.67 shares of common stock, subject to certain conditions.

The Company concluded that the Quellis Acquisition was not the acquisition of a business, as substantially all of the fair value of the non-monetary assets acquired was concentrated in a single identifiable asset, STAR-0215.

The Company determined that the cost to acquire the Quellis assets was \$170.7 million, based on the fair value of the equity consideration issued and including direct costs of the acquisition of \$1.8 million. The net assets acquired in connection with the Quellis Acquisition were recorded at their estimated fair values as of January 28, 2021, which is the date the Quellis Acquisition was completed. The following table summarizes the net assets acquired based on their estimated fair values as of January 28, 2021 (in thousands):

Acquired IPR&D	\$	164,612
Cash and cash equivalents		8,307
Prepaid expenses and other assets		136
Accounts payable		(1,974)
Accrued liabilities		(400)
Net acquired tangible assets	\$	<u>170,681</u>

[Table of Contents](#)

In the estimation of fair value of the asset purchase consideration, the Company used the carrying value of the cash and cash equivalents, prepaid expenses and other assets, accounts payable and accrued liabilities as the most reliable indicator of fair value based on the associated short-term nature of the balances. The remaining fair value was attributable to the acquired IPR&D. As STAR-0215 had not, at the time of the Quellis Acquisition, received regulatory approval in any territory, the cost attributable to the IPR&D was expensed in the Company’s unaudited condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2021 as the acquired IPR&D had no alternative future use, as determined by the Company in accordance with U.S. GAAP.

4. 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 June 30, 2022 and December 31, 2021, 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 six months ended June 30, 2022 and 2021.

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 June 30, 2022			
	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash equivalents:				
Money market funds	\$ 3,391	\$ —	\$ —	\$ 3,391
Corporate debt securities	—	1,000	—	1,000
Reverse repurchase agreements	—	10,500	—	10,500
Short term investments				
Corporate debt securities	—	23,685	—	23,685
Commercial paper	—	8,984	—	8,984
Yankee securities	—	6,998	—	6,998
U.S. agency bonds	—	2,985	—	2,985
Reverse repurchase agreements	—	30,000	—	30,000
Total	\$ 3,391	\$ 84,152	\$ —	\$ 87,543

	As of December 31, 2021			
	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash equivalents:				
Money market funds	\$ 1,853	\$ —	\$ —	\$ 1,853
Short-term investments:				
Reverse repurchase agreements	—	39,000	—	39,000
Total	\$ 1,853	\$ 39,000	\$ —	\$ 40,853

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 June 30, 2022 and December 31, 2021.

5. Short-Term Investments

The following table summarizes the short-term investments held at June 30, 2022 and December 31, 2021 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
June 30, 2022				
Corporate debt securities	\$ 23,808	\$ —	\$ (123)	\$ 23,685
Commercial paper	8,991	—	(7)	8,984
Yankee securities	7,039	—	(41)	6,998
U.S. agency bonds	3,000	—	(15)	2,985
Reverse repurchase agreements	30,000	—	—	30,000
Total	\$ 72,838	\$ —	\$ (186)	\$ 72,652
December 31, 2021				
Reverse repurchase agreements	\$ 39,000	\$ —	\$ —	\$ 39,000
Total	\$ 39,000	\$ —	\$ —	\$ 39,000

The contractual maturities of all short-term investments held at June 30, 2022 and December 31, 2021 were one year or less. There were 21 short-term investments in an unrealized loss position at June 30, 2022 with an aggregate value of \$42.9 million. These investments were in a loss position for less than 12 months and the Company considered the loss to be temporary in nature. The Company considered the decline in market value for these securities to be primarily attributable to economic and market conditions. As of June 30, 2022, the Company did not intend to sell, and it was not likely that the Company would be required to sell, the investments that were in an unrealized loss position before recovery of their amortized cost basis. Accordingly, the Company did not recognize any other-than-temporary impairments related to its short-term investments in an unrealized loss position. There were no short-term investments in an unrealized loss position at December 31, 2021.

Gross realized gains and losses on the sales of short-term investments are included in other income, net. Unrealized holding gains or losses for the period that have been included in accumulated other comprehensive income, as well as gains and losses reclassified out of accumulated other comprehensive income into other income, net, were not material to the Company's condensed consolidated results of operations. The cost of investments sold or the amount reclassified out of the accumulated other comprehensive income into other income, net is based on the specific identification method for purposes of recording realized gains and losses. All proceeds in the three and six-month periods ended June 30, 2022 and 2021 related to maturities of underlying investments. The gains on proceeds from maturities of short-term investments were not material to the Company's condensed consolidated results of operations for the three and six months ended June 30, 2022 and 2021.

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Accrued compensation	\$ 1,407	\$ 1,958
Accrued contracted costs	1,349	760
Accrued professional fees	604	268
Accrued other	297	295
Total	<u>\$ 3,657</u>	<u>\$ 3,281</u>

7. Commitments

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

Future minimum payments required under the Company’s non-cancelable operating lease as of June 30, 2022 are summarized as follows (in thousands):

Period Ending December 31,	Amount
2022	\$ 271
2023	663
2024	395
Total lease payments	\$ 1,329
Less: imputed interest	(107)
Total operating lease liabilities	<u>\$ 1,222</u>

Rent expense was \$0.3 million and \$0.2 million for the three months ended June 30, 2022 and 2021, respectively. Rent expense was \$0.5 million and \$0.3 million for the six months ended June 30, 2022 and 2021, respectively. Lease payments were \$0.3 and \$0.2 million for the three months ended June 30, 2022 and 2021, respectively. Lease payments were \$0.5 million and \$0.4 million for the six months ended June 30, 2022 and 2021, respectively.

8. Stockholders’ Equity

Preferred Stock

Under the Company’s Restated Certificate of Incorporation, the Company has 5,000,000 shares of preferred stock authorized for issuance, with a \$0.001 par value per share. Preferred stock may be issued from time to time in one or more series, each series to have such terms as stated or expressed in the resolutions providing for the issue of such series adopted by the Board of Directors of the Company. Preferred stock which may be redeemed, purchased or acquired by the Company may be reissued except as otherwise provided by law. As of June 30, 2022, the Company had 31,455 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 5,242,501. Refer to Note 1, “*Organization and Operations*” regarding the Company’s issuance of Series X Preferred Stock in January 2021 and February 2021.

Outstanding Warrants

The following table presents information about warrants that are issued and outstanding at June 30, 2022:

Year Issued	Equity Instrument	Warrants Outstanding	Exercise Price	Date of Expiration
2018	Common Stock	699,962	\$ 72.00	6/21/2023
2019	Common Stock	331,858	\$ 37.50	2/7/2024
2021	Common Stock	498,356	\$ 2.10	12/14/2030
Total		<u>1,530,176</u>		
Weighted average exercise price			\$ 41.75	
Weighted average life in years				3.55

9. Reserved for Future Issuance

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

	June 30, 2022	December 31, 2021
Series X Preferred Stock	5,242,501	5,242,501
Warrants for the purchase of common stock	1,530,176	1,530,380
Options outstanding to purchase common stock	2,106,150	1,346,733
Reserve under the 2015 Stock Incentive Plan and the 2022 Inducement Stock Incentive Plan	1,189,215	1,633,736
Shares reserved for the employee stock purchase plan	36,982	30,904
Total	<u>10,105,024</u>	<u>9,784,254</u>

10. 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, 2021	1,346,733	\$ 22.25	9.02	\$ 168
Granted	796,481	\$ 6.17		
Cancelled or forfeited	(37,013)	\$ 21.87		
Expired	(51)	\$ 115.80		
Outstanding at June 30, 2022	<u>2,106,150</u>	\$ 16.18	8.96	\$ 61
Vested and exercisable at June 30, 2022	<u>485,217</u>	\$ 31.42	8.14	\$ 61

There were no stock options exercised in the three or six months ended June 30, 2022 and 2021. The total grant date fair value of stock options vested for the three months ended June 30, 2022 and 2021 was \$3.3 million and \$0.4 million, respectively. The total grant date fair value of stock options vested for the six months ended June 30, 2022 and 2021 was \$3.9 million and \$1.0 million, respectively. The weighted-average grant date fair value of options granted to employees and non-employees for the three months ended June 30, 2022 and 2021 was \$3.04 and \$10.38, respectively. The weighted-average grant date fair value of options granted to employees and non-employees for the six months ended June 30, 2022 and 2021 was \$3.87 and \$10.38, respectively.

At June 30, 2022, the total unrecognized compensation expense related to unvested stock option awards was \$11.2 million. The Company expects to recognize that cost over a weighted-average period of approximately 2.7 years.

On February 17, 2022, the Company’s Board of Directors adopted the 2022 Inducement Stock Incentive Plan (the “Inducement Plan”). The Inducement Plan provides for the grant of nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards with respect to an aggregate of 300,000 shares of the Company’s common stock. 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 June 30, 2022, 38,000 options have been granted under the Inducement Plan, which are included in the table above.

11. 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, 2021, or the 2021 Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the sections entitled "Risk Factors" and "Summary of the Material Risks Associated with Our Business" in our 2021 Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. This section provides additional information regarding our business, current developments, results of operations, cash flows, financial condition, contractual commitments and critical accounting policies and estimates that require significant judgement and have the most potential impact on our unaudited condensed consolidated financial statements. This discussion and analysis is intended to better allow investors to view the Company from management's perspective.

Overview

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

HAE is a rare, debilitating and potentially life-threatening disease. The treatment options for patients with HAE have improved, however, there is remaining unmet medical need and the global market for HAE therapy is strong and growing. The vision for our lead program, STAR-0215, is to develop a best-in-class monoclonal antibody inhibitor of plasma kallikrein able to provide long-acting, effective attack prevention for HAE with dosing once every three months or longer. Targeted plasma kallikrein inhibition can prevent HAE attacks by suppressing the pathway that generates bradykinin and causes excessive swelling. We submitted an Investigational New Drug application, or IND, for STAR-0215 in June 2022, the U.S. Food and Drug Administration, or FDA, cleared the IND for STAR-0215 in July 2022, and we have initiated a Phase 1a clinical trial for STAR-0215 with preliminary results anticipated by year-end 2022. We believe that this clinical trial has the opportunity to establish proof of concept for the differentiated profile of STAR-0215. The Phase 1a randomized, double blind, placebo controlled single ascending dose clinical trial is evaluating the safety, pharmacokinetics, and pharmacodynamics of STAR-0215 at a single U.S. center. Approximately 24 healthy subjects are planned to receive a single dose of STAR-0215 or placebo in at least three cohorts of 100mg, 300mg, and 600mg administered subcutaneously. Our goals for this trial with STAR-0215 are to assess safety and tolerability, establish the prolonged half-life, demonstrate inhibition of plasma kallikrein activity, which, if favorable, would provide proof of mechanism in HAE, and to refine dose and dosing regimen for studies in HAE participants. Assuming positive data from the Phase 1a trial, we plan to initiate a Phase 1b/2 trial in participants with HAE in 2023. We expect the Phase 1b/2 trial, if initiated, would be a global multi-center trial in HAE participants, and that the primary goal for the trial would be to demonstrate proof of concept in HAE by assessing safety and tolerability, establish prolonged half-life, demonstrate durability of inhibition of plasma kallikrein activity, and provide an initial assessment of the impact of STAR-0215 on HAE attack rate.

Our vision for STAR-0215 is supported by preclinical data showing potent inhibition of the production of bradykinin by plasma kallikrein and a long plasma half-life that could potentially enable patients to dose once every three months or longer. At the Fc Receptor and IgG Targeted Therapies Conference in April 2022, we presented pharmacokinetic modeling data supporting that STAR-0215 has the potential to effectively inhibit plasma kallikrein and prevent HAE attacks with subcutaneous dosing volumes appropriate for a self-injectable device dosed once every three months or longer. We also presented preclinical data that demonstrate STAR-0215's rapid and durable inhibition of plasma kallikrein in cynomolgus monkeys, supporting the potential for once every three month or longer dosing in humans, at the European Academy of Allergy and Clinical Immunology 2022 Hybrid Congress in July 2022. The study demonstrated rapid inhibition of plasma kallikrein after subcutaneous administration. Inhibition of high molecular weight kininogen cleavage was rapid and sustained throughout the entire 84-day dose-free period in the extended portion of the study. These data confirm the long half-life of STAR-0215 and demonstrate prolonged pharmacological activity of STAR-0215 in circulation in cynomolgus monkeys. The preclinical and modeling data to date support that STAR-0215 could be an effective preventative therapy for patients with HAE due to inhibition of the pathologic activity of plasma kallikrein for an extended time period.

January 2021 Quellis Acquisition and February 2021 Financing

In January 2021, we acquired Quellis Biosciences, Inc., or Quellis, including the STAR-0215 program, and announced a private placement that, upon closing in February 2021, resulted in gross proceeds to us of approximately \$110.0 million before deducting placement agent and other offering expenses, which we refer to as the February 2021 Financing. We acquired Quellis pursuant to an Agreement and Plan of Merger, or the Merger Agreement, by and among us, Cabo Merger Sub I, Inc., a Delaware corporation and our wholly owned subsidiary, or the First Merger Sub, Cabo Merger Sub II, LLC, a Delaware limited liability company and our wholly owned subsidiary, or the Second Merger Sub, and Quellis, or the Quellis Acquisition. Pursuant to the Merger Agreement, the First Merger Sub merged with and into Quellis, pursuant to which Quellis was the surviving entity and became a wholly owned subsidiary of ours, or the First Merger. Immediately following the First Merger, Quellis merged with and into the Second Merger Sub, pursuant to which the Second Merger Sub was the surviving entity, or the Second Merger and, together with the First Merger, the Merger. Under the terms of the Merger Agreement, at the closing of the Merger, we issued to the Quellis stockholders 555,444 shares of our common stock, and 50,504 shares of newly designated Series X Preferred Stock (as described below). In addition, we assumed outstanding Quellis stock options, which became options for 55,414 shares of our common stock, and assumed a warrant exercisable for Quellis common stock, which became a warrant to purchase 2,805 shares of Series X Preferred Stock at an exercise price of \$341.70 per share, and a warrant to purchase 30,856 shares of our common stock at an exercise price of \$2.10 per share. Upon stockholder approval of the Conversion Proposal (as defined below) on June 2, 2021, the warrant to purchase Series X Preferred Stock was converted into the right to purchase 467,500 shares of our common stock, at a per share exercise price of \$2.10 per share. We concluded that the Quellis Acquisition was not the acquisition of a business, as substantially all of the fair value of the non-monetary assets acquired was concentrated in a single identifiable asset, STAR-0215.

In January 2021, we also entered into a Stock Purchase Agreement, or the Purchase Agreement, with certain institutional and accredited investors pursuant to which we sold an aggregate of 35,573 shares of Series X Preferred Stock for an aggregate purchase price of \$110.0 million, or the February 2021 Financing. Our stockholders approved the conversion of the Series X Preferred Stock into shares of common stock in accordance with Nasdaq Listing Rule 5635(a), or the Conversion Proposal, at our Annual Meeting of Stockholders on June 2, 2021. On the fourth business day after the approval of the Conversion Proposal, each share of Series X Preferred Stock automatically converted into 166.67 shares of common stock, subject to certain beneficial ownership limitations, including that a holder of Series X Preferred Stock is prohibited from converting shares of Series X Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than a specified percentage (as of June 30, 2022, these percentages are set at 4.99% to 9.99% and can be adjusted by the holder to a number between 4.99% and 19.99%) of the total number of shares of common stock issued and outstanding immediately after giving effect to such conversion. Shares of Series X Preferred Stock not converted automatically are thereafter subject to conversion at the option of the holder, subject to certain beneficial ownership limitations. As of July 29, 2022, 54,622 shares of Series X Preferred Stock have been converted into 9,103,664 shares of common stock and 31,455 shares of Series X Preferred Stock remained 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 outstanding shares Series X Preferred Stock is 5,242,501. Outstanding shares of Series X Preferred Stock are subject to conversion at the option of the holder.

Financial Overview

Our business is almost entirely dependent on the success of STAR-0215, which is in the early clinical stage of development, and has only produced results in preclinical and nonclinical settings. Our net losses were \$26.6 million and \$177.6 million (including \$164.6 million of in-process research and development expenses) for the six months ended June 30, 2022 and 2021, respectively. As of June 30, 2022, we had an accumulated deficit of \$482.4 million. We have financed our operations to date primarily through private placements of preferred stock before we became a public company and our private placement of preferred stock in the February 2021 Financing, registered offerings of our common stock and our at-the-market offering programs, and have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical development programs. As of June 30, 2022, we had \$102.5 million in cash, cash equivalents and short-term investments. We expect that our existing cash, cash equivalents and short-term investments are sufficient to support our operating expenses and capital expenditures through 2023. Advancing the development of STAR-0215 or any future product candidates will require a significant amount of capital. Our existing cash, cash equivalents and short-term investments will not be sufficient to fund STAR-0215 or any future product candidates through regulatory approval. We will need to obtain substantial additional funding to complete the development and commercialization of STAR-0215 or any future product candidates and support our continuing operations, future clinical trials and expansion of our pipeline. Furthermore, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional financing to fund our long-term operations sooner than planned. See the section titled “Liquidity and Capital Resources” below for additional information.

Research and Development Expenses

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

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

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

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

[Table of Contents](#)

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

	Six Months Ended June 30,	
	2022	2021
STAR-0215	\$ 10,070	\$ 2,861
Edasalonexent	67	615
Other research programs	807	478
Costs not directly allocated to programs:		
Employee expenses including cash compensation, benefits and stock-based compensation	3,060	2,200
Consultants and professional expenses, including stock-based compensation	2,629	(292)
Facilities	242	156
Other	100	53
Total costs not directly allocated to programs	6,031	2,117
Total research and development expenses	\$ 16,975	\$ 6,071

Based on the results of the Phase 3 PolarisDMD trial of edasalonexent for the treatment of DMD, in October 2020 we stopped all activities related to the development of edasalonexent, including the then-ongoing GalaxyDMD open-label extension trial, and wound down substantially all activities related to edasalonexent by mid-2021.

We expect to incur significant research and development expenses in the year ending December 31, 2022 and in future periods in connection with the preclinical and clinical activities related to the development of STAR-0215. Because of this, we expect that our research and development expenses over the next several quarters will be higher than the prior year periods. Development of STAR-0215 and any future product candidates is highly uncertain and we cannot reasonably estimate at this time the nature, timing and costs of the efforts that would be necessary to complete the development of any such product candidates. We are also unable to predict when, if ever, material net cash inflows would commence from any such product candidates. This is due to the fact that we would need to raise substantial additional capital to fund the clinical development of any such product candidates and the numerous risks and uncertainties associated with developing and commercializing product candidates, including the uncertainties of:

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

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

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance, accounting, commercial, 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 in the near term our general and administrative expenses will remain relatively consistent with their current levels, although as we continue to develop STAR-0215 and potentially expand our pipeline to include other product candidates, our general and administrative expenses may increase.

Acquired In-process Research and Development Expense

Acquired in-process research and development (“IPR&D”) expense resulted from the Quellis Acquisition in January 2021. The acquisition cost allocated to acquire IPR&D with no alternative future use was recorded as expense at the acquisition date and no additional IPR&D expense relating to the Quellis Acquisition is expected to be reported in future periods.

Reduction in Workforce

In December 2020, following the decision to stop development of edasalonexent, we announced that we were reducing our workforce during the quarter ended December 31, 2020. The reduction resulted in total expenses for employee severance and employee benefits of \$0.6 million, of which \$0.2 million was recorded during the six months ended June 30, 2021. As of June 30, 2022, all severance and employee benefits related to the reduction of workforce has been paid.

Other Income, Net

Other income (expense), 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 six months ended June 30, 2022, there were no material changes to our critical accounting policies as reported in our 2021 Annual Report on Form 10-K.

Results of Operations

We anticipate that our results of operations may fluctuate for the foreseeable future due to several factors, such as the progress of our research and development efforts and the timing and outcome of regulatory submissions.

Comparison of the Three Months Ended June 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended June 30, 2022 and 2021, together with the dollar change in those items (in thousands):

	Three Months Ended June 30,		Period-to-
	2022	2021	Period Change
Operating expenses:			
Research and development	\$ 6,617	\$ 3,478	\$ 3,139
General and administrative	4,832	4,008	824
Total operating expenses	11,449	7,486	3,963
Loss from operations	(11,449)	(7,486)	(3,963)
Other income, net	199	20	179
Net loss	<u>\$ (11,250)</u>	<u>\$ (7,466)</u>	<u>\$ (3,784)</u>

Research and Development Expenses

Research and development expenses increased by \$3.1 million to \$6.6 million for the three months ended June 30, 2022 from \$3.5 million for the three months ended June 30, 2021, an increase of 90%. The increase in research and development expenses was primarily attributable to a \$1.4 million increase in direct costs to support preclinical development of the STAR-0215 program, a \$1.0 million increase in professional services expense primarily related to a one-time gain recognized during the three months ended June 30, 2021 on the fair value of warrants inherited in the Quellis Acquisition as described in Note 1, “*Organization and Operations*,” a \$0.7 million increase in employee expenses, a \$0.1 million increase in other research expense, and a \$0.1 million increase in the research and development portion of facilities expense. These increases were partially offset by a \$0.2 million decrease in costs to support the edasalonexent program due to stopping all development activities associated with the program.

General and Administrative Expenses

General and administrative expenses increased by \$0.8 million to \$4.8 million for the three months ended June 30, 2022 from \$4.0 million for the three months ended June 30, 2021, an increase of 21%. The increase was attributable to a \$0.7 million increase in employee related costs, a \$0.1 million increase in other office costs, \$0.1 million increase in insurance expense, and a \$0.1 million increase in the general and administrative portion of facilities expense. These costs were partially offset by a \$0.2 million decrease in professional services and consultant expense.

Other Income, Net

Other income, net increased by \$179,000 to \$199,000 for the three months ended June 30, 2022 from \$20,000 for the three months ended June 30, 2021. The increase was primarily attributable to an increase in interest and investment income due to higher yields on our interest-earning assets.

Comparison of the Six Months Ended June 30, 2022 and 2021

The following table summarizes our results of operations for the six months ended June 30, 2022 and 2021, together with the dollar change in those items (in thousands):

	<u>Six Months Ended June 30,</u>		<u>Period-to-</u>
	<u>2022</u>	<u>2021</u>	<u>Period Change</u>
Operating expenses:			
Research and development	\$ 16,975	\$ 6,071	\$ 10,904
General and administrative	9,852	6,881	2,971
Acquired in-process research and development	—	164,617	(164,617)
Total operating expenses	<u>26,827</u>	<u>177,569</u>	<u>(150,742)</u>
Loss from operations	(26,827)	(177,569)	150,742
Other income, net	253	19	234
Net loss	<u>\$ (26,574)</u>	<u>\$ (177,550)</u>	<u>\$ 150,976</u>

Research and Development Expenses

Research and development expenses increased by \$10.9 million to \$17.0 million for the six months ended June 30, 2022 from \$6.1 million for the six months ended June 30, 2021, an increase of 180%. The increase in research and development expenses was primarily attributable to a \$7.2 million increase in direct costs to support preclinical development of the STAR-0215 program, a \$2.9 million increase in professional services expense primarily due to expense recognized on vested warrants inherited in the Quellis Acquisition as described in Note 1, “*Organization and Operations*,” a \$0.9 million increase in employee expenses, a \$0.3 million increase in other research expense, and a \$0.1 million increase in the research and development portion of facilities expense. These increases were partially offset by a \$0.5 million decrease in costs to support the edasalonexent program due to stopping all development activities associated with the program.

General and Administrative Expenses

General and administrative expenses increased by \$3.0 million to \$9.9 million for the six months ended June 30, 2022 from \$6.9 million for the six months ended June 30, 2021, an increase of 43%. The increase was attributable to a \$1.1 million increase in employee related costs, a \$0.6 million increase in professional services expense primarily due to new product planning and business development activities, a \$0.7 million increase in stock-based compensation expense, a \$0.4 million increase in other costs such as general office and our Delaware franchise fee, and a \$0.2 million increase in insurance expense.

Acquired In-process Research and Development Expense

Acquired IPR&D expense was \$164.6 million for the six months ended June 30, 2021. Acquired IPR&D expense resulted from the Quellis Acquisition in January 2021. The acquisition cost allocated to acquire IPR&D with no alternative future use was recorded as an expense as of the closing date of the Quellis Acquisition. No acquired IPR&D expenses were incurred for the six months ended June 30, 2022.

Other Income, Net

Other income, net increased by \$234,000 to \$253,000 for the six months ended June 30, 2022 from \$19,000 for the six months ended June 30, 2021. The increase was primarily attributable to an increase in interest and investment income due to higher yields on our interest-earning assets.

Liquidity and Capital Resources

From our inception through June 30, 2022, we raised an aggregate of \$426.0 million through private placements of preferred stock before we became a public company and our private placement of preferred stock in the February 2021 Financing, registered offerings of our common stock and our at-the-market offering programs. As of June 30, 2022, we had cash, cash equivalents and short-term investments of \$102.5 million. We expect that our existing cash, cash equivalents and short-term investments are sufficient to support our operating expenses and capital expenditures through 2023. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we anticipate.

We will need to obtain substantial additional funding to complete the development and commercialization of STAR-0215 or any future product candidates and support our continuing operations, future clinical trials and expansion of our pipeline. In addition, STAR-0215 or any future product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of product candidates that we do not expect to be commercially available for years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. The terms of any financing may adversely affect the holdings or the rights of our stockholders. Market volatility, inflation, interest rate fluctuations and concerns related to the COVID-19 pandemic may have a significant impact on the availability of funding sources and the terms on which any funding may be available. 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.

February 2021 Financing

On January 28, 2021, we entered into the Purchase Agreement and sold an aggregate of 35,573 shares of Series X Preferred Stock on the February 1, 2021 closing date for gross proceeds of approximately \$110.0 million, and net proceeds of \$104.3 million.

At-the-Market Offering Programs

We had entered into various sales agreements with Cowen and Company LLC, or Cowen, pursuant to which we could issue and sell shares of common stock, par value \$0.001 per share, under at-the-market offering programs. On May 20, 2021, we terminated our sales agreement with Cowen. On June 30, 2021, we entered into an Open Market Sale AgreementSM with Jefferies LLC, or the Jefferies Sale Agreement, pursuant to which we can issue and sell shares of common stock of up to \$25.0 million under at-the-market offering programs (collectively, with the Cowen at-the-market offering program, the ATM Programs). We pay the sales agent commissions of 3.0% of the gross proceeds from any common stock sold through the ATM Programs. As of June 30, 2022, we have not sold any shares of common stock pursuant to the Jefferies Sale Agreement. There was also no activity from the ATM Programs during the six months ended June 30, 2021.

Cash Flows

Comparison of the Six Months Ended June 30, 2022 and 2021

The following table provides information regarding our cash flows for the six months ended June 30, 2022 and 2021 (in thousands):

	Six Months Ended June 30,	
	2022	2021
Net cash used in operating activities	\$ (22,620)	\$ (16,116)
Net cash (used in) provided by investing activities	(33,899)	26,445
Net cash provided by financing activities	—	104,261
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>\$ (56,519)</u>	<u>\$ 114,590</u>

Net Cash Used in Operating Activities

Net cash used in operating activities was \$22.6 million for the six months ended June 30, 2022 and consisted primarily of a net loss of \$26.6 million adjusted for stock-based compensation expense of \$2.3 million, expense recognized for warrants of \$1.6 million, and other non-cash items of \$0.1 million.

Net cash used in operating activities was \$16.1 million for the six months ended June 30, 2021 and consisted primarily of a net loss of \$177.6 million adjusted for the non-cash portion of acquired IPR&D of \$164.6 million, stock-based compensation expense of \$1.4 million, a gain on warrants of \$0.7 million, and a net increase in net assets of \$3.8 million, which resulted primarily from a decrease in accounts payable of \$2.9 million, and a decrease in accrued expenses of \$1.9 million, partially offset by a decrease in prepaid expenses of \$1.0 million.

Net Cash (Used in) Provided by Investing Activities

Net cash used in investing activities was \$33.9 million for the six months ended June 30, 2022 and consisted primarily of purchases of short-term investments of \$164.9 million offset by maturities of short-term investments of \$131.0 million. Net cash provided by investing activities was \$26.4 million for the six months ended June 30, 2021 and consisted primarily of proceeds from maturities of short-term investments of \$20.0 million and cash acquired in the Quellis Acquisition of \$6.4 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$104.3 million for the six months ended June 30, 2021, which was attributable to net proceeds of \$104.3 million from the February 2021 Financing.

Funding Requirements

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

As of June 30, 2022, we had an accumulated deficit of \$482.4 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.

[Table of Contents](#)

As of June 30, 2022, we had available cash, cash equivalents and short-term investments of \$102.5 million. We expect that our existing cash, cash equivalents and short-term investments are sufficient to support our operating expenses and capital expenditures through 2023.

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

- the progress, timing, costs and results of clinical trials of, and research and preclinical development efforts for, STAR-0215 and any future product candidates, including potential future clinical trials;
- our ability to enter into and the terms and timing of any additional 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, 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, revenues, if any, received from commercial sales of our product candidates;
- if we obtain marketing approval of any of our product candidates, our ability to successfully compete against other approved products that are approved or used as treatments for the indications for which our products are approved, including with respect to STAR-0215 in HAE;
- our headcount growth and associated costs;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims;
- the progress, timing, costs and results of clinical trials of, and research and preclinical development efforts for, STAR-0215 and any future product candidates, including potential future clinical trials;
- the impact of the COVID-19 pandemic on our operations, business and prospects; and
- the costs of operating as a public company.

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

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

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

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

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

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of June 30, 2022, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the six months ended June 30, 2022, 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, 2021, which could materially affect our business, financial condition or future results, in addition to the information set forth in this Quarterly Report on Form 10-Q.

Item 6. Exhibits

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

Exhibit Number	Exhibit
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: August 9, 2022

By: /s/ NOAH C. CLAUSER

Noah C. Clauser

Chief Financial Officer (Principal Financial Officer)

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: August 9, 2022

/s/ JILL C. MILNE, PH.D.

Jill C. Milne, Ph.D.

President and Chief Executive Officer (Principal
Executive Officer)

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: August 9, 2022

/s/ NOAH C. CLAUSER

Noah C. Clauser

Chief Financial Officer (Principal Financial Officer)

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 June 30, 2022 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: August 9, 2022

/s/ JILL C. MILNE, PH.D.

Jill C. Milne, Ph.D.

President and Chief Executive Officer (Principal Executive Officer)

Date: August 9, 2022

/s/ NOAH C. CLAUSER

Noah C. Clauser

Chief Financial Officer (Principal Financial Officer)
