

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2021

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)
100 High Street
Floor 28
Boston, Massachusetts
(Address of Principal Executive Offices)

26-3687168
(IRS Employer
Identification No.)

02110
(Zip Code)

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

Catabasis Pharmaceuticals, Inc.

(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 November 1, 2021, there were 13,009,477 shares of the registrant's Common Stock, par value \$0.001 per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. 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 revenue, projected costs, prospects, plans and objectives of management 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 of our planned filing of an initial investigational new drug application, or IND, for our product candidate STAR-0215 (formerly known as QLS-215) and the timing, nature, goals and results of our planned Phase 1 and clinical trial of STAR-0215, including that the results from the Phase 1 trial could establish proof of concept for the differentiation of STAR-0215 as a potential treatment for hereditary angioedema, or HAE, and the timing of the Phase 1b/2 clinical trial of STAR-0215;
- 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 the best-in-class and most patient-friendly chronic treatment option for HAE, and the profile, nature and anticipated growth of the global HAE market and HAE therapies;
- our expectations that pre-clinical data of STAR-0215 may be replicated in clinical data;
- our expectations that the acquisition of Quellis Biosciences, Inc., or “Quellis”, may be an opportunity to create significant stockholder value;
- our expectations regarding our ability to expand our pipeline;
- the potential benefits of any future acquisition, in-license, collaboration or pre-clinical development activities;
- our commercialization, marketing and manufacturing plans, capabilities and strategy;
- our intellectual property position and strategy;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our use of the proceeds from the private placement completed in February 2021;
- 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 as a result of various important factors, including risks and uncertainties related to our ability to recognize the anticipated benefits of the Quellis acquisition (as described below); the outcome of any legal proceedings that may be instituted against us or Quellis following the announcement of the acquisition and related transactions; changes in applicable laws or regulations; the possibility that we may be adversely affected by other economic, business, and/or competitive factors, including the COVID-19 pandemic; risks inherent in pharmaceutical research and development, such as adverse results in our drug discovery, preclinical and clinical development activities, the risk that the results of preclinical studies may not be replicated in clinical studies, our ability to enroll patients in our clinical trials, and the risk that any of our clinical trials may not commence, continue or be completed on time, or at all; feedback and guidance from and decisions made by the U.S. Food and Drug Administration and other regulatory authorities, investigational review boards at clinical trial sites and other review bodies with respect

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to STAR-0215 and any future product candidates; our ability to manufacture sufficient quantities of drug substance and drug product on a cost-effective and timely basis; our ability to obtain, maintain and enforce intellectual property rights for STAR-0215 and any other future product candidates; competition with respect to STAR-0215 or any other future product candidates or approved products; our ability to manage our cash usage and the possibility of unexpected cash expenditures; our ability to obtain necessary financing to conduct our planned activities and to manage unplanned cash requirements; and general economic and market conditions.

We have included important factors in the cautionary statements included in our most recent Annual Report on Form 10-K, particularly in the sections entitled “Summary of the Material Risks Associated with Our Business” and “Risk Factors”, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

PART I- FINANCIAL INFORMATION**Item 1. Financial Statements****Astria Therapeutics, Inc.**
Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)*(Unaudited)*

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 131,777	\$ 24,930
Short-term investments	—	20,000
Prepaid expenses and other current assets	2,745	1,395
Total current assets	134,522	46,325
Right-of-use asset	557	966
Other assets	50	165
Total assets	<u>\$ 135,129</u>	<u>\$ 47,456</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 574	\$ 1,544
Accrued expenses	3,585	4,197
Current portion of operating lease liabilities	541	649
Total current liabilities	4,700	6,390
Long-term portion of operating lease liabilities	—	397
Total liabilities	4,700	6,787
Stockholders' equity:		
Series X redeemable convertible preferred stock, \$0.001 par value per share, 36,758 shares authorized; 31,455 shares issued and outstanding as of September 30, 2021 and no shares issued and outstanding as of December 31, 2020	96,398	—
Common stock, \$0.001 par value per share, 150,000,000 shares authorized; 13,009,477 and 3,347,389 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	13	3
Additional paid-in capital	480,336	301,563
Accumulated deficit	(446,318)	(260,897)
Total stockholders' equity	130,429	40,669
Total liabilities and stockholders' equity	<u>\$ 135,129</u>	<u>\$ 47,456</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 September 30,		Nine Months Ended September 30	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 3,788	\$ 7,806	\$ 9,859	\$ 19,845
General and administrative	4,110	3,057	10,992	8,612
Acquired in-process research and development	—	—	164,617	—
Total operating expenses	<u>7,898</u>	<u>10,863</u>	<u>185,468</u>	<u>28,457</u>
Loss from operations	(7,898)	(10,863)	(185,468)	(28,457)
Other income (expense):				
Interest and investment income	35	4	89	231
Other expense, net	(8)	(3)	(42)	(96)
Total other income, net	<u>27</u>	<u>1</u>	<u>47</u>	<u>135</u>
Net loss	(7,871)	(10,862)	(185,421)	(28,322)
Dividend on convertible preferred stock related to beneficial conversion feature and issuance costs	—	—	(24,437)	—
Net loss attributable to common shareholders	<u>\$ (7,871)</u>	<u>\$ (10,862)</u>	<u>\$ (209,858)</u>	<u>\$ (28,322)</u>
Net loss per share - basic and diluted	<u>\$ (0.61)</u>	<u>\$ (3.36)</u>	<u>\$ (27.81)</u>	<u>\$ (9.56)</u>
Weighted-average common shares outstanding used in net loss per share - basic and diluted	<u>12,830,782</u>	<u>3,237,477</u>	<u>7,546,969</u>	<u>2,961,623</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 September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Net loss	\$ (7,871)	\$ (10,862)	\$ (185,421)	\$ (28,322)
Other comprehensive loss:				
Loss on short-term investments	—	(1)	—	—
Total other comprehensive loss:	—	(1)	—	—
Comprehensive loss	<u>\$ (7,871)</u>	<u>\$ (10,863)</u>	<u>\$ (185,421)</u>	<u>\$ (28,322)</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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Series X redeemable convertible preferred stock, shares				
Balance, beginning of period	—	—	—	—
Issuance of preferred stock in a private offering of public equity, net of issuance costs	—	—	35,573	—
Issuance of preferred stock upon acquisition of Quellis	—	—	50,504	—
Reclassification of preferred stock to permanent equity	—	—	(86,077)	—
Balance, end of period	—	—	—	—
Series X redeemable convertible preferred stock, value				
Balance, beginning of period	\$ —	\$ —	\$ —	\$ —
Issuance of preferred stock in a private offering of public equity, net of issuance costs	—	—	84,696	—
Issuance of preferred stock upon acquisition of Quellis	—	—	156,185	—
Reclassification of preferred stock to permanent equity	—	—	(240,881)	—
Balance, end of period	\$ —	\$ —	\$ —	\$ —
Series X redeemable convertible preferred stock, shares				
Balance, beginning of period	32,545	—	—	—
Reclassification of preferred stock to permanent equity	—	—	86,077	—
Conversion of preferred stock into common stock	(1,090)	—	(54,622)	—
Balance, end of period	31,455	—	31,455	—
Series X redeemable convertible preferred stock, value				
Balance, beginning of period	\$ 99,770	\$ —	\$ —	\$ —
Reclassification of preferred stock to permanent equity	—	—	240,881	—
Conversion of preferred stock into common stock	(3,372)	—	(168,920)	—
Dividend on convertible preferred stock related to beneficial conversion feature and issuance costs	—	—	24,437	—
Balance, end of period	\$ 96,398	\$ —	\$ 96,398	\$ —
Common stock, shares				
Balance, beginning of period	12,824,796	3,137,264	3,347,386	2,072,266
Issuance of common stock upon acquisition of Quellis	—	—	555,444	—
Issuance of common stock upon the conversion of preferred stock	181,698	—	9,103,664	—
Issuance of common stock for at-the-market offerings	—	208,956	—	392,288
Issuance of common stock and warrants in public offerings	—	—	—	881,666
Issuance of common stock upon exercise of options	2,992	—	2,992	—
Fractional shares eliminated pursuant to reverse stock split	(9)	—	(9)	—
Balance, end of period	13,009,477	3,346,220	13,009,477	3,346,220
Common stock, par value				
Balance, beginning of period	\$ 13	\$ 3	\$ 4	\$ 2
Issuance of common stock upon the conversion of preferred stock	—	—	9	—
Issuance of common stock in underwritten public offerings	—	—	—	1
Balance, end of period	\$ 13	\$ 3	\$ 13	\$ 3
Additional paid-in capital				
Balance, beginning of period	\$ 475,563	\$ 291,912	\$ 301,562	\$ 259,315
Issuance of preferred stock in a private offering of public equity, net of issuance costs	—	—	19,565	—
Issuance of common stock upon acquisition of Quellis	—	—	8,098	—
Issuance of common stock for at-the-market offerings	—	8,939	—	16,268
Issuance of common stock in an underwritten public offering, net of issuance costs	—	—	—	24,558
Issuance of common stock upon the conversion of preferred stock	3,372	—	168,912	—
Issuance of common stock upon exercise of options	6	—	6	—
Dividend on convertible preferred stock related to beneficial conversion feature and issuance costs	—	—	(24,437)	—
Expense related to warrants inherited in acquisition of Quellis	385	—	772	—
Reclassification of warrant liability to additional paid-in capital	—	—	3,468	—
Stock-based compensation expense	1,010	375	2,390	1,085
Balance, end of period	\$ 480,336	\$ 301,226	\$ 480,336	\$ 301,226
Accumulated deficit				
Balance, beginning of period	\$ (438,447)	\$ (241,057)	\$ (260,897)	\$ (223,597)
Net loss	(7,871)	(10,862)	(185,421)	(28,322)
Balance, end of period	\$ (446,318)	\$ (251,919)	\$ (446,318)	\$ (251,919)
Accumulated other comprehensive loss				
Balance, beginning of period	\$ —	\$ 1	\$ —	\$ —
Realized loss on short-term investments	—	(1)	—	—
Balance, end of period	\$ —	\$ —	\$ —	\$ —
Total stockholders' equity	\$ 130,429	\$ 49,310	\$ 130,429	\$ 49,310

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

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

(Unaudited)

	Nine Months Ended September 30,	
	2021	2020
Operating activities		
Net loss	\$ (185,421)	\$ (28,322)
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	2,390	1,085
Net gain on warrants inherited in acquisition of Quellis	(315)	—
Other non-cash items	15	42
Changes in assets and liabilities:		
Prepaid expenses and other assets	(1,092)	121
Right-of-use asset- operating	(96)	125
Accounts payable	(2,947)	211
Accrued expenses	(1,011)	2,314
Net cash used in operating activities	<u>(23,865)</u>	<u>(24,424)</u>
Investing activities		
Purchases of short-term investments	—	(42,777)
Sales and maturities of short-term investments	20,000	69,110
Cash acquired in acquisition of Quellis	6,466	—
Purchases of property and equipment	(21)	(23)
Net cash provided by investing activities	<u>26,445</u>	<u>26,310</u>
Financing activities		
Proceeds from underwritten public offering, net of issuance costs	—	24,559
Proceeds from private offering of public equity, net of issuance costs	104,261	—
Proceeds from at-the-market offering, net of issuance costs	—	16,270
Proceeds from exercise of common stock options	6	—
Net cash provided by financing activities	<u>104,267</u>	<u>40,829</u>
Net increase in cash, cash equivalents and restricted cash	106,847	42,715
Cash, cash equivalents and restricted cash, beginning of period	25,051	10,376
Cash, cash equivalents and restricted cash, end of period	<u>\$ 131,898</u>	<u>\$ 53,091</u>
Supplemental disclosure of non-cash transactions:		
Conversion of Series X Preferred Stock into common stock	<u>\$ 168,920</u>	<u>\$ —</u>
Non-cash dividend on convertible preferred stock	<u>\$ 24,437</u>	<u>\$ —</u>
Reclassification of warrant liability to additional paid-in capital	<u>\$ 3,468</u>	<u>\$ —</u>

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. 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 (“DMD”) 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 (formerly known as QLS-215), a monoclonal antibody inhibitor of plasma kallikrein in preclinical development for the treatment of hereditary angioedema, or 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 Certificate of Incorporation filed with the Secretary of State of the State of Delaware. The reverse stock split was reflected on Nasdaq beginning with the opening of trading on August 20, 2021. 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, 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 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 stock option 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, which warrants are exercisable until December 14, 2030. 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

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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 or warrants to purchase Series X Preferred Stock:

	Series X Preferred Stock
Outstanding shares issued in merger	50,504
Outstanding shares issued in February 2021 Financing	35,573
Warrants assumed in merger	2,805
Total	88,882

At its 2021 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 September 30, 2021, 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 September 30, 2021, 54,622 shares of Series X Preferred Stock were 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 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.

Prior to stockholder approval of the Conversion Proposal, the terms of the Series X Preferred Stock included a cash redemption feature. This cash redemption feature resulted in substantial doubt about the Company’s ability to continue as a going concern as disclosed in the Company’s annual report on Form 10-K for the year ended December 31, 2020 (the “2020 Annual Report on Form 10-K”) and the Company’s quarterly report on Form 10-Q for the three months ended March 31, 2021. Upon stockholder approval of the Conversion Proposal, the cash redemption feature was eliminated and, consequently, there is no longer substantial doubt about the Company’s ability to continue as a going concern for at least twelve months subsequent to the issuance of these financial statements.

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 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.

January 2020 Financing

On January 30, 2020, the Company entered into an underwriting agreement with Oppenheimer & Co. Inc. relating to an underwritten public offering (the “January 2020 Financing”) of 881,666 shares of common stock at a price to the public of \$30.00 per share, including 115,000 shares issued upon the exercise in full by Oppenheimer & Co. Inc. of its overallotment option. This resulted in gross proceeds of \$26.5 million, and net proceeds of \$24.6 million.

Liquidity

The Company has 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 (“Jefferies”), 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 3% of the gross proceeds from any common stock sold through the ATM Programs. As of June 30, 2021, the Company has not sold any shares of common stock pursuant to the Jefferies agreement and, as a result, \$25.0 million of common stock remains available for sale under the Jefferies agreement.

During the nine months ended September 30, 2020, the Company sold an aggregate of 392,288 shares of common stock pursuant to the ATM Programs, at an average price of \$42.76 per share, for net proceeds of \$16.3 million after deducting sales commissions and offering expenses. There was no activity from the ATM Programs during the nine months ended September 30, 2021.

As of September 30, 2021, the Company had an accumulated deficit of \$446.3 million and had available cash and cash equivalents of \$131.8 million. The Company has been primarily involved with research and development activities and has incurred operating losses and negative cash flows from operations since its inception. The Company has not generated any product revenues and has financed its operations primarily through public offerings and private placements of its equity securities. There can be no assurance that the Company will be able to obtain additional debt, equity or other financing or generate product revenue or revenues from collaborative partners, on terms acceptable to the Company, on a timely basis or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company’s business, results of operations, and financial condition.

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

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying financial statements and the related disclosures are unaudited and have been prepared in accordance with United States generally accepted accounting principles (“U.S. GAAP”). Additionally, certain information and footnote disclosures normally included in the Company’s annual financial statements have been condensed or omitted from this report. Accordingly, these condensed financial statements should be read in conjunction with the financial statements as of and for the year ended December 31, 2020 and notes thereto included in the 2020 Annual Report on Form 10-K.

The unaudited interim 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 interim condensed consolidated financial statements contain all adjustments, including those adjustments that are of a normal and recurring nature, which are necessary to fairly present the Company’s results for the interim periods presented. The results for the three and nine months ended September 30, 2021 are not necessarily indicative of the results for the year ending December 31, 2021, or for any future period.

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

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

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss attributable to common shareholders 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 were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	Three and Nine Months Ended September 30,	
	2021	2020
Series X Preferred Stock (1)	5,242,501	—
Stock options	1,334,399	222,710
Common stock warrants	1,530,380	1,032,291
	<u>8,107,280</u>	<u>1,255,001</u>

(1) Shown as common stock equivalents

Cash, Cash Equivalents and Restricted Cash

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

	September 30,	
	2021	2020
Cash and cash equivalents	\$ 131,777	\$ 52,856
Restricted cash (1)	121	235
Total	<u>\$ 131,898</u>	<u>\$ 53,091</u>

(1) Included in prepaid expenses and other current assets and other assets.

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 the shareholder approval of the conversion in June 2021. The issuance costs are recognized as a dividend at the time of conversion to common shares. As of September 30, 2021, \$24.4 million of the above amounts were accounted for as a non-cash return 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 (“ASU”) 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 ASU 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.

Summary of Significant Accounting Policies

The Company’s significant accounting policies are described in Note 2, “Summary of Significant Accounting Policies,” in the Company’s 2020 Annual Report on Form 10-K, and there were no significant changes to such policies in the three and nine months ended September 30, 2021 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>

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, 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 consolidated statements of operations and comprehensive loss for the nine months ended September 30, 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 September 30, 2021 and December 31, 2020 and indicate the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize observable inputs such as quoted prices in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are either directly or indirectly observable, such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points for which there is little or no market data, which require the Company to develop its own assumptions for the asset or liability. There were no transfers between fair value measurement levels during the three and nine months ended September 30, 2021 or 2020.

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 has from time to time invested 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 has not recorded an asset or liability for the collateral as the Company was not permitted to sell or re-pledge the collateral. The collateral had 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.

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

	As of September 30, 2021			Total
	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Assets:				
Cash and cash equivalents:				
Money market funds	\$ 1,847	\$ —	\$ —	\$ 1,847
Reverse repurchase agreements	—	39,000	—	39,000
Total assets	<u>\$ 1,847</u>	<u>\$ 39,000</u>	<u>\$ —</u>	<u>\$ 40,847</u>

	As of December 31, 2020			Total
	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Assets:				
Cash and cash equivalents:				
Money market funds	\$ 22,999	\$ —	\$ —	\$ 22,999
Short-term investments:				
Reverse repurchase agreements	—	20,000	—	20,000
Total assets	<u>\$ 22,999</u>	<u>\$ 20,000</u>	<u>\$ —</u>	<u>\$ 42,999</u>

At September 30, 2021 and December 31, 2020, cash equivalents approximated their fair value due to their short-term nature.

In connection with the Quellis Acquisition, the Company issued a warrant to purchase 2,805 shares of Series X Preferred Stock at an exercise price of \$341.70 per share. Upon stockholder approval of the Conversion Proposal, and reflecting the reverse stock split, the warrant became a warrant to purchase 467,500 shares of common stock at a purchase price of \$2.10. This was originally accounted for as a liability until stockholder approval of the Conversion Proposal on June 2, 2021, at which point the warrant was reclassified to permanent equity. The warrant liability was valued based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The Company estimated the fair value of the warrant liability using Black-Scholes option-pricing models and assumptions that are based on the individual characteristics of the warrants on the valuation date, as well as assumptions including the fair value per share of the underlying security, the remaining contractual term of the warrant, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying security (in thousands).

	September 30, 2021
Balance at beginning of year	\$ —
Issuance of warrant	4,332
Decrease in the fair value of the warrant	(864)
Reclassification of warrant liability to additional paid in-capital	(3,468)
Ending balance	<u>\$ —</u>

5. Short-Term Investments

The Company did not hold any short-term investments at September 30, 2021. The following table summarizes the short-term investments held at December 31, 2020 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2020				
Reverse repurchase agreements	\$ 20,000	\$ —	\$ —	\$ 20,000
Total	\$ 20,000	\$ —	\$ —	\$ 20,000

The contractual maturities of all short-term investments held at December 31, 2020 were one year or less. There were no short-term investments in an unrealized loss position at December 31, 2020.

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 nine-month periods ended September 30, 2021 and 2020 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 nine months ended September 30, 2021 and 2020.

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Accrued compensation	\$ 1,513	\$ 1,719
Accrued contracted research costs	1,211	1,726
Accrued professional fees	612	356
Accrued other	249	—
Accrued severance	—	396
Total	\$ 3,585	\$ 4,197

7. Stockholders' Equity

Preferred Stock

Under the Company's amended and 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 September 30, 2021, 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 September 30, 2021:

Year Issued	Equity Instrument	Warrants Outstanding	Exercise Price	Date of Expiration
2015	Common Stock	204	\$ 732.72	3/30/2022
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>1,530,380</u>		
Weighted average exercise price			\$ 41.84	
Weighted average life in years				4.30

8. Reserved for Future Issuance

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

	September 30, 2021	December 31, 2020
Series X Preferred Stock	5,242,501	—
Warrants for the purchase of common stock	1,530,380	1,032,291
Options outstanding to purchase common stock	1,334,399	227,846
Options available for future issuance to purchase common stock	254,748	322,695
Shares reserved for the employee stock purchase plan	30,904	24,825
Total	<u>8,392,932</u>	<u>1,607,657</u>

As of September 30, 2021, the Company also had 31,455 shares of Series X Preferred Stock outstanding. Each share of Series X Preferred Stock outstanding is convertible into 166.67 shares of the Company’s common stock, subject to certain beneficial ownership limitations at the holder’s option. See Note 1 – “*Organization and Operations*” for additional detail.

9. Stock Incentive Plans

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

	Shares	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2020	227,846	\$ 68.25	8.13	\$ —
Granted	1,113,982	\$ 16.21		
Assumed in Quellis Acquisition	55,414	\$ 1.73		
Exercised	(2,992)	\$ 2.10		
Cancelled or forfeited	(58,344)	\$ 62.08		
Expired	(1,507)	\$ 100.85		
Outstanding at September 30, 2021	<u>1,334,399</u>	\$ 22.43	9.25	\$ 374
Vested and exercisable at September 30, 2021	<u>127,064</u>	\$ 74.71	7.38	\$ 178

The total intrinsic value of options exercised in the three and nine months ended September 30, 2021 was \$38 thousand. There were no options exercised in the three or nine months ended September 30, 2020. The total grant date fair value of options vested for the three months ended September 30, 2021 and 2020 was \$0.3 million. The total grant date fair value of options vested for the nine months ended September 30, 2021 and 2020 was \$1.3 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 September 30, 2021 and 2020 was \$6.20 and \$29.10, respectively. The weighted-average grant date fair value of options granted to employees and non-employees for the nine months ended September 30, 2021 and 2020 was \$10.15 and \$22.32, respectively.

At September 30, 2021, the total unrecognized compensation expense related to unvested stock option awards was \$11.8 million. The Company expects to recognize that cost over a weighted-average period of approximately 3.1 years.

10. Subsequent Events

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

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

You should read the following discussion and analysis of our financial condition and results of operations together with our 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, 2020 (the “2020 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 2020 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.

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. Our lead product candidate is STAR-0215 (formerly known as QLS-215), a potential best-in-class monoclonal antibody inhibitor of plasma kallikrein in preclinical 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, based on the data generated to date and the existing HAE treatment landscape.

In January 2021, as further described below, 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. In November 2020, after we stopped the development of our edasalonexent program as a potential treatment for Duchenne Muscular Dystrophy, or DMD, we decided to explore and evaluate strategic options and engaged Ladenburg Thalmann & Co., Inc. as our strategic financial advisor. The acquisition of Quellis was the result of our evaluation of strategic options and we believe that the acquisition represents an opportunity to create substantial value for our stockholders.

On September 8, 2021, we formally changed our name to Astria Therapeutics, Inc. from Catabasis Pharmaceuticals, Inc. The name “Astria” originates from the Greek word for star, demonstrating our commitment to patients who serve as our guiding stars.

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. At the 2021 NORD Rare Diseases and Orphan Products Breakthrough Summit in October 2021, we presented findings on the burdens of HAE disease and treatment indicating a substantial need for new HAE treatments, and that HAE patients are open to trying new therapies that could reduce their disease and treatment burdens.

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. STAR-0215 is currently in preclinical development and we expect to submit an Investigational New Drug application, or IND, for STAR-0215 in mid-2022 and plan to initiate a Phase 1 clinical trial with initial results anticipated by the end of 2022. We believe that this clinical trial has the opportunity to establish proof of concept for the differentiated profile of STAR-0215. Our goals for this trial with STAR-0215 are to demonstrate safety, establish the long half-life, demonstrate the duration of inhibition of plasma kallikrein activity and to refine dose and dosing regimen for future studies in HAE patients. Assuming positive data from the Phase 1 trial, we plan to initiate a Phase 1b/2 trial in patients with HAE in 2023.

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 less frequently. Multiple experiments have confirmed that STAR-0215 is approximately 10-fold more potent than lanadelumab, a monoclonal antibody inhibitor of plasma kallikrein commercialized under the name TAKHZYRO and an approved preventative treatment for HAE, in inhibiting bradykinin production. In cynomolgus monkey studies, lanadelumab was observed to have a half-life of approximately 10 days, which is consistent with what has been reported in U.S. Food and Drug Administration review documents and publications for lanadelumab in non-human primates. STAR-0215 was administered at the same dose as lanadelumab and the observed half-life was approximately 34 days, which is about a three to four-fold longer half-life than observed for lanadelumab. We believe this could translate to a half-life of several months for STAR-0215 in humans. If this longer half-life is demonstrated in clinical trials, it has the potential to enable dosing once every three months or longer.

We presented new preclinical data from the STAR-0215 program at the American College of Allergy, Asthma and Immunology, or ACAAI, Annual Scientific Meeting in November 2021, demonstrating the high potency of STAR-0215 for binding to and inhibition of plasma kallikrein on a different site than lanadelumab and supporting the ability of YTE technology to extend half-life. YTE modifications in STAR-0215 are designed to enable a longer duration of action. In cynomolgus monkeys dosed with STAR-0215, the YTE modifications protected STAR-0215 from antibody clearance leading to a more than three-fold increase in plasma half-life compared to an antibody without the YTE modifications. The preclinical data to date suggest that at equal doses STAR-0215 would have a significantly longer duration of action than lanadelumab and could result in STAR-0215 being 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 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.

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 stockholders meeting on June 2, 2021. On the fourth business day after the approval, 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 September 30, 2021, 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 September 30, 2021, 54,622 shares of Series X Preferred Stock were 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.

Reverse Stock Split

On August 4, 2021, our Board of Directors approved a reverse stock split of our outstanding shares of common stock at a ratio of one-for-six (1:6). The reverse stock split became effective on August 19, 2021. The reverse stock split was approved by our stockholders at our Annual Meeting of Stockholders on June 2, 2021. All share and per share amounts of the common stock included in this Quarterly Report on Form 10-Q, including in the accompanying 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.

Financial Overview

Research and Development Expenses

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

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

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

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

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

	Nine Months Ended September 30,	
	2021	2020
STAR-0215	\$ 4,422	\$ —
Edasalonexent	660	13,765
Other research programs	765	—
Costs not directly allocated to programs:		
Employee expenses including cash compensation, benefits and stock-based compensation	3,405	4,421
Facilities	265	427
Consultants and professional expenses, including stock-based compensation	247	924
Other	95	308
Total costs not directly allocated to programs	4,012	6,080
Total research and development expenses	\$ 9,859	\$ 19,845

Based on the results of the Phase 3 PolarisDMD trial of edasalonexent for the treatment of DMD, which we announced in October 2020, we stopped all activities related to the development of edasalonexent, including the ongoing GalaxyDMD open-label extension trial.

We expect to incur significant research and development expenses in the year ending December 31, 2021 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 comparable to 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;
- 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 and when 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 nine months ended September 30, 2021. As of September 30, 2021, all severance related to the reduction of workforce has been paid.

Other Income (Expense)

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 Policies and Significant Judgments and Estimates

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

During the nine months ended September 30, 2021, there were no material changes to our critical accounting policies as reported in our 2020 Annual Report on Form 10-K, other than the addition of accounting for IPR&D expense as described in Note 3, “Acquisition of Quellis” to condensed consolidated financial statements including in this Quarterly Report on Form 10-Q.

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 September 30, 2021 and 2020

The following table summarizes our results of operations for the three months ended September 30, 2021 and 2020, together with the dollar change in those items (in thousands):

	Three Months Ended September 30,		Period-to- Period Change
	2021	2020	
Operating expenses:			
Research and development	\$ 3,788	\$ 7,806	\$ (4,018)
General and administrative	4,110	3,057	1,053
Total operating expenses	7,898	10,863	(2,965)
Loss from operations	(7,898)	(10,863)	2,965
Other income, net	27	1	26
Net loss	<u>\$ (7,871)</u>	<u>\$ (10,862)</u>	<u>\$ 2,991</u>

Research and Development Expenses

Research and development expenses decreased by \$4.0 million to \$3.8 million for the three months ended September 30, 2021 from \$7.8 million for the three months ended September 30, 2020, a decrease of 51%. The decrease in research and development expenses was primarily attributable to a \$5.8 million decrease in costs to support our edasalonexent program due to stopping all development activities associated with the program and a \$0.2 million decrease in employee related expenses. These decreases were partially offset by a \$1.4 million increase in costs to support pre-clinical development of the STAR-0215 program, a \$0.3 million increase in other research and platform programs, and a \$0.3 million increase in consulting and professional fees.

General and Administrative Expenses

General and administrative expenses increased by \$1.1 million to \$4.1 million for the three months ended September 30, 2021 from \$3.1 million for the three months ended September 30, 2020, an increase of 34%. The increase was attributable to a \$0.5 million increase in stock-based compensation expense, a \$0.2 million increase in our Delaware franchise tax fee, a \$0.1 million increase in other employee related costs, a \$0.1 million increase in consulting and professional fees, a \$0.1 million increase in insurance expense, and a \$0.1 million increase in the general and administrative portion of facilities expense.

Other Income, Net

Other income, net increased by \$26,000 to \$27,000 for the three months ended September 30, 2021 from \$1,000 for the three months ended September 30, 2020. The increase was primarily attributable to an increase in interest and investment income due to higher interest yields and an increase in our interest-earning assets.

Comparison of the Nine Months Ended September 30, 2021 and 2020

The following table summarizes our results of operations for the nine months ended September 30, 2021 and 2020, together with the dollar change in those items (in thousands):

	<u>Nine Months Ended September 30,</u>		<u>Period-to- Period Change</u>
	<u>2021</u>	<u>2020</u>	
Operating expenses:			
Research and development	\$ 9,859	\$ 19,845	\$ (9,986)
General and administrative	10,992	8,612	2,380
Acquired in-process research and development	164,617	—	164,617
Total operating expenses	185,468	28,457	157,011
Loss from operations	(185,468)	(28,457)	(157,011)
Other income, net	47	135	(88)
Net loss	<u>\$ (185,421)</u>	<u>\$ (28,322)</u>	<u>\$ (157,099)</u>

Research and Development Expenses

Research and development expenses decreased by \$10.0 million to \$9.9 million for the nine months ended September 30, 2021 from \$19.8 million for the nine months ended September 30, 2020, a decrease of 50%. The decrease in research and development expenses was primarily attributable to a \$13.1 million decrease in costs to support our edasalonexent program due to stopping development activities associated with the program, a \$1.0 million decrease in employee related expenses, a \$0.6 million decrease in professional fees, a \$0.2 million decrease to the research and development portion of facilities expense and a \$0.2 million decrease to the research and development portion of general office expenses. These decreases were partially offset by a \$4.3 million increase in costs to support pre-clinical development of the STAR-0215 program and a \$0.8 million increase in other research and platform programs.

General and Administrative Expenses

General and administrative expenses increased by \$2.4 million to \$11.0 million for the nine months ended September 30, 2021 from \$8.6 million for the nine months ended September 30, 2020, an increase of 28%. The increase was attributable to a \$0.9 million increase in stock-based compensation expense, a \$0.7 million increase in other employee-related costs, a \$0.3 million increase in consulting and professional fees, a \$0.3 million increase in insurance expense, a \$0.1 million increase in the general and administrative portion of general office expense, and a \$0.1 million increase in our Delaware franchise tax fee.

Acquired In-process Research and Development (IPR&D) Expense

Acquired IPR&D expense was \$164.6 million during the nine months ended September 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 during the nine months ended September 30, 2020.

Other Income, Net

Other (expense) income, net decreased by \$0.1 million to \$47,000 for the nine months ended September 30, 2021 from \$0.1 million for the nine months ended September 30, 2020. The decrease was primarily attributable to a decrease in interest and investment income due to lower interest rates and an increase in losses due to changes in foreign currency exchange rates.

Liquidity and Capital Resources

From our inception through September 30, 2021, we raised an aggregate of \$426.0 million, through various private placements of preferred stock, our initial public offering, as well as various other registered equity offerings, including underwritten public offerings, ATM Programs (as defined below), and stock option and warrant exercises.

As of September 30, 2021, we had cash and cash equivalents of \$131.8 million. We expect that our existing cash and cash equivalents are sufficient to support our operating expenses through 2023.

We will need substantial additional funding to 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. 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 a Stock Purchase Agreement, or the Purchase Agreement, with certain institutional and accredited investors (the “February 2021 Financing”). Pursuant to the Purchase Agreement, we 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.

January 2020 Financing

On January 30, 2020, we entered into an underwriting agreement with Oppenheimer & Co. Inc. relating to an underwritten public offering (the “January 2020 Financing”), of 881,666 shares of common stock at a price to the public of \$30.00 per share, including 115,000 shares issued upon the exercise in full by Oppenheimer & Co. Inc. of its overallotment option. This resulted in gross proceeds of \$26.5 million, and net proceeds of \$24.6 million.

At-the-Market Offering

We have entered into various sales agreements with Cowen and Company LLC (“Cowen”), pursuant to which we could issue and sell shares of common stock, 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 (“Jefferies”), 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 3% of the gross proceeds from any common stock sold through the ATM Programs. As of September 30, 2021, we have not sold any shares of common stock pursuant to the Jefferies agreement and \$25.0 million of common stock remains available for sale under the Jefferies agreement.

During the nine months ended September 30, 2020, we sold an aggregate of 392,288 shares of common stock pursuant to our ATM Programs at a weighted average price of \$42.76 per share, for gross proceeds of \$16.8 million and net proceeds of \$16.3 million. There was no activity from the ATM Programs during the nine months ended September 30, 2021.

Cash Flows

Comparison of the Nine Months Ended September 30, 2021 and 2020

The following table provides information regarding our cash flows for the six months ended June 30, 2021 and 2020 (in thousands):

	Nine Months Ended September 30,	
	2021	2020
Net cash used in operating activities	\$ (23,865)	\$ (24,424)
Net cash provided by investing activities	26,445	26,310
Net cash provided by financing activities	104,267	40,829
Net increase in cash, cash equivalents and restricted cash	<u>\$ 106,847</u>	<u>\$ 42,715</u>

Net Cash Used in Operating Activities

Net cash used in operating activities was \$23.9 million for the nine months ended September 30, 2021 and consisted primarily of a net loss of \$185.4 million adjusted for the non-cash portion of acquired IPR&D of \$164.6 million, stock-based compensation expense of \$2.4 million, a gain on warrants of \$0.3 million, and a net increase in net assets of \$5.2 million, which resulted primarily from a decrease in accounts payable of \$3.0 million, an increase in prepaid expenses and other assets of \$1.1 million, a decrease in accrued expenses of \$1.0 million, and a decrease in our operating lease of \$0.1 million.

Net cash used in operating activities was \$24.4 million for the nine months ended September 30, 2020 and consisted primarily of a net loss of \$28.3 million adjusted for stock based compensation expense of \$1.1 million and a net decrease in net assets of \$2.8 million, which resulted primarily from an increase in accrued expenses of \$2.3 million, an increase in accounts payable of \$0.2 million, and a decrease in prepaid expense, other assets and operating lease of \$0.3 million.

Net Cash Provided by Investing Activities

Net cash provided by investing activities was \$26.4 million for the nine months ended September 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 investing activities was \$26.3 million for the nine months ended September 30, 2020 and consisted of proceeds from maturities of short-term investments of \$69.1 million partially offset by purchases of short-term investments of \$42.8 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$104.3 million during the nine months ended September 30, 2021, which was attributable to net proceeds of \$104.3 million from the February 2021 Financing. Net cash provided by financing activities was \$40.8 million during the nine months ended September 30, 2020, which was primarily attributable to net proceeds of \$24.6 million from the January 2020 Financing and net proceeds of \$16.3 million from our ATM programs.

Funding Requirements

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

As of September 30, 2021, we had an accumulated deficit of \$446.3 million. We have been primarily involved with research and development activities and have incurred operating losses and negative cash flows from operations since our inception.

As of September 30, 2021, we had available cash and cash equivalents of \$131.8 million. We expect that our existing cash and cash equivalents are sufficient to support our operating expenses 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. 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, revenue, if any, received from commercial sales of our product candidates;
- if we obtain marketing approval of any of our product candidates, our ability to successfully compete against other approved products that are approved or used as treatments for the indications for which our products are approved, including with respect to STAR-0215 in HAE;
- our headcount growth and associated costs;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims;
- the impact of the COVID-19 pandemic on our operations, business and prospects; and · the costs of operating as a public company.

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

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

If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds 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.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable U.S. Securities and Exchange Commission rules.

Contractual Obligations

As of September 30, 2021, there had been no material changes to our contractual obligations and commitments disclosed under Management's Discussion and Analysis of Financial Condition and Results of Operations in our 2020 Annual Report on Form 10-K.

Item 3. Qualitative and Quantitative Disclosures about Market Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of September 30, 2021, we had cash and cash equivalents of \$131.8 million and, as of December 31, 2020, we had cash, cash equivalents and short-term investments of \$44.9 million. Our cash equivalents as of September 30, 2021 consisted of money market funds and U.S. reverse repurchase agreements. Our cash equivalents as of December 31, 2020 consisted of money market funds. Our short-term investments as of December 31, 2020 consisted of U.S. reverse repurchase agreements. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio and interest income.

As of September 30, 2021 and December 31, 2020, we had no material liabilities denominated in foreign currencies.

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

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of September 30, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

We continue to review and document our disclosure controls and procedures, including our internal controls and procedures for financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

Changes in Internal Control over Financial Reporting

During the nine months ended September 30, 2021, 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, 2020, 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
3.1	Certificate of Amendment to Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Form 8-K (File No. 001-37467) filed with the Securities and Exchange Commission on August 20, 2021)
3.2	Certificate of Amendment to Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Form 8-K (File No. 001-37467) filed with the Securities and Exchange Commission on September 8, 2021)
3.3	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.2 to the Form 8-K (File No. 001-37467) filed with the Securities and Exchange Commission on September 8, 2021)
3.4	Amended and Restated By-laws of the Registrant (incorporated by reference to Exhibit 3.3 to the Form 8-K (File No. 001-37467) filed with the Securities and Exchange Commission on September 8, 2021)
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	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Label Linkbase Document
104	Cover Page Data File (the cover page XBRL tags are embedded within the iXBRL document).

SIGNATURES

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

Astria Therapeutics, Inc.

Date: November 10, 2021

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: November 10, 2021

/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: November 10, 2021

/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 September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officers of the Company hereby certify, pursuant to 18 U.S.C. Section 1350, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 10, 2021

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

Jill C. Milne, Ph.D.

President and Chief Executive Officer (Principal Executive Officer)

Date: November 10, 2021

/s/ NOAH C. CLAUSER

Noah C. Clauser

Chief Financial Officer (Principal Financial Officer)
