

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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

Catabasis Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

26-3687168
(IRS Employer
Identification No.)

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

02110
(Zip Code)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	CATB	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 April 30, 2021, there were 23,417,006 shares of the registrant's Common Stock, par value \$0.001 per share, outstanding.

TABLE OF CONTENTS

	<u>Page</u>
<u>PART I. FINANCIAL INFORMATION</u>	<u>2</u>
<u>Item 1. Financial Statements (unaudited)</u>	<u>2</u>
<u>Condensed Consolidated Balance Sheet as of March 31, 2021 and December 31, 2020</u>	<u>2</u>
<u>Condensed Consolidated Statements of Operations for the three months ended March 31, 2021 and 2020</u>	<u>3</u>
<u>Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2021 and 2020</u>	<u>4</u>
<u>Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) for the three months ended March 31, 2021 and 2020</u>	<u>5</u>
<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2021 and 2020</u>	<u>6</u>
<u>Notes to Condensed Consolidated Financial Statements</u>	<u>7</u>
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>15</u>
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>24</u>
<u>Item 4. Controls and Procedures</u>	<u>24</u>
<u>PART II. OTHER INFORMATION</u>	<u>25</u>
<u>Item 1A. Risk Factors</u>	<u>25</u>
<u>Item 5. Other Information</u>	<u>25</u>
<u>Item 6. Exhibits</u>	<u>26</u>
<u>SIGNATURES</u>	<u>27</u>

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 QLS-215 and the timing, nature, goals and results of our planned Phase 1a and Phase 1b/2 clinical trials of QLS-215, including that favorable results from such trials could establish proof of concept for the differentiation of QLS-215 as a potential treatment for hereditary angioedema, or HAE;
- our expectations about the unmet medical need for HAE, the potential differentiating attributes of QLS-215 as a potential treatment for HAE, along with the potential market impact of such differentiation, the potential of QLS-215 to be a best-in-class treatment for HAE, and the nature and anticipated growth of the global HAE market and HAE therapies;
- our expectations that pre-clinical data of QLS-215 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 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; costs related to the Quellis acquisition; 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; 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 to QLS-215 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 QLS-215 and any other future product candidates; competition with respect to QLS-215 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; our ability to obtain stockholder approval of the conversion rights of our Series X Preferred Stock by July 28, 2021, which, if we are unable to obtain, would trigger the rights of such stockholders to require repayment, in cash, for the shares of common stock underlying their shares of Series X Preferred Stock at their then fair market value; 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

Catabasis Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 146,920	\$ 24,930
Short-term investments	-	20,000
Prepaid expenses and other current assets	764	1,395
Total current assets	147,684	46,325
Right-of-use asset	874	966
Other assets	182	165
Total assets	<u>\$ 148,740</u>	<u>\$ 47,456</u>
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 1,809	\$ 1,544
Accrued expenses	1,945	4,197
Current portion of operating lease liabilities	652	649
Total current liabilities	4,406	6,390
Warrant liability	4,369	-
Long-term portion of operating lease liabilities	229	397
Total liabilities	9,004	6,787
Commitments		
Series X redeemable convertible preferred stock, \$0.001 par value per share, 91,380 shares authorized; 86,077 shares issued and outstanding as of March 31, 2021 and no shares issued and outstanding as of December 31, 2020	240,881	-
Stockholders' equity (deficit):		
Common stock, \$0.001 par value per share, 150,000,000 shares authorized; 23,417,006 and 20,084,337 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	23	20
Additional paid-in capital	329,813	301,546
Accumulated deficit	(430,981)	(260,897)
Total stockholders' equity (deficit)	(101,145)	40,669
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	<u>\$ 148,740</u>	<u>\$ 47,456</u>

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

Catabasis Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 2,593	\$ 5,289
General and administrative	2,880	2,753
Acquired in-process research and development	164,612	-
Total operating expenses	170,085	8,042
Loss from operations	(170,085)	(8,042)
Total other income, net	1	90
Net loss	\$ (170,084)	\$ (7,952)
Net loss per share - basic and diluted	\$ (7.60)	\$ (0.50)
Weighted-average common shares outstanding used in net loss per share - basic and diluted	22,380,176	15,898,664

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

Catabasis Pharmaceuticals, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2021	2020
Net loss	\$ (170,084)	\$ (7,952)
Other comprehensive loss:		
Loss on short-term investments	-	(15)
Total other comprehensive loss:	-	(15)
Comprehensive loss	\$ (170,084)	\$ (7,967)

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

Catabasis Pharmaceuticals, Inc.
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except shares)(*Unaudited*)

	Three Months Ended March 31,	
	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	-
Balance, end of period	<u>86,077</u>	<u>-</u>
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	-
Balance, end of period	<u>\$ 240,881</u>	<u>\$ -</u>
Total Series X redeemable convertible preferred stock	<u>\$ 240,881</u>	<u>\$ -</u>
Common stock, shares		
Balance, beginning of period	20,084,337	12,433,600
Issuance of common stock upon acquisition of Quellis	3,332,669	-
Issuance of common stock for at-the-market offerings	-	173,572
Issuance of common stock and warrants in public offerings	-	5,290,000
Balance, end of period	<u>23,417,006</u>	<u>17,897,172</u>
Common stock, par value		
Balance, beginning of period	\$ 20	\$ 12
Issuance of common stock upon acquisition of Quellis	3	-
Issuance of common stock for at-the-market offerings	-	1
Issuance of common stock and warrants in public offerings	-	5
Balance, end of period	<u>\$ 23</u>	<u>\$ 18</u>
Additional paid-in capital		
Balance, beginning of period	\$ 301,546	\$ 259,305
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	8,095	-
Issuance of common stock in a public offering, net of issuance costs	-	24,554
Expense related to warrants inherited in acquisition of Quellis	241	-
Issuance of common stock for at-the-market offerings	-	1,059
Stock-based compensation expense	366	339
Balance, end of period	<u>\$ 329,813</u>	<u>\$ 285,257</u>
Accumulated deficit		
Balance, beginning of period	\$ (260,897)	\$ (223,597)
Net loss	(170,084)	(7,952)
Balance, end of period	<u>\$ (430,981)</u>	<u>\$ (231,549)</u>
Accumulated other comprehensive loss		
Balance, beginning of period	\$ -	\$ -
Realized loss on short-term investments	-	(15)
Balance, end of period	<u>\$ -</u>	<u>\$ (15)</u>
Total stockholders' equity (deficit)	<u>\$ (101,145)</u>	<u>\$ 53,711</u>

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

Catabasis Pharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2021	2020
Operating activities		
Net loss	\$ (170,084)	\$ (7,952)
Reconciliation of net loss to net cash used in operating activities:		
Non-cash portion of acquired in-process research and development	164,612	-
Other non-cash items	425	351
Changes in assets and liabilities:		
Prepaid expenses and other current assets	767	669
Right-of-use asset- operating	(73)	51
Accounts payable	(1,712)	(501)
Accrued expenses	(2,651)	393
Net cash used in operating activities	<u>(8,716)</u>	<u>(6,989)</u>
Investing activities		
Purchases of short-term investments	-	(42,777)
Sales and maturities of short-term investments	20,000	27,345
Cash acquired in acquisition of Quellis	6,466	-
Purchases of property and equipment	(21)	-
Net cash provided by (used in) investing activities	<u>26,445</u>	<u>(15,432)</u>
Financing activities		
Proceeds from public offering, net of issuance costs	-	24,564
Proceeds from private offering of public equity, net of issuance costs	104,261	-
Proceeds from at-the-market offering, net of issuance costs	-	1,060
Net cash provided by financing activities	<u>104,261</u>	<u>25,624</u>
Net increase in cash, cash equivalents and restricted cash	121,990	3,203
Cash, cash equivalents and restricted cash, beginning of period	25,051	10,376
Cash, cash equivalents and restricted cash, end of period	<u>\$ 147,041</u>	<u>\$ 13,579</u>
Non-cash investing activities:		
Fixed asset purchases included in accounts payable	<u>\$ -</u>	<u>\$ 9</u>
Non-cash financing activities:		
Public offering issuance costs included in current liabilities	<u>\$ -</u>	<u>\$ 5</u>

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

Catabasis Pharmaceuticals, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Organization and Operations

The Company

Catabasis Pharmaceuticals, Inc. (the “Company”) 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 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.

Agreement and Plan of Merger

On January 28, 2021, the Company acquired Quellis (the “Quellis Acquisition”). Under the terms of the Merger Agreement, the Company issued to the stockholders of Quellis 3,332,669 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 332,494 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 185,136 shares of the Company’s common stock at an exercise price of \$0.35 per share, which warrants are exercisable until December 14, 2030.

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”). In accounting for the Purchase Agreement, the Company recorded a beneficial conversion feature of \$19.6 million, which is included in Additional Paid in Capital in the accompanying Condensed Consolidated Balance Sheet as of March 31, 2021.

As a result of the Quellis Acquisition and the February 2021 Financing, in 2021 the Company issued the following Series X Preferred Stock or warrants to purchase Series X Preferred Stock:

	Series X Preferred Stock	Common Stock Issuable Upon Conversion (1)
Outstanding shares issued in merger	50,504	50,504,000
Outstanding shares issued in February 2021 Financing	35,573	35,573,000
Warrants assumed in merger	2,805	2,805,000
Total	88,882	88,882,000

(1) Requires stockholder approval for conversion.

Subject to stockholder approval, each share of Series X Preferred Stock is convertible into 1,000 shares of common stock.

The Company is required to hold a stockholders' meeting to request the approval of the conversion of the Series X Preferred Stock into shares of the Company's common stock in accordance with Nasdaq Listing Rule 5635(a) (the "Conversion Proposal"). The Company has scheduled its 2021 Annual Meeting of Stockholders for June 2, 2021 and has included the Conversion Proposal as one of the proposals to be voted on at the meeting.

If the Company's stockholders do not approve the conversion of the Series X Preferred Stock by July 28, 2021, then the holders of the Series X Preferred Stock are entitled to require the Company to make redemption payments at a price per share equal to the fair value of undelivered shares of common stock, defined as the last reported closing price of the Company's common stock on the trading day on which notice of conversion is delivered to the Company. Using the closing price on May 10, 2021 of \$1.86, if all currently outstanding Series X Preferred Stock was redeemed for cash, the Company would be required to make a payment of \$160.1 million. The Company has insufficient liquidity to make such a payment, if required.

Holders of Series X Preferred Stock are entitled to receive dividends 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. Additionally, the approval of the holders of a majority of the Series X Preferred Stock is required for certain change of control transactions, provided that this approval right will terminate upon stockholder approval of the Conversion Proposal.

Following stockholder approval of the Conversion Proposal, on the fourth business day after the date on which such stockholder approval is received, each share of Series X Preferred Stock then outstanding automatically converts into 1,000 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 (to be initially set at 9.99% and thereafter adjustable 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. Shares of Series X Preferred Stock not converted automatically are thereafter subject to conversion at the option of the holder.

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 5,290,000 shares of common stock at a price to the public of \$5.00 per share, including 690,000 shares issued upon the exercise in full by Oppenheimer & Co. Inc. of its over-allotment 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, par value of \$0.001 per share, under at-the-market offering programs (the "ATM Programs"). The Company pays Cowen 3% of the gross proceeds from any common stock sold through these sales agreements. On May 10, 2021, the Company notified Cowen that it was terminating its current sales agreement with Cowen, such termination to take effect on May 20, 2021.

During the three months ended March 31, 2020, the Company sold an aggregate of 173,572 shares of common stock pursuant to the ATM Programs, at an average price of \$6.29 per share, for net proceeds of \$1.1 million after deducting sales commissions and offering expenses. There was no activity from the ATM Programs during the three months ended March 31, 2021.

As of March 31, 2021, the Company had an accumulated deficit of \$431.0 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 has been primarily involved with research and development activities and has incurred operating losses and negative cash flows from operations since its inception. The Company anticipates that it will continue to incur significant operating losses for the next several years as it continues to develop its product candidates.

As of March 31, 2021, the Company had available cash and cash equivalents of \$146.9 million. As part of the Quellis Acquisition and the February 2021 Financing, the Company issued 86,077 shares of Series X Preferred Stock, which upon stockholder approval, will be converted to 86,077,000 shares of common stock, subject to applicable beneficial ownership limitations. The terms of the Series X Preferred Stock include a cash redemption feature which, as described above, provide that, if the Company's stockholders fail to approve the Conversion Proposal by July 28, 2021, the Company could be required to make redemption payments to the holders of Series X Preferred Stock significantly in excess of its current liquidity. Based on precedent transactions and the terms of the Series X Preferred Stock, the Company believes that stockholders who are entitled to vote on the Conversion Proposal at the Company's 2021 Annual Meeting of Stockholders, which is scheduled for June 2, 2021, will vote to approve the proposal. However, as the vote of the Company's common stockholders is outside of the control of the Company, there is substantial doubt about its ability to continue as a going concern for at least 12 months following the issuance of these condensed consolidated financial statements. The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

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 Company's 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 months ended March 31, 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, Catabasis 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.

Derivative Instruments

The Company generally does not use derivative instruments to hedge exposures to cash-flow or market risks; however, certain warrants to purchase preferred stock that do not meet the requirements for classification as equity are classified as liabilities. Such financial instruments are initially recorded at fair value, with subsequent changes in fair value charged to operations in each reporting period. If these instruments subsequently meet the requirements for classification as equity, the Company reclassifies the fair value to equity.

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss 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 Months Ended March 31,	
	2021	2020
Series X Preferred Stock (1)	86,077,000	-
Stock options	1,631,322	1,206,644
Common stock warrants	6,378,885	6,193,749
Preferred stock warrants (1)	2,805,000	-
	<u>96,892,207</u>	<u>7,400,393</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):

	March 31,	
	2021	2020
Cash and cash equivalents	\$ 146,920	\$ 13,344
Restricted cash (1)	121	235
Total	<u>\$ 147,041</u>	<u>\$ 13,579</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.

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 months ended March 31, 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 its acquisition of Quellis 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 3,332,669 shares of Common Stock and 50,504 shares of Series X Preferred Stock. Each share of Series X Preferred Stock is convertible into 1,000 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, QLS-215.

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 QLS-215 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 three months ended March 31, 2021 as the acquired IPR&D had no alternative future use, as determined by the Company in accordance with U.S. GAAP.

4. Financial Instruments

The tables below present information about the Company’s assets and liabilities that are measured at fair value on a recurring basis as of March 31, 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 months ended March 31, 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 accounts 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 other income, expense. The warrants classified as equity are reported at their estimated fair value with no subsequent remeasurement.

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

	As of March 31, 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	\$ 1,833	\$ -	\$ -	\$ 1,833
Reverse repurchase agreements	-	39,000	-	39,000
Total assets	\$ 1,833	\$ 39,000	\$ -	\$ 40,833
Liabilities:				
Warrant liability	\$ -	\$ -	\$ 4,369	\$ 4,369
Total liabilities	\$ -	\$ -	\$ 4,369	\$ 4,369

	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	\$ 22,999	\$ 20,000	\$ -	\$ 42,999

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

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 estimates 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.

	March 31, 2021
Beginning balance	\$ -
Issuance of liability classified warrants	4,332
Change in fair value and current period expense	37
Ending balance	\$ 4,369

5. Short-Term Investments

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

	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>
December 31, 2020				
Reverse repurchase agreements	\$ 20,000	\$ -	\$ -	\$ 20,000
Total	<u>\$ 20,000</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 20,000</u>

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-month periods ended March 31, 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 months ended March 31, 2021 and 2020.

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	<u>March 31, 2021</u>	<u>December 31, 2020</u>
Accrued compensation	\$ 704	\$ 1,719
Accrued other	384	-
Accrued professional fees	371	356
Accrued severance	205	396
Accrued contracted research costs	281	1,726
Total	<u>\$ 1,945</u>	<u>\$ 4,197</u>

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 March 31, 2021, the Company had 86,077 shares of Series X preferred stock outstanding. 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 March 31, 2021:

Year Issued	Equity Instrument	Warrants Outstanding	Exercise Price	Date of Expiration
2014	Common Stock	1,227	\$ 122.12	8/26/2021
2015	Common Stock	1,227	\$ 122.12	3/30/2022
2018	Common Stock	4,199,995	\$ 12.00	6/21/2023
2019	Common Stock	1,991,300	\$ 6.25	2/7/2024
2021	Common Stock	185,136	\$ 0.35	12/14/2030
2021 (1)	Series X Preferred Stock	2,805,000	\$ 0.34	12/14/2030
Total		9,183,885		
Weighted average exercise price			\$ 6.99	
Weighted average life in years				4.80

(1) Includes 2,805 warrants exercisable for Series X Preferred Stock at an exercise price of \$341.17 shown as common stock equivalents

8. Reserved for Future Issuance

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

	March 31, 2021	December 31, 2020
Warrants for the purchase of common stock	6,378,885	6,193,749
Options outstanding to purchase common stock	1,631,322	1,367,667
Options available for future issuance to purchase common stock	1,996,322	1,936,173
Shares reserved for the employee stock purchase plan	185,421	148,951
Total	10,191,950	9,646,540

As of March 31, 2021, the Company also had 86,077 shares of Series X Preferred Stock and 2,805 Series X Preferred Stock warrants outstanding. Following stockholder approval of the Conversion Proposal, on the fourth business day after the date on which such stockholder approval is received, each share of Series X Preferred Stock then outstanding automatically converts into 1,000 shares of the Company's common stock, subject to certain beneficial ownership limitations. 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	1,367,667	\$ 11.38	8.13	\$ -
Granted	30,000	\$ 2.43		
Assumed in Quellis Acquisition	332,494	\$ 0.29		
Cancelled or forfeited	(90,164)	\$ 16.70		
Expired	(8,675)	\$ 9.16		
Outstanding at March 31, 2021	1,631,322	\$ 17.83	8.25	\$ 879
Vested and exercisable at March 31, 2021	622,533	\$ 9.16	7.00	\$ -

There were no options exercised in the three months ended March 31, 2021 and 2020. The total grant date fair value of options vested for the three months ended March 31, 2021 and 2020 was \$0.5 million and \$0.4 million, respectively. The weighted-average grant date fair value of options granted to employees and non-employees for the three months ended March 31, 2021 and 2020 was \$1.50 and \$3.57, respectively.

At March 31, 2021, the total unrecognized compensation expense related to unvested stock option awards was \$2.8 million. The Company expects to recognize that cost over a weighted-average period of approximately 2.2 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 most recent 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 most recent 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 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.

In January 2021, as further described below, we acquired Quellis Biosciences, Inc., or Quellis, including the QLS-215 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.

HAE is a rare, debilitating and potentially life-threatening disease. The treatment options for patients with HAE have improved, however there is remaining unmet medical need and the global market for HAE therapy is strong and growing. The vision for our lead program, QLS-215, is to develop a best-in-class monoclonal antibody inhibitor of plasma kallikrein for HAE prophylaxis that is able to treat HAE by achieving sustained blood levels of QLS-215 with infrequent dosing. Plasma kallikrein, when uninhibited as occurs in HAE, produces bradykinin that causes pathologic vascular permeability, vasodilation and ultimately excessive tissue swelling. QLS-215 is a humanized monoclonal antibody that in preclinical studies potently inhibits the production of bradykinin by plasma kallikrein and has a long plasma half-life that may potentially enable patients to dose less frequently and potentially be more effective than existing HAE treatments. QLS-215 is currently in preclinical development and we expect to submit an Investigational New Drug application, or IND, for QLS-215 in the first half of 2022 and plan to initiate a Phase 1a clinical trial with initial results anticipated by the end of 2022. Subsequently, assuming positive data from the Phase 1a clinical trial, we plan to initiate a Phase 1b/2 trial in patients with HAE in 2023 with initial results anticipated by the end of 2023. We believe that these clinical trials have the opportunity to establish proof of concept for the differentiated profile of QLS-215.

QLS-215 Preclinical Results

Our vision for QLS-215 is supported by the following pre-clinical data. A physiologically relevant functional assay was used to characterize the in vitro potency of QLS-215 as compared to lanadelumab, another monoclonal antibody known to inhibit plasma kallikrein. Lanadelumab is commercialized under the brand name TAKHZYRO and approved as a prophylactic treatment for HAE. The assay measured bradykinin release from high molecular weight kininogen, or HMWK, as catalyzed by plasma kallikrein in the same biochemical reaction that occurs during an HAE attack. The assay parameters were physiologically relevant due to the concentration of HMWK being the concentration that circulates in humans and the concentration of plasma kallikrein being in the range of what has been estimated in plasma from patients with HAE during an attack. In HAE, the therapeutically relevant level of inhibition to prevent HAE attacks is thought to be approximately 90% inhibition of plasma kallikrein. This corresponds to a measurement referred to as IC90, which is the concentration of an agent that results in a 90% inhibitory effect. Both QLS-215 and lanadelumab showed a dose-dependent inhibition of bradykinin, indicating reduced plasma kallikrein activity and QLS-215 exhibited a greater potency for inhibition of plasma kallikrein activity and bradykinin release than lanadelumab. Multiple experiments have confirmed that QLS-215 is approximately 10-fold more potent than lanadelumab in inhibiting bradykinin production.

In separate studies, cynomolgus monkeys were used to evaluate the pharmacokinetics and plasma half-life of QLS-215 as well as lanadelumab. These studies of QLS-215 and lanadelumab were conducted concurrently but were independent studies rather than a head-to-head comparison. In these 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. This half-life is also consistent with what has been reported for similar types of antibodies. QLS-215 was administered at the same dose as lanadelumab in these studies and the observed half-life of QLS-215 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 QLS-215 in humans. If this longer half-life is demonstrated in clinical trials, it has the potential to enable infrequent dosing.

Taken together, the half-life results from the cynomolgus monkey studies and the data from the in vitro potency assay can be interpreted to suggest a potential duration of efficacy for the antibodies. Specifically, the measured plasma concentration of an antibody at each timepoint from the cynomolgus monkey studies can be used to predict an expected level of plasma kallikrein inhibition at that time point based on the plasma kallikrein inhibition observed for that concentration of antibody in the in vitro potency assay. In the cynomolgus monkey studies, lanadelumab plasma levels fell below the minimum therapeutic concentration, or IC90, predicted by the in vitro potency assay by approximately day 10, and by day 20 were at levels the in vitro potency assay predicted would result in approximately 50% inhibition of plasma kallikrein. In contrast, in the cynomolgus monkey studies, QLS-215 plasma levels remained above the IC90 predicted by the in vitro potency assay for 84 days, which was the full duration of the experiment. These preclinical data suggest that at equal doses QLS-215 would have a significantly longer duration of action than lanadelumab. This could potentially enable a lower dose of QLS-215 that would have a longer duration of action than lanadelumab. We believe that this could result in QLS-215 being an effective prophylactic 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 Catabasis, 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 3,332,669 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 332,494 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 185,136 shares of our common stock at an exercise price of \$0.35 per share.

In January 2021, we also entered into a Stock Purchase Agreement, or the Purchase Agreement, with certain institutional and accredited investors, or the 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. Subject to stockholder approval, each share of Series X Preferred Stock issued in the Merger and pursuant to the Purchase Agreement is convertible into 1,000 shares of common stock. Pursuant to the Merger Agreement, we have agreed to hold a stockholders' meeting, which is scheduled for June 2, 2021, to submit the following matters to our stockholders for their consideration: (i) the approval of 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, and (ii) if necessary or appropriate, the approval of an amendment to our certificate of incorporation to authorize sufficient shares of common stock after the conversion of the Series X Preferred Stock issued pursuant to the Merger Agreement and the Purchase Agreement and/or to effectuate a reverse stock split. Assuming stockholder approval of the Conversion Proposal, on the fourth business day after such approval, each share of Series X Preferred Stock then outstanding would automatically convert into 1,000 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 (to be initially set at 9.99% and thereafter adjustable 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.

Capital and Liquidity

To date, we have primarily financed our operations through private placements of our preferred stock, registered offerings of our common stock, including our initial public offering, or IPO, as well as a secured debt financing. From our inception through March 31, 2021, we raised an aggregate of \$426.0 million through various private placements of preferred stock, our IPO, debt financing as well as various other registered equity offerings, including underwritten public offerings, at-the-market, or ATM, offerings, and stock option and warrant exercises.

As of March 31, 2021, we had cash and cash equivalents of \$146.9 million. We expect that our existing cash and cash equivalents are sufficient to support our operating expenses through 2023, assuming our stockholders approve the Conversion Proposal.

We will need substantial additional funding to support our continuing operations, future clinical trials and expansion of our pipeline. In addition, QLS-215 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. 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.

In connection with the Quellis Acquisition, we issued Series X Preferred Stock to Quellis stockholders in the Merger and to the Investors in the February 2021 Financing. We are obligated under the Merger Agreement to seek stockholder approval for the conversion of the Series X Preferred Stock into common stock. In the event that we fail to timely hold the stockholder meeting or fail to obtain stockholder approval, then the holders of the Series X Preferred Stock would be entitled to require us to redeem, in cash, the shares of common stock underlying their Series X Preferred Stock at a price per share equal to the fair value of the common stock. If we are forced to redeem a significant amount of shares underlying the Series X Preferred Stock, it could, among other things, materially affect our results of operations and cash usage forecasts, require us to slow down or stop the development of QLS-215 and any other future product candidates, require us to raise additional capital and impact our ability to raise additional capital. Also, while we cannot predict the amount with any level of certainty, there is a level of cash settlement at which, if it is exceeded, could require us to make redemption payments in excess of our current liquidity. Based on precedent transactions and the terms of the Series X Preferred Stock, we believe that our stockholders who are entitled to vote on the Conversion Proposal at our 2021 Annual Meeting of Stockholders, which is scheduled for June 2, 2021, will vote to approve the proposal. However, as the vote of our stockholders is outside of our control, there is substantial doubt about our ability to continue as a going concern within one year from the filing of this Quarterly Report on Form 10-Q.

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):

	Three Months Ended March 31,	
	2021	2020
Edasalonexent	\$ 456	\$ 3,200
QLS-215	458	-
Costs not directly allocated to programs:		
Employee expenses including cash compensation, benefits and stock-based compensation	1,226	1,536
Facilities	88	163
Consultants and professional expenses, including stock-based compensation	276	262
Other	89	128
Total costs not directly allocated to programs	1,679	2,089
Total research and development expenses	\$ 2,593	\$ 5,289

Since inception of our edasalonexent program, total direct expenses to support this program have been \$67.2 million.

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 have also stopped substantially all activities related to our CAT-5571 program.

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 QLS-215. 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 QLS-215 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 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
- a continued acceptable safety profile following approval.

A change in the outcome of any of these variables with respect to the development of QLS-215 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 QLS-215 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 three months ended March 31, 2021. No additional severance expense related to the reduction in workforce is expected in future periods. As of March 31, 2021, \$0.2 million remains to be paid out, all of which will be paid in 2021.

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 three months ended March 31, 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

Comparison of the Three Months Ended March 31, 2021 and 2020

The following table summarizes our results of operations for the three months ended March 31, 2021 and 2020, together with the dollar change in those items (in thousands):

	Three Months Ended March 31,		Period-to- Period Change
	2021	2020	
Operating expenses:			
Research and development	\$ 2,593	\$ 5,289	\$ (2,696)
General and administrative	2,880	2,753	127
Acquired in-process research and development	164,612	-	164,612
Total operating expenses	170,085	8,042	162,043
Loss from operations	(170,085)	(8,042)	(162,043)
Other income, net	1	90	(89)
Net loss	<u>\$ (170,084)</u>	<u>\$ (7,952)</u>	<u>\$ (162,132)</u>

Research and Development Expenses

Research and development expenses decreased by \$2.7 million to \$2.6 million for the three months ended March 31, 2021 from \$5.3 million for the three months ended March 31, 2020, a decrease of 51%. The decrease in research and development expenses was primarily attributable to a \$2.7 million decrease in costs to support our edasalonexent program due to stopping activities associated with conducting ongoing clinical trials, a \$0.3 million decrease in employee related expenses, and a \$0.1 million decrease to the research and development portion of facilities expense. These decreases were partially offset by a \$0.4 million increase in costs to support pre-clinical development of the QLS-215 program.

General and Administrative Expenses

General and administrative expenses increased by \$0.1 million to \$2.9 million for the three months ended March 31, 2021 from \$2.8 million for the three months ended March 31, 2020, an increase of 5%. The increase was attributable to a \$0.2 million increase in employee related costs and a \$0.1 million increase in insurance expense. These increases were partially offset by a \$0.2 million decrease in consulting and other professional services associated with stopping activities to prepare for edasalonexent commercialization.

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

Acquired IPR&D expense was \$164.6 million during the three months ended March 31, 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 year ended December 31, 2020.

Other Income, Net

Other income, net decreased by \$89,000 to \$1,000 for the three months ended March 31, 2021 from \$90,000 for the three months ended March 31, 2020, which was primarily attributable to a decrease in interest and investment income due to lower interest rates and a decrease in foreign currency fluctuation.

Liquidity and Capital Resources

From our inception through March 31, 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, and stock option and warrant exercises. As of March 31, 2021, we had \$146.9 million in cash and cash equivalents.

February 2021 Financing

On January 28, 2021 we entered into a Stock Purchase Agreement, or the Purchase Agreement, with certain institutional and accredited investors. 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 5,290,000 shares of common stock at a price to the public of \$5.00 per share, including 690,000 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

During the three months ended March 31, 2020, we sold an aggregate of 173,572 shares of common stock pursuant to our ATM Programs at a weighted average price of \$6.29 per share, for gross and net proceeds of \$1.1 million. There was no activity from the ATM Programs during the three months ended March 31, 2021.

Cash Flows

Comparison of the Three Months Ended March 31, 2021 and 2020

The following table provides information regarding our cash flows for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Net cash used in operating activities	\$ (8,716)	\$ (6,989)
Net cash provided by (used in) investing activities	26,445	(15,432)
Net cash provided by financing activities	104,261	25,624
Net increase in cash, cash equivalents and restricted cash	<u>\$ 121,990</u>	<u>\$ 3,203</u>

Net Cash Used in Operating Activities

Net cash used in operating activities was \$8.7 million for the three months ended March 31, 2021 and consisted primarily of a net loss of \$170.1 million adjusted for the non-cash portion of acquired IPR&D of \$164.6 million and other non-cash items such as stock-based compensation expense of \$0.4 million and a net increase in operating assets of \$3.6 million, which resulted primarily from a decrease in accrued expenses of \$2.7 million, a decrease in accounts payable of \$1.7 million, partially offset by a decrease in prepaid expenses of \$0.8 million.

Net cash used in operating activities was \$7.0 million for the three months ended March 31, 2020 and consisted primarily of a net loss of \$8.0 million adjusted for non-cash items of \$0.4 million and a net decrease in operating assets of \$0.6 million, which resulted primarily from a decrease in prepaid expenses and other current assets of \$0.7 million, and an increase in accrued expenses of \$0.4 million, partially offset by a decrease in accounts payable of \$0.5 million.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was \$26.4 million for the three months ended March 31, 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 used in investing activities was \$15.4 million for the three months ended March 31, 2020 and consisted of purchases of short-term investments of \$42.8 million partially offset by proceeds from maturities of short-term investments of \$27.4 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$104.3 million during the three months ended March 31, 2021, which was attributable to net proceeds of \$104.3 million from the February 2021 Financing.

Net cash provided by financing activities was \$25.6 million during the three months ended March 31, 2020, which was primarily attributable to net proceeds of \$24.5 million from the January 2020 Financing and net proceeds of \$1.1 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 March 31, 2021, we had an accumulated deficit of \$431.0 million. We have been primarily involved with research and development activities and have incurred operating losses and negative cash flows from operations since our inception.

As of March 31, 2021, we had available cash and cash equivalents of \$146.9 million. We expect that our existing cash and cash equivalents are sufficient to support our operating expenses through 2023, assuming our stockholders approve the Conversion Proposal.

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:

- our ability to integrate QLS-215 into our operations and meet our overall timing expectations for the program;
- the progress, timing, costs and results of clinical trials of, and research and preclinical development efforts for, QLS-215 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 QLS-215 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.

In connection with the Quellis Acquisition, we issued Series X Preferred Stock to Quellis stockholders in the Merger and to the Investors in the February 2021 Financing. We are obligated under the Merger Agreement to seek stockholder approval for the conversion of the Series X Preferred Stock into common stock. In the event that we fail to timely hold the stockholders' meeting or fail to obtain stockholder approval of the Conversion Proposal, then the holders of the Series X Preferred Stock would be entitled to require us to redeem, in cash, the shares of common stock underlying their Series X Preferred Stock at a price per share equal to the fair value of the common stock. If we are forced to redeem a significant amount of shares underlying the Series X Preferred Stock, it could, among other things, materially affect our results of operations and cash usage forecasts, require us to slow down or stop the development of QLS-215 and any other future product candidates, require us to raise additional capital and impact our ability to raise additional capital. Also, while we cannot predict the amount with any level of certainty, there is a level of cash settlement at which, if it is exceeded, could require us to make redemption payments in excess of our current liquidity. Based on precedent transactions and the terms of the Series X Preferred Stock, we believe that our stockholders who are entitled to vote on the Conversion Proposal at our 2021 Annual Meeting of Stockholders, which is scheduled for June 2, 2021, will vote to approve the proposal. However, as the vote of our stockholders is outside of our control, there is substantial doubt about our ability to continue as a going concern within one year from the filing of this Quarterly Report on Form 10-Q.

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, QLS-215 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 March 31, 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 March 31, 2021, we had cash and cash equivalents of \$146.9 million and, as of December 31, 2020, we had cash, cash equivalents and short-term investments of \$24.9 million. Our cash equivalents as of March 31, 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 March 31, 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 March 31, 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 three months ended March 31, 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

There have been no material changes to the risk factors described in Part I, Item 1A, Risk Factors of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

Item 5. Other Information

On May 10, 2021, we provided notice to Cowen and Company LLC, or Cowen, of our termination of the Sales Agreement, dated May 14, 2019, that we had entered into with Cowen, or the Sales Agreement, pursuant to which we could issue and sell shares of common stock under an at-the-market program registered under our Registration Statement on Form S-3 (File No. 333-231441), or the Shelf Registration Statement. Under the Sales Agreement, we were obligated to pay Cowen a commission of 3% of the gross proceeds from any common stock sold pursuant to the Sales Agreement. The termination is to be effective as of May 20, 2021. We did not incur any termination penalties as a result of the termination. Prior to the termination of the Sales Agreement, we had sold an aggregate of 3,282,895 shares of common stock pursuant to the Sales Agreement, for aggregate gross proceeds of \$22.1 million resulting in net proceeds of \$21.5 million after deducting sales commissions and offering expenses payable by us. Approximately \$27.9 million of common stock that had been available for sale pursuant to the Sales Agreement remained unsold at the time of its termination and remains available for sale under the Shelf Registration Statement.

A copy of the Sales Agreement was filed as Exhibit 1.1 to the Shelf Registration Statement, filed with the Securities and Exchange Commission on May 14, 2019.

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
2.1*	Agreement and Plan of Merger, dated January 28, 2021, by and among Catabasis Pharmaceuticals, Inc., Cabo Merger Sub I, Inc., Cabo Merger Sub II, LLC and Quellis Biosciences, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant’s Current Report on Form 8-K (File No. 001-37467) filed with the SEC on January 29, 2021)
3.1	Certificate of Designation of Series X Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant’s Current Report on Form 8-K (File No. 001-37467) filed with the SEC on January 29, 2021)
10.1+	Stock Purchase Agreement, dated as of January 28, 2021, by and among the Registrant and each purchaser identified on Annex A thereto (incorporated by reference to Exhibit 10.1 to the Registrant’s Current Report on Form 8-K (File No. 001-37467) filed with the SEC on January 29, 2021)
10.2+	Registration Rights Agreement, dated as of January 28, 2021, by and among the Registrant and each purchaser identified therein (incorporated by reference to Exhibit 10.3 to the Registrant’s Annual Report on Form 10-K (File No. 001-37467) filed with the SEC on March 11, 2021)
10.3	Warrant to Purchase Shares of Series X Preferred Stock issued on January 28, 2021 to Viridian LLC (incorporated by reference to Exhibit 10.9 to the Registrant’s Annual Report on Form 10-K (File No. 001-37467) filed with the SEC on March 11, 2021)
10.4	Warrant to Purchase Shares of Common Stock issued on January 28, 2021 to Viridian LLC (incorporated by reference to Exhibit 10.10 to the Registrant’s Annual Report on Form 10-K (File No. 001-37467) filed with the SEC on March 11, 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
101.PRE	XBRL Taxonomy Presentation Linkbase Document

* Exhibits and/or schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant hereby undertakes to furnish supplementally copies of any of the omitted exhibits and schedules upon request by the SEC; provided, however, that the Registrant may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act for any exhibits or schedules so furnished. A list identifying the contents of all omitted exhibits and schedules can be found on page iii of Exhibit 2.1.

+ Certain portions of this exhibit (indicated by “[***]”) have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.

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.

Catabasis Pharmaceuticals, Inc.

Date: May 13, 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 Catabasis Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2021

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

Jill C. Milne, Ph.D.

President and Chief Executive Officer (Principal Executive 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 Catabasis Pharmaceuticals, Inc. (the "Company") for the period ended March 31, 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: May 13, 2021

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

Jill C. Milne, Ph.D.

President and Chief Executive Officer (Principal Executive Officer)

Date: May 13, 2021

/s/ NOAH C. CLAUSER

Noah C. Clauser

Chief Financial Officer (Principal Financial Officer)

CERTIFICATION

I, Noah C. Clauser, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Catabasis Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2021

/s/ NOAH C. CLAUSER

Noah C. Clauser

Chief Financial Officer (Principal Financial Officer)
