

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 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: 000-51173

Catalyst Biosciences, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)
611 Gateway Blvd., Suite 710
South San Francisco, California
(Address of Principal Executive Offices)

56-2020050
(I.R.S. Employer
Identification No.)

94080
(Zip Code)

(650) 871-0761

(Registrant's Telephone Number, Including Area Code)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class
Common Stock

Trading Symbol(s)
CBIO

Name of each exchange on which registered
NASDAQ

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, or a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer
Non-accelerated filer
Emerging growth company

Accelerated filer
Smaller reporting company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial 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 29, 2021, the number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 31,349,740.

CATALYST BIOSCIENCES, INC.
TABLE OF CONTENTS

	<u>Page No.</u>
<u>PART I. FINANCIAL INFORMATION</u>	3
Item 1. <u>Financial Statements:</u>	3
<u>Condensed Consolidated Balance Sheets as of March 31, 2021 (unaudited) and December 31, 2020</u>	3
<u>Condensed Consolidated Statements of Operations for the three months ended March 31, 2021 and 2020 (unaudited)</u>	4
<u>Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2021 and 2020 (unaudited)</u>	5
<u>Condensed Consolidated Statements of Stockholders' Equity for the three months ended March 31, 2021 and 2020 (unaudited)</u>	6
<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2021 and 2020 (unaudited)</u>	7
<u>Notes to the Unaudited Interim Condensed Consolidated Financial Statements</u>	8
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	16
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	24
Item 4. <u>Controls and Procedures</u>	25
<u>PART II. OTHER INFORMATION</u>	26
Item 1. <u>Legal Proceedings</u>	26
Item 1A. <u>Risk Factors</u>	26
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	27
Item 3. <u>Defaults Upon Senior Securities</u>	27
Item 4. <u>Mine Safety Disclosures</u>	27
Item 5. <u>Other Information</u>	27
Item 6. <u>Exhibits</u>	27
<u>Exhibit Index</u>	28
<u>Signatures</u>	29

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Catalyst Biosciences, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	<u>March 31, 2021</u> (Unaudited)	<u>December 31, 2020</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 83,044	\$ 30,360
Short-term investments	23,956	48,994
Accounts receivable	1,006	3,313
Prepaid and other current assets	8,514	6,843
Total current assets	<u>116,520</u>	<u>89,510</u>
Long-term investments	—	2,543
Other assets, noncurrent	528	528
Right-of-use assets	1,646	1,832
Property and equipment, net	382	433
Total assets	<u>\$ 119,076</u>	<u>\$ 94,846</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,956	\$ 5,931
Accrued compensation	2,232	2,476
Deferred revenue	1,332	1,983
Other accrued liabilities	6,983	6,743
Operating lease liability	678	663
Total current liabilities	<u>14,181</u>	<u>17,796</u>
Operating lease liability, noncurrent	806	981
Total liabilities	<u>14,987</u>	<u>18,777</u>
Commitments and Contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized; zero shares issued and outstanding	—	—
Common stock, \$0.001 par value, 100,000,000 shares authorized; 31,331,027 and 22,097,820 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	31	22
Additional paid-in capital	441,252	390,803
Accumulated other comprehensive income	5	5
Accumulated deficit	<u>(337,199)</u>	<u>(314,761)</u>
Total stockholders' equity	<u>104,089</u>	<u>76,069</u>
Total liabilities and stockholders' equity	<u>\$ 119,076</u>	<u>\$ 94,846</u>

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

Catalyst Biosciences, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31, 2021	Three Months Ended March 31, 2020
License	\$ —	\$ 15,045
Collaboration	1,467	1,321
License and collaboration revenue	<u>1,467</u>	<u>16,366</u>
Operating expenses:		
Cost of license	—	3,047
Cost of collaboration	1,480	1,432
Research and development	17,013	13,264
General and administrative	5,412	3,691
Total operating expenses	<u>23,905</u>	<u>21,434</u>
Loss from operations	(22,438)	(5,068)
Interest and other income (expense), net	-	1,015
Net loss	<u>\$ (22,438)</u>	<u>\$ (4,053)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.79)</u>	<u>\$ (0.28)</u>
Shares used to compute net loss per share attributable to common stockholders, basic and diluted	<u>28,385,432</u>	<u>14,592,451</u>

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

Catalyst Biosciences, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(In thousands)
(Unaudited)

	<u>Three Months Ended</u> <u>March 31,</u> <u>2021</u>	<u>Three Months Ended</u> <u>March 31,</u> <u>2020</u>
Net loss	\$ (22,438)	\$ (4,053)
Other comprehensive income:		
Unrealized gain on available-for-sale debt securities	—	106
Total comprehensive loss	<u>\$ (22,438)</u>	<u>\$ (3,947)</u>

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

Catalyst Biosciences, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(In thousands, except share amounts)
(Unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2020	—	\$ —	22,097,820	\$ 22	\$ 390,803	\$ 5	\$ (314,761)	\$ 76,069
Stock-based compensation expense	—	—	10,149	—	1,026	—	—	1,026
Issuance of common stock for public offering, net of issuance costs of \$3,563	—	—	9,185,000	9	49,241	—	—	49,250
Issuance of common stock from stock grants	—	—	38,058	—	182	—	—	182
Net loss	—	—	—	—	—	—	(22,438)	(22,438)
Balance at March 31, 2021	—	\$ —	31,331,027	\$ 31	\$ 441,252	\$ 5	\$ (337,199)	\$ 104,089

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2019	—	\$ —	12,040,835	\$ 12	\$ 326,810	\$ 34	\$ (258,520)	\$ 68,336
Stock-based compensation expense	—	—	7,817	—	805	—	—	805
Issuance of common stock from stock grants and option exercises	—	—	62,969	—	339	—	—	339
Issuance of common stock for public offering, net of issuance costs of \$2,514	—	—	5,307,692	5	31,981	—	—	31,986
Unrealized gain on available-for-sale debt securities	—	—	—	—	—	106	—	106
Net loss	—	—	—	—	—	—	(4,053)	(4,053)
Balance at March 31, 2020	—	\$ —	17,419,313	\$ 17	\$ 359,935	\$ 140	\$ (262,573)	\$ 97,519

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

Catalyst Biosciences, Inc.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2021	2020
Operating Activities		
Net loss	\$ (22,438)	\$ (4,053)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,026	805
Depreciation and amortization	45	25
Changes in operating assets and liabilities:		
Accounts receivable	2,307	13,634
Prepaid and other current assets	(1,671)	1,880
Accounts payable	(2,969)	(2,963)
Accrued compensation and other accrued liabilities	(31)	866
Operating lease liability and right-of-use asset	26	16
Deferred revenue	(651)	(15,000)
Net cash flows used in operating activities	<u>(24,356)</u>	<u>(4,790)</u>
Investing Activities		
Proceeds from maturities of short-term investments	27,581	33,457
Purchase of short-term investments	—	(6,019)
Purchases of property and equipment	—	(17)
Net cash flows provided by investing activities	<u>27,581</u>	<u>27,421</u>
Financing Activities		
Issuance of common stock for public offering, net of issuance costs	49,277	32,025
Issuance of common stock from stock grants and option exercises	182	339
Net cash flow provided by financing activities	<u>49,459</u>	<u>32,364</u>
Net increase in cash and cash equivalents	52,684	54,995
Cash and cash equivalents at beginning of the period	30,360	15,369
Cash and cash equivalents at end of the period	<u>\$ 83,044</u>	<u>\$ 70,364</u>

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

Catalyst Biosciences, Inc.
Notes to Condensed Consolidated Financial Statements (Unaudited)

1. Nature of Operations and Liquidity

Catalyst Biosciences, Inc. and its subsidiary (the “Company” or “Catalyst”) is a fully integrated research and clinical development biopharmaceutical company with expertise in protease engineering, discovery, translational research, clinical development, and manufacturing. The Company is focused on advancing its protease product candidates in the fields of hemostasis and complement regulation. The Company is located in South San Francisco, California and operates in one segment.

The Company had a net loss of \$22.4 million for the three months ended March 31, 2021 and an accumulated deficit of \$337.2 million as of March 31, 2021. The Company expects to continue to incur losses for the next several years. As of March 31, 2021, the Company had \$107.0 million of cash, cash equivalents and short-term investments. Its primary uses of cash are to fund operating expenses, including research and development expenditures and general and administrative expenditures. Based on the current status of its research and development plans, the Company believes that its existing cash, cash equivalents and short-term investments as of March 31, 2021 will be sufficient to fund its cash requirements for at least the next 12 months from the date of the filing of this quarterly report. If, at any time, the Company’s prospects for financing its research and development programs decline, the Company may decide to reduce research and development expenses by delaying, discontinuing or reducing its funding of one or more of its research or development programs. Alternatively, the Company might raise funds through strategic collaborations, public or private financings or other arrangements. Such funding, if needed, may not be available on favorable terms, or at all.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company’s condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) and following the requirements of the Securities and Exchange Commission (the “SEC”) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP can be condensed or omitted. These financial statements have been prepared on the same basis as the Company’s annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair presentation of the Company’s financial information. These interim results and cash flows for any interim period are not necessarily indicative of the results to be expected for the year ending December 31, 2021, or for any other future annual or interim period.

The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with the consolidated financial statements filed with the Company’s Annual Report on Form 10-K for the year ended December 31, 2020 (“Annual Report”).

Accounting Pronouncements Recently Adopted

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes. The amendments in ASU 2019-12 are intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. The Company adopted ASU 2019-12 as of January 1, 2021, on a prospective transition basis. The adoption of ASU 2019-12 did not have a material impact on the Company’s condensed consolidated financial statements.

New Accounting Pronouncements Recently Issued But Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, Measurement of Credit Losses on Financial Instruments (“ASU 2016-13”). The main objective of ASU 2016-13 is to provide financial statement users with more decision-useful information about an entity’s expected credit losses on financial instruments and other commitments to extend credit at each reporting date. To achieve this objective, the amendments in this update replace the incurred loss impairment methodology currently used today with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to develop credit loss estimates. Subsequent to issuing ASU 2016-13, the FASB issued ASU 2018-19, Codification Improvements to Topic 326, Financial Instruments – Credit Losses, for the purpose of clarifying certain aspects of ASU 2016-13. In May 2019, the FASB issued ASU 2019-05, Financial Instruments – Credit Losses (Topic 326): Targeted Transition Relief, to provide entities with more flexibility in applying the fair value option on adoption of the credit impairment standard. ASU 2018-19 and ASU 2019-05 have the same effective date and transition requirements as ASU 2016-13. ASU 2016-13 will be effective for the Company for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, using a modified retrospective approach. Early adoption is permitted. The Company plans to adopt ASU 2016-13 and related updates as of January 1, 2023. The Company will assess the impact of adoption of this standard on its consolidated financial statements.

Research and Development Expenses

Research and development costs are expensed as incurred. Nonrefundable advance payments for goods or services used in research and development are initially deferred and capitalized in prepaid and other current assets. The capitalized amounts are then expensed as the related goods are delivered or services are performed, or until it is no longer expected that the goods or services will be delivered. Research and development costs consist of payroll and other personnel-related expenses, laboratory supplies and reagents, contract research and development services, materials, and consulting costs, as well as allocations of facilities and other overhead costs. Under the Company's collaboration agreement with Biogen, certain specific expenditures are reimbursed by third parties. During the three months ended March 31, 2021 and 2020, \$1.4 million and \$1.3 million, respectively, of research and development expense was recorded as cost of collaboration revenue related to the collaboration agreement with Biogen signed in December 2019.

Stock-Based Compensation

The Company measures the cost of employee, non-employee and director services received in exchange for an award of equity instruments based on the fair value of the award on the date of grant and recognizes the related expense over the period during which the employee, non-employee or director is required to provide service in exchange for the award on a straight-line basis. The estimated fair value of equity awards that contain performance conditions is expensed over the term of the award once the Company has determined that it is probable that performance conditions will be satisfied.

The Company uses the Black-Scholes option-pricing valuation model to estimate the grant-date fair value of stock-based awards. The determination of fair value for stock-based awards on the date of grant using an option-pricing model requires management to make certain assumptions regarding a number of variables. The Company elected to account for forfeitures when they occur. As such, the Company recognizes stock-based compensation expense, over their requisite service period, based on the vesting provisions of the individual grants.

3. Fair Value Measurements

For a description of the fair value hierarchy and the Company's fair value methodology, see "Part II - Item 8 - Financial Statements and Supplementary Data - Note 3 – Summary of Significant Accounting Policies" in the Company's Annual Report. There were no significant changes in these methodologies during the three months ended March 31, 2021.

There were no transfers in or out of Level 1 or 2 during the periods presented. The following tables present the fair value hierarchy for assets and liabilities measured at fair value on a recurring basis as of March 31, 2021 and December 31, 2020 (*in thousands*):

	March 31, 2021			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds(1)	\$ 83,044	\$ —	\$ —	\$ 83,044
U.S. government agency securities(2)	16,807	—	—	16,807
Federal agency securities(2)	—	7,149	—	7,149
Total financial assets	<u>\$ 99,851</u>	<u>\$ 7,149</u>	<u>\$ —</u>	<u>\$ 107,000</u>

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds(1)	\$ 30,360	\$ —	\$ —	\$ 30,360
U.S. government agency securities(2)	37,837	—	—	37,837
Federal agency securities(2)	—	13,700	—	13,700
Total financial assets	<u>\$ 68,197</u>	<u>\$ 13,700</u>	<u>\$ —</u>	<u>\$ 81,897</u>

(1) Included in cash and cash equivalents on the accompanying condensed consolidated balance sheets.

(2)

-) Included in short-term investments on the accompanying condensed consolidated balance sheets and classified as available-for-sale debt securities. \$2.5 million of U.S. government agency securities as of December 31, 2020 are included in long-term investments on the accompanying condensed consolidated balance sheets due to the maturity being more than 12 months.

4. Financial Instruments

Cash equivalents, short-term investments (debt securities) which are classified as available-for-sale debt securities, and long-term investments, consisted of the following (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
March 31, 2021				
Money market funds (cash equivalents)	\$ 83,044	\$ —	\$ —	\$ 83,044
U.S. government agency securities	16,804	3	—	16,807
Federal agency securities	7,147	2	—	7,149
Total financial assets	<u>\$ 106,995</u>	<u>\$ 5</u>	<u>\$ —</u>	<u>\$ 107,000</u>
Classified as:				
Cash and cash equivalents				\$ 83,044
Short-term investments				23,956
				<u>\$ 107,000</u>
December 31, 2020				
Money market funds (cash equivalents)	\$ 30,360	\$ —	\$ —	\$ 30,360
U.S. government agency securities	37,835	2	—	37,837
Federal agency securities	13,697	3	—	13,700
Total financial assets	<u>\$ 81,892</u>	<u>\$ 5</u>	<u>\$ —</u>	<u>\$ 81,897</u>
Classified as:				
Cash and cash equivalents				\$ 30,360
Short-term investments				48,994
Long-term investments				2,543
				<u>\$ 81,897</u>

There have been no material realized gains or losses on available-for-sale debt securities for the periods presented. As of March 31, 2021, the remaining contractual maturities of \$24.0 million of available-for-sale debt securities was less than one year.

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, and accrued liabilities approximate their fair values due to the short-term maturity of these instruments.

5. Lease

The Company leases office space for its corporate headquarters, located in South San Francisco, CA. The lease term is through April 30, 2023 and there are no stated renewal options. Operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term. In calculating the present value of the lease payments, the Company has elected to utilize its incremental borrowing rate based on the original lease term and not the remaining lease term. The lease includes non-lease components (e.g., common area maintenance) that are paid separately from rent based on actual costs incurred and therefore were not included in the right-of-use asset and lease liability but are reflected as an expense in the period incurred.

For the three months ended March 31, 2021 and 2020, the Company's operating lease expense was \$0.2 million and \$0.2 million, respectively. The present value assumptions used in calculating the present value of the lease payments were as follows:

	March 31, 2021	December 31, 2020
Weighted-average remaining lease term	2.08 years	2.33 years
Weighted-average discount rate	5.7%	5.7%

The maturity of the Company's operating lease liabilities as of March 31, 2021 were as follows (*in thousands*):

Undiscounted lease payments	Operating Leases	
Remaining in 2021	\$	557
2022		762
2023		259
Total undiscounted lease payments		1,578
Less imputed interest		(94)
Total operating lease liability	\$	1,484

Supplemental cash flow information related to operating leases was as follows (*in thousands*):

	Three Months Ended March 31,	
	2021	2020
Cash paid for leases that were included in operating cash outflows	\$ 182	\$ 142

6. Stock Based Compensation

2018 Omnibus Incentive Plan

In June 2018, stockholders of the Company approved the Company's 2018 Omnibus Incentive Plan (the "2018 Plan"). The 2018 Plan had previously been approved by the Company's Board of Directors (the "Board") and the Compensation Committee (the "Committee") of the Board, subject to stockholder approval. The 2018 Plan became effective on June 13, 2018.

Performance-Based Stock Option Grants

In February 2021, the Committee approved the issuance of option grants to purchase 647,000 shares of common stock for executive officers pursuant to the 2018 Plan, which will vest upon (a) the achievement of specified performance goals and (b) the grantees' continued employment during the service period specified in each grant.

The following table summarizes stock option activity under the Company's equity incentive plans and related information:

	Number of Shares Underlying Outstanding Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (Years)
Outstanding — December 31, 2020	2,355,615	\$ 8.59	7.96
Options granted	939,613	\$ 6.21	
Options exercised	—	\$ —	
Options forfeited	(87,083)	\$ 7.62	
Options expired	—	\$ —	
Outstanding — March 31, 2021	3,208,145	\$ 7.92	8.37
Exercisable — March 31, 2021	1,213,061	\$ 10.18	

Valuation Assumptions

The Company estimated the fair value of stock options granted using the Black-Scholes option-pricing formula and a single option award approach. Due to its limited history as a public company and limited number of sales of its common stock, the Company estimated its volatility considering a number of factors including the use of the volatility of comparable public companies. The expected term of options granted under the Plan, all of which qualify as "plain vanilla" per SEC Staff Accounting Bulletin 107, is determined based on the simplified method due to the Company's limited operating history. The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the option. This fair value is being amortized ratably over the requisite service periods of the awards, which is generally the vesting period.

The fair value of employee stock options was estimated using the following weighted-average assumptions for the three months ended March 31, 2021 and 2020:

	Three Months Ended March 31,	
	2021	2020
Employee Stock Options:		
Risk-free interest rate	0.69%	1.57%
Expected term (in years)	6.05	5.53
Dividend yield	—	—
Volatility	93.83%	110.00%
Weighted-average fair value of stock options granted	\$ 4.70	\$ 5.58

Total stock-based compensation recognized was as follows (*in thousands*):

	Three Months Ended March 31,	
	2021	2020
Research and development	\$ 369	\$ 344
General and administrative ⁽¹⁾	657	461
Total stock-based compensation	\$ 1,026	\$ 805

- (1) Included in general and administrative stock-based compensation for the three months ended March 31, 2021 is expense related to 10,149 shares of common stock issued to certain board members in lieu of their cash compensation.

As of March 31, 2021, 391,477 shares of common stock were available for future grant and 3,208,145 options to purchase shares of common stock were outstanding. As of March 31, 2021, the Company had unrecognized employee stock-based compensation expense of \$8.2 million, related to unvested stock awards, which is expected to be recognized over an estimated weighted-average period of 2.9 years.

7. Collaborations

Pfizer

Pursuant to the termination agreement entered into on December 8, 2016, in connection with the termination of a prior license and development agreement, Pfizer granted the Company an exclusive license to Pfizer's proprietary rights for manufacturing materials and processes that apply to Factor VIIa variants, CB 813a and marzeptacog alfa (activated) - MarzAA. Pfizer also transferred to the Company the IND application and documentation related to the development, manufacturing and testing of the Factor VIIa products as well as the orphan drug designation. The Company agreed to make contingent cash payments to Pfizer in an aggregate amount up to \$17.5 million, payable upon the achievement of certain clinical, regulatory and commercial milestones. Following commercialization of any covered product, Pfizer will also receive a single-digit royalty on net product sales on a country-by-country basis for a predefined royalty term. In February 2018, the Company paid Pfizer a \$1.0 million milestone payment based on the dosing of the first patient in its Phase 2 study; the amount was recorded as a research and development expense. No payments were made to Pfizer in the three months ended March 31, 2021 and 2020.

Mosaic

In October 2017, the Company entered into a strategic research collaboration with Mosaic to develop intravitreal anti-complement factor 3 (C3) products for the treatment of dry Age-related Macular Degeneration (AMD) and other retinal diseases. The Company entered into two amendments to the Mosaic research collaboration agreements in December 2019 and May 2020. See Note 11.

ISU Abxis

In December 2018, the Company entered into an amended and restated license agreement with ISU Abxis (the "A&R ISU Abxis Agreement"), which amended and restated its previous license and collaboration agreement with ISU Abxis previously entered into in September 2013, as subsequently amended in October 2014 and December 2016 (the "Original ISU Abxis Agreement"). Under the A&R ISU Abxis Agreement, ISU Abxis will receive commercialization rights in South Korea to the Company's engineered Factor IX dalcinonacog alfa - DalcA and the Company will receive clinical development and commercialization rights in the rest of world (excluding South Korea) and manufacturing development and manufacturing rights worldwide (including South Korea). The A&R ISU Abxis Agreement eliminates the profit-sharing arrangement in the Original

ISU Abxis Agreement and provides for a low single-digit royalty payment to ISU Abxis, on a country-by-country basis, for net product sales of Dalca by the Company or its affiliates in each country other than South Korea. Pursuant to the A&R ISU Abxis Agreement, the Company will also pay up to an aggregate of \$19.5 million in milestone payments to ISU Abxis, including \$2.5 million in regulatory and development milestone payments and up to \$17.0 million in commercial milestone payments, if the applicable milestones are met. As of March 31, 2021, no milestones have been met.

Biogen

On December 18, 2019, the Company and Biogen International GmbH (“Biogen”) entered into a License and Collaboration Agreement (the “Biogen Agreement”), under which the Company granted Biogen a worldwide, royalty-bearing, exclusive, with the right to sublicense, license (“Exclusive License”) to develop and commercialize CB 2782-PEG and other anti-C3 proteases for potential treatment of dry age-related macular degeneration (“AMD”) and other disorders. Pursuant to the Biogen Agreement, the Company will perform certain pre-clinical and manufacturing activities (“Research Services”), and Biogen will be solely responsible for funding the pre-clinical and manufacturing activities and performing IND-enabling activities, worldwide clinical development, and commercialization. The Company will provide the Research Services over a term of thirty months with Biogen having the option to extend the term for two additional twelve-month periods.

Under the terms of the Biogen Agreement, the Company received an up-front payment for the transfer of the Exclusive License (inclusive of certain know-how) of \$15.0 million in January 2020. The Company is eligible to receive development milestones and sales milestones of up to \$340.0 million. In addition, the Company is eligible to receive royalties in the range of single-digit to low double-digit percentage rates of annual net sales on a product-by-product and country-by-country basis. The Company will also receive reimbursements for costs associated with the performance of the Research Services.

The Company determined that the performance obligations under the Biogen Agreement were the Exclusive License and the Research Services. For the Exclusive License, the Company used the residual approach in determining the standalone selling price, or SSP, which includes the upfront payments, milestones and royalties. For the Research Services, the Company used the historical pricing approach for determining the SSP, which includes the reimbursement of personnel and out-of-pocket costs.

The Biogen Agreement will continue on a product-by-product and country-by-country basis until the tenth anniversary of the first commercial sale of the first product in a country, unless terminated earlier by either party as specified under the agreement.

For the three months ended March 31, 2021 and 2020, respectively, the Company recognized \$0.0 million and \$15.0 million in license revenue upon the transfer of the Exclusive License and the related know-how, and \$0.0 million and less than \$0.1 million in license revenue for reimbursable out-of-pocket costs incurred.

For the three months ended March 31, 2021 and 2020, respectively, the Company recognized \$1.5 million and \$1.3 million in collaboration revenue for reimbursable out-of-pocket and personnel costs incurred related to research services.

For the three months ended March 31, 2021, the Company recognized \$0.8 million of revenue from the beginning of period deferred revenue balance.

8. Net Loss per Share Attributable to Common Stockholders

The following table sets forth the computation of the basic and diluted net loss per common share during the three months ended March 31, 2021 and 2020 (*in thousands, except share and per share data*):

	Three Months Ended March 31,	
	2021	2020
Net loss attributable to common stockholders	\$ (22,438)	\$ (4,053)
Weighted-average number of shares used in computing net loss per share, basic and diluted	28,385,432	14,592,451
Net loss available for common stockholders per share, basic and diluted	\$ (0.79)	\$ (0.28)

Since the Company was in a loss position for all periods presented, diluted net loss per share is the same as basic net loss per share for all periods as the inclusion of all potential common shares outstanding would have been anti-dilutive. Potentially dilutive securities on an as-if converted basis that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	Three Months Ended March 31,	
	2021	2020
Options to purchase common stock	3,208,145	1,972,652
Common stock warrants	85	7,857
Total	3,208,230	1,980,509

9. Stockholders' Equity

In the first quarter of 2021, the Company sold an aggregate of 9,185,000 registered shares of its common stock (including 485,000 shares sold pursuant to the exercise of the underwriters' overallotment option) at a price of \$5.75 per share. The net proceeds to the Company, after deducting \$3.6 million in underwriting discounts and commissions, and offering expenses, were approximately \$49.3 million.

10. Commitments and Contingencies

Manufacturing Agreements

On May 20, 2016, the Company signed a development and manufacturing services agreement with AGC Biologics, Inc. ("AGC"), formerly known as CMC ICOS Biologics, Inc., pursuant to which AGC will conduct manufacturing development of agreed upon product candidates. The Company currently has firm work orders with AGC to manufacture MarzAA and DalcA to support its clinical trials totaling \$17.1 million and the payment obligations remaining at March 31, 2021 were \$4.5 million.

COVID-19

The current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, potential trial participants and business operations. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national, and international markets. The COVID-19 pandemic may disrupt the operations of the Company's manufacturers or disrupt supply logistics, which could impact the timing of deliveries and potentially increase expenses under our agreements. We are actively monitoring the impact of COVID-19 and the possible effects on our financial condition, liquidity, operations, clinical trials, suppliers, industry and workforce. All required MarzAA supplies for the MAA-304 and MAA-202 studies have been manufactured.

11. Related Parties

On October 24, 2017, the Company announced a strategic research collaboration with Mosaic to develop intravitreal anti-complement factor C3 products for the treatment of dry AMD and other retinal diseases. Dr. Usman, the Company's Chief Executive Officer and a member of the Company's board of directors, and Mr. Lawlor, a member of the Company's board of directors, were also members of the board of directors of Mosaic. On December 21, 2018, the Company amended its collaboration agreement with Mosaic to, among other things, include certain additional products. According to the Mosaic collaboration agreement, as amended, the Company and Mosaic co-funded certain research.

On December 18, 2019, the Company entered into the second amendment to the Mosaic collaboration agreement following completion of the co-funded research. Pursuant to the second amendment, any future services provided by Mosaic will be performed on a fee-for-service basis. In connection with the Biogen Agreement, the Company received a \$15.0 million upfront license fee on January 10, 2020, see Note 7.

On May 8, 2020, the Company entered into a subsequent amendment to the Mosaic collaboration agreement. As part of this amendment, the Company paid a one-time \$0.8 million cash payment to Mosaic, and Mosaic is eligible to receive up to \$4.0 million in potential future milestone payments related to regulatory and clinical development events for CB 2782-PEG and an additional anti-complement product candidate in lieu of the Company's obligations to pay Mosaic a double-digit percentage of funds the Company receives from Biogen or any other amounts the Company receives related to sublicense fees, research and development payments, or any other research, regulatory, clinical or commercial milestones and royalties on any other development candidates. The Company now owns one hundred percent of all future payment streams related to these product candidates.

As of June 30, 2020, Mosaic was no longer a related party.

12. Interest and Other Income (expense), Net

The following table shows the detail of interest and other income (expense), net for the three months ended March 31, 2021 and 2020 (in thousands):

	<u>Three Months Ended March 31,</u>	
	<u>2021</u>	<u>2020</u>
Interest income	\$ 17	\$ 334
Miscellaneous income	9	679
Other	(26)	2
Total interest and other income (expense), net	<u>\$ —</u>	<u>\$ 1,015</u>

13. Subsequent Event

In April 2021, the Company entered into a lease arrangement to lease laboratory and office space located in South San Francisco, California. The Company paid approximately \$0.3 million upon execution of the lease, which will be included in total lease costs. The monthly lease payment is approximately \$0.1 million and will increase approximately 3.5% upon each anniversary of the lease commencement. The initial lease term is one year, which will commence on May 1, 2021, and expire at the end of April 2022. The lease arrangement provides an option to extend for an additional six months beyond the initial lease term.

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

Unless otherwise indicated, in this Quarterly Report on Form 10-Q, references to "Catalyst," "we," "us," "our" or the "Company" mean Catalyst Biosciences, Inc. and our subsidiary. The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited condensed consolidated financial statements and related notes that appear in this Quarterly Report on Form 10-Q (this "Report") and with the audited consolidated financial statements and related notes that are included as part of our Annual Report on Form 10-K for the year ended December 31, 2020 ("Annual Report").

In addition to historical information, this Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended ("the Exchange Act"). Forward-looking statements are identified by words such as "believe," "will," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "could," "potentially" or the negative of these terms or similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. For example, forward-looking statements include any statements regarding the strategies, prospects, plans, expectations or objectives of management for future operations, the progress, scope or duration of the development of product candidates or programs, clinical trial plans, timelines and potential results, the benefits that may be derived from product candidates or the commercial or market opportunity in any target indication, our ability to protect intellectual property rights, our anticipated operations, financial position, revenues, costs or expenses, statements regarding future economic conditions or performance, statements of belief and any statement of assumptions underlying any of the foregoing. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this report in Part II, Item 1A — "Risk Factors," elsewhere in this Report and in Part I - Item 1A – "Risk Factors" in the Annual Report. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These statements, like all statements in this Report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Overview

We are a research and clinical development biopharmaceutical company focused on developing protease therapeutics to address unmet medical needs in disorders of the complement and coagulation systems. Proteases are the natural regulators of these biological systems. We engineer proteases to create improved or novel molecules to treat diseases that result from dysregulation of the complement and coagulation cascades. Our protease engineering platform has generated two late-stage clinical programs including marzeptacog alfa (activated) ("MarzAA"), a subcutaneously ("SQ") administered next-generation engineered coagulation Factor VIIa ("FVIIa") for the treatment of episodic bleeding in subjects with rare bleeding disorders. Our complement pipeline includes a preclinical program licensed to Biogen International GmbH ("Biogen") for dry age-related macular degeneration ("AMD"), an improved complement factor I protease CB 4332 for SQ prophylaxis in patients with complement factor I ("CFI") deficiency and C4b-degraders designed to target disorders of the classical complement pathway as well as other complement programs in development.

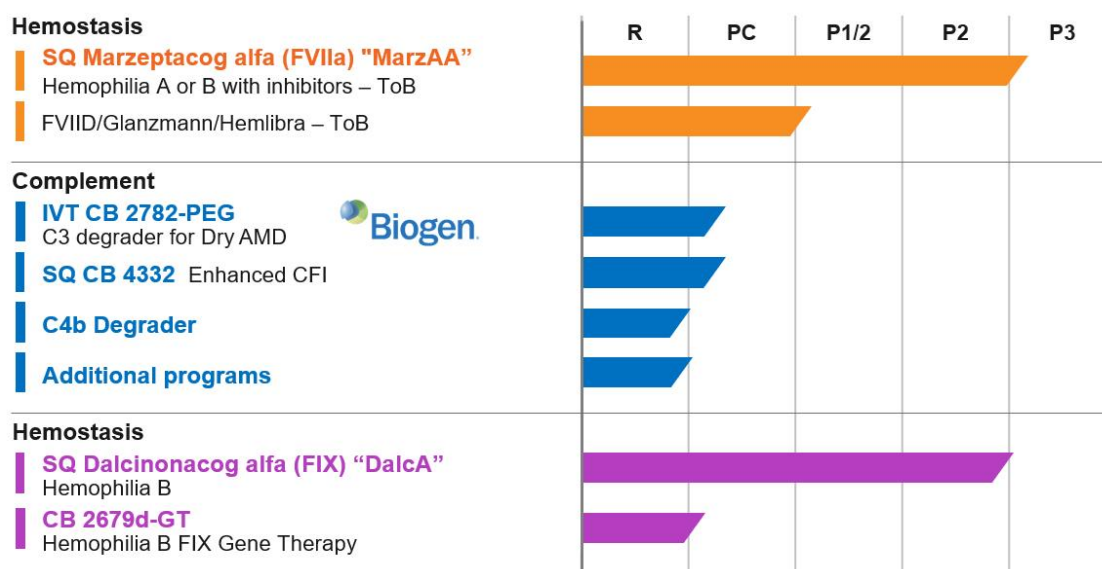
The product candidates generated by our protease engineering platform have improved functional properties such as longer half-life, improved specificity, higher potency and increased bioavailability. These characteristics potentially allow for improved efficacy, SQ administration of recombinant coagulation factors and complement inhibitors, or less frequently dosed intravitreal therapeutics.

We dosed the first patient in our registrational Phase 3 trial (MAA-304) of MarzAA in patients with Hemophilia A or B with inhibitors. We are enrolling patients in a Phase 1/2 trial of MarzAA in Factor VII Deficiency, Glanzmann Thrombasthenia, and Hemophilia A with inhibitor patients on Hemlibra prophylaxis for treatment of episodic bleeding (MAA-202).

Our complement portfolio is led by the development candidates CB 4332 and CB 2782-PEG. CB 4332 is a wholly owned first-in-class improved CFI intended for lifelong prophylactic SQ administration in individuals with CFI deficiency. CB 2782-PEG is a potential best-in-class C3 degrader product candidate in preclinical development for the treatment of dry AMD that we have licensed to Biogen. We have several engineered protease programs in discovery or early non-clinical development. These programs all target diseases caused by deficient regulation of the complement system.

Our next most advanced hemophilia product candidate is dalcinonacog alfa ("DalcA"), a next-generation SQ FIX, which has shown efficacy and safety in a Phase 2b clinical trial in individuals with Hemophilia B. We have a discovery stage Factor IX gene therapy construct, CB 2679d-GT for Hemophilia B, that has demonstrated superiority compared with the Padua FIX variant in preclinical models.

The following table summarizes our current development programs.



We are experiencing operational and other challenges as a result of the COVID-19 global pandemic, which could delay or impact our development programs. See Other Recent Developments and Item 1A - Risk Factors for further discussion of the current and expected impact on our business and development programs.

Recent Development Program Updates

MarzAA

We dosed our first patient in a registrational Phase 3 trial (MAA-304) for our most advanced product candidate, MarzAA, a potent, subcutaneously administered, next-generation Factor VIIa variant.

In December 2020, we announced that the FDA had granted Fast Track designation for MarzAA. The Fast Track program is designed to facilitate and expedite the development and review of drug candidates that have demonstrated the potential to address an unmet medical need in treating serious diseases or conditions. A drug candidate with Fast Track designation is eligible for greater access to the FDA as well as a priority review and rolling review of the marketing application. We believe the FDA Fast Track designation validates MarzAA's potential to improve patient care. As the only SQ delivered therapy in development for episodic treatment of bleeding events, MarzAA is uniquely positioned to become an important addition to the treatment landscape.

The Phase 3 registration trial – MAA-304 – is an open-label, global, multi-center, randomized, cross-over study, designed to evaluate the safety and efficacy of MarzAA for episodic treatment of spontaneous or traumatic bleeding episodes, in adolescents and adults with congenital Hemophilia A or B with inhibitors, compared with Standard of Care, either intravenous rFVIIa or intravenous activated prothrombin complex concentrates (APCC *e.g.*, FEIBA). The study will enroll approximately 60 subjects to treat 244 eligible bleeding episodes with each treatment. The primary endpoint is hemostatic efficacy using a standard 4-point assessment scale at the 24-hour timepoint. The study will assess the effectiveness of SQ MarzAA, using up to three doses to treat a bleeding episode, compared with the Standard of Care. We plan to submit our first report to the Data and Safety Monitoring Board ("DSMB") in 2021.

We are enrolling patients in a Phase 1/2 trial (MAA-202) of MarzAA for treatment of bleeding in Factor VII Deficiency, Glanzmann Thrombasthenia, and in individuals with Hemophilia A with inhibitors treated with Hemlibra and plan to report interim PK data in 2021.

Complement

We currently have several protease programs in preclinical discovery or early non-clinical development. Common to the programs is that they target diseases caused by aberrant regulation of the complement system. An ocular program for dry AMD is licensed to Biogen; the remaining complement programs are focused on systemic complement disorders and are wholly owned by Catalyst.

CB 2782-PEG is an engineered pegylated C3 degrader that we designed with a best-in-class anti-C3 profile for dry AMD. Dry AMD is an ocular disease leading to vision loss and blindness for which there is currently no approved therapies. Complement hyperreactivity plays an important role in dry AMD. Using the protease CB 2782-PEG to degrade C3 allows for the neutralization of C3 activity. It is expected that maintaining low C3 levels in the eye can significantly slow disease progression in dry AMD in patients who would otherwise lose their vision over time.

CB 4332 is an engineered version of the CFI protease with an extended half-life that was designed for SQ use in patients with deficient CFI activity. We intend to commence enrollment of an observational trial in mid-2021 to assess CFI blood levels in patients who have diseases related to CFI deficiency in order to identify those who would benefit from CB 4332 treatment. This will prepare us for a P1/2 clinical study of CB 4332 in 2022.

Complete CFI deficiency may present with a variety of disease manifestations, such as recurrent invasive infections with encapsulated bacteria, but patients are also at risk for developing autoimmune and/or immune-complex diseases such as chronic inflammation of the blood vessels of the brain, spinal cord heart or the kidneys. Clinical presentations of bacterial infections include but are not limited to peritonitis, meningitis, pneumonia and sepsis. No primary prophylaxis is approved, and patients often receive lifelong antibiotic treatment, which may cause a range of additional problems.

The non-infectious CFI deficiency manifestations include a sizeable proportion of kidney disease, also called glomerulonephritis such as: Atypical Hemolytic Uremic Syndrome (“aHUS”), C3 Glomerulonephritis (C3G) or Immune Complex Membranoproliferative Glomerulonephritis (IC-MPGN). These are severe, chronic, life-threatening diseases that result in renal impairment and may require renal transplant.

Low circulating serum CFI levels have been shown to be associated with rare CFI genetic variants and advanced AMD. Studies have estimated that the prevalence of rare CFI variants in the overall AMD population to be approximately 6%, of which approximately 40% are expected to display low serum CFI levels and could potentially benefit from targeted CFI therapy.

The heterogenous clinical presentation of CFI deficiencies likely makes the disease significantly underdiagnosed, and some patients may experience life threatening emergencies that may have severe long-term impact on the quality of life. Currently, there are no therapeutic options approved to specifically replace the deficient CFI protein with a well-functioning CFI to treat these disorders. While not specifically targeting CFI deficiency, eculizumab and ravulizumab are indicated for the treatment of aHUS. Neither eculizumab nor ravulizumab address the root cause of the CFI deficiency; instead, they are designed to prevent the downstream effects of uncontrolled complement activity. Patients with aberrant CFI may therefore still have uncontrolled complement activation downstream of CFI. This may cause deposition of complement proteins, for example, on red blood cells, and some CFI deficient patients may have a worse prognosis than others even when on non-replacement therapy. CB 4332 is designed to address this unmet need by providing a therapeutic option that corrects the root problem of these diseases using simple, fast and easy SQ administration.

As a major, key complement regulator, CFI has also the potential to be used in non-CFI-deficient complement dysregulated diseases (*e.g.*, hyperactive alternative pathway) in which additional upstream regulation may prove more effective than inhibiting specific downstream targets. We have additional early stage complement targeted discovery programs that target different proteins from C3b and C4b.

Dalca

Dalca is a next-generation SQ Factor IX product candidate for the prophylactic treatment of individuals with Hemophilia B that completed an open-label Phase 2b study in 2020.

Factor IX Gene Therapy

Our Factor IX gene therapy construct CB 2679d-GT has demonstrated a 2-fold to 3-fold higher activity resulting in improved clotting time and blood loss in a preclinical Hemophilia B mouse model compared with the Padua variant of Factor IX. Fidanacogene elaparovec (Pfizer/Spark), AMT-061 (uniQure), TAK-748 (Takeda) and FLT180A (Freeline) use the Padua FIX variant as the transgene in their AAV-based gene therapy clinical programs. Fidanacogene elaparovec, AMT-061 and FLT180A have demonstrated encouraging Factor IX levels in their respective Phase 1/2 and Phase 2/3 studies with median Factor IX activity levels in the upper end of the mild to normal ranges. By its increased activity, CB 2679d-GT has the potential to reach higher Factor IX activity levels at

lower vector doses which could improve tolerability of the vector as well as efficacy of the transgene, and ultimately lower manufacturing costs.

We have licensed AAV technology from The Board of Trustees of The Leland Stanford Junior University (“Stanford”) and are currently optimizing the vector under a sponsored research agreement with Stanford. Data presented at European Association for Haemophilia and Allied Disorders (“EAHAD”) show that the combination of our proprietary potency enhanced CB 2679d-GT Factor IX construct with a novel chimeric AAV capsid may reduce the vector dose required in gene therapy while maintaining high Factor IX levels.

Recent Manufacturing Updates

Drug Substance manufacturing

We have a long-term development and manufacturing services agreement with AGC Biologics, Inc. (“AGC”). AGC has global manufacturing sites, and we use their facilities in the U.S. and Europe for drug substance manufacturing of MarzAA, DalcA, and CB 2782-PEG. We have successfully manufactured MarzAA to support our global Phase 3 clinical trial to evaluate the safety and efficacy of MarzAA for episodic treatment and control of bleeding episodes in subjects with Hemophilia A or Hemophilia B with inhibitors. As of March 2021, we have successfully completed two large-scale GMP batches of MarzAA that will be sufficient to support the Phase 3 clinical trial through its completion. Additionally, we have entered into a firm purchase commitment, with AGC, to validate the MarzAA manufacturing process including production of three Process Performance Qualification batches.

Drug Product manufacturing

We have a long-term clinical supply services agreement with Catalent Indiana, LLC (“Catalent”). Catalent has facilities in the U.S. and Europe and conducts drug product development and manufacturing for MarzAA and DalcA. We successfully completed development work for a variety of vial sizes which supports flexible dosing.

We also work with Symbiosis Pharmaceutical Services Limited on drug product manufacturing for MarzAA on a fee-for-services basis. Symbiosis has a facility in the United Kingdom. In March 2021 a GMP batch of MarzAA drug product was successfully completed at Symbiosis to support the MAA-304 MarzAA pivotal trial.

Other Recent Developments

COVID-19 business impact

The global coronavirus pandemic has resulted in widespread requirements for individuals to work from their homes, strained medical facilities worldwide and is causing disruptions to certain pharmaceutical manufacturing and product supply chains. We are experiencing operational and other challenges as a result of the COVID-19 global pandemic, which have delayed our enrollment in MAA-304 and MAA-202, and which may delay or halt our development in these or other programs.

Recent Financing

In the first quarter of 2021, we sold an aggregate of 9,185,000 shares of our common stock (including 485,000 shares sold pursuant to the exercise of the underwriters’ over-allotment option) at a price of \$5.75 per share. The net proceeds to us, after deducting \$3.6 million in underwriting discounts and commissions and offering expenses, were approximately \$49.3 million.

We have no products approved for commercial sale and have not generated any revenue from product sales. From inception to March 31, 2021, we have raised net proceeds of approximately \$505.3 million, primarily from private placements of convertible preferred stock, proceeds from our merger with Targacept, issuances of shares of common stock and warrants, including \$79.5 million in total cash receipts from our license and collaboration agreements.

We have never been profitable and have incurred significant operating losses in each year since inception. Our net losses were \$22.4 million and \$4.1 million for the three months ended March 31, 2021 and 2020, respectively. As of March 31, 2021, we had an accumulated deficit of \$337.2 million. As of March 31, 2021, our cash, cash equivalents and investments balance were \$107.0 million. Substantially all our operating losses were incurred in our research and development programs and in our general and administrative operations.

We expect to incur significant expenses and increasing operating losses for at least the next several years as we continue the preclinical, manufacturing and clinical development, and seek regulatory approval for our drug candidates. Our operating losses may

fluctuate significantly from quarter to quarter and year to year due to timing of preclinical, manufacturing, clinical development programs and regulatory guidance spending.

Financial Operations Overview

License and Collaboration Revenue

License and collaboration revenue consist of revenue earned for performance obligations satisfied pursuant to our license and collaboration agreement with Biogen which was entered into in December 2019. In consideration for the grant of an exclusive license and related know-how, we received an up-front license payment of \$15.0 million in January 2020, which was recorded in license revenue during the year ended December 31, 2020. We recognized collaboration revenue for reimbursable third-party vendor, out-of-pocket and personnel costs pertaining to the Biogen Agreement of \$5.8 million during the year ended December 31, 2020 and \$1.5 million for the three months ended March 31, 2021. There can be no assurance when any future milestone or royalty payments under the Biogen agreement may occur, if at all.

We have not generated any revenue from the sale of any drugs, and we do not expect to generate any revenue from the sale of drugs until we obtain regulatory approval of and commercialize our product candidates.

Cost of License and Collaboration Revenue

Cost of license and collaboration revenue consists of fees for research and development services payable to third-party vendors, and personnel costs, corresponding to the recognition of license and collaboration revenue from Biogen. Cost of license and collaboration revenue does not include any allocated overhead costs. In connection with the license revenue recognized from Biogen as discussed above in 2020, we paid Mosaic a \$3.0 million sublicense fee and recorded such payment as cost of license. We recognized third-party vendor, out-of-pocket and personnel costs, most of which were reimbursable, pertaining to the Biogen Agreement of \$6.1 million during the year ended December 31, 2020 and \$1.5 million for the three months ended March 31, 2021 and recorded such costs as cost of collaboration revenue.

Research and Development Expenses

Research and development expenses represent costs incurred to conduct research, such as the discovery and development of our product candidates. We recognize all research and development costs as they are incurred. Nonrefundable advance payments for goods or services used in research and development are deferred and capitalized. The capitalized amounts are then expensed as the related goods are delivered or services are performed, or until it is no longer expected that the goods or services will be delivered.

Research and development expenses consist primarily of the following:

- employee-related expenses, which include salaries, benefits and stock-based compensation;
- laboratory and vendor expenses, including payments to consultants and third parties, related to the execution of preclinical, non-clinical, and clinical studies;
- the cost of acquiring and manufacturing preclinical and clinical materials and developing manufacturing processes;
- clinical trial expenses, including costs of third-party clinical research organizations;
- performing toxicity and other preclinical studies; and
- facilities and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation and amortization expense and other supplies.

The following table summarizes our research and development expenses for the periods presented (*in thousands*):

	Three Months Ended March 31,	
	2021	2020
Personnel costs	\$ 3,879	\$ 2,265
Preclinical research	4,620	2,286
Clinical and manufacturing	7,989	8,477
Facility and overhead	525	236
Total research and development expenses	\$ 17,013	\$ 13,264

The table below details our internal and external costs for research and development for the period presented (*in thousands*). See Overview and Recent Development Program Updates for further discussion of the current research and development programs.

	Three Months Ended March 31, 2021
Hemophilia	\$ 7,370
Complement	4,650
Personnel and other	4,624
Stock-based compensation	369
Total research and development expenses	\$ 17,013

The largest component of our total operating expenses has historically been our investment in research and development activities, including the clinical and manufacturing development of our product candidates. We are currently focusing substantially all our resources and development efforts on MarzAA and our complement programs. Costs listed for our hemophilia and complement programs above consist of clinical trial, manufacturing and research costs. Our internal resources, employees and infrastructure are generally not directly tied to individual product candidates or development programs. As such, we do not maintain information regarding these costs incurred for these research and development programs on a project-specific basis.

We expect our aggregate research and development expenses will increase during the next year as we advance the clinical and manufacturing development of our programs. The global coronavirus pandemic may also delay and increase costs of our current development plans.

On May 20, 2016, we signed a development and manufacturing services agreement with AGC, formerly known as CMC ICOS Biologics, Inc., pursuant to which AGC will conduct manufacturing development of agreed upon product candidates. We will own all intellectual property developed in such manufacturing development activities that are specifically related to our product candidates and will have a royalty-free and perpetual license to use AGC's intellectual property to the extent reasonably necessary to make these product candidates, including commercial manufacturing. As of March 31, 2021, six GMP batches have been manufactured at AGC in addition to an engineering batch to support the planned clinical trials.

The initial term of the agreement is ten years or, if later, until all stages under outstanding statements of work have been completed. Either party may terminate the agreement in its entirety upon written notice of a material uncured breach or upon the other party's bankruptcy, and we may terminate the agreement upon prior notice for any reason. In addition, each party may terminate the agreement in the event that the manufacturing development activities cannot be completed for technical or scientific reasons. We have firm work orders with AGC to manufacture MarzAA and DalcA to support clinical trials totaling \$17.1 million. The payment obligations remaining as of March 31, 2021 were \$4.5 million.

We also have a long-term clinical supply services agreement with Catalent Indiana, LLC ("Catalent"). Catalent has facilities in the U.S. and Europe and conducts drug product development and manufacturing for MarzAA and DalcA. We successfully completed development work for a variety of vial sizes which supports flexible dosing.

The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in achieving marketing approval for our product candidates. The probability of success of each product candidate may be affected by numerous factors, including clinical data, competition, manufacturing capability and commercial viability. As a result, we are unable to determine the duration of and costs to complete our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

Successful development of current and future product candidates is highly uncertain. Completion dates and costs for our research programs can vary significantly for each current and future product candidate and are difficult to predict. Thus, we cannot estimate with any degree of certainty the costs we will incur in the development of our product candidates. We anticipate we will determine which programs and product candidates to pursue and how much funding to direct to each program and product candidate on an ongoing basis in response to the scientific success of early research programs, results of ongoing and future clinical trials, our ability to enter into collaborative agreements with respect to programs or potential product candidates, as well as ongoing assessments as to each current or future product candidate's commercial potential.

General and Administrative Expenses

General and administrative expenses consist of personnel costs, allocated expenses and other expenses for outside professional services, including legal, human resources, audit and accounting services. Personnel costs consist of salaries, bonus, benefits and stock-based compensation. We incur expenses associated with operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and Nasdaq Stock Market LLC (“Nasdaq”), insurance expenses, audit expenses, investor relations activities, Sarbanes-Oxley compliance expenses and other administrative expenses and professional services. We expect such expenses to increase as we advance our programs.

Results of Operations

The following table set forth our results of operations data for the periods presented (*in thousands*):

	Three Months Ended March 31,		Change (\$)	Change (%)
	2021	2020		
License	\$ —	\$ 15,045	\$ (15,045)	(100)%
Collaboration	1,467	1,321	146	11%
License and collaboration revenue	1,467	16,366	(14,899)	(91)%
Operating expenses:				
Cost of license	—	3,047	(3,047)	(100)%
Cost of collaboration	1,480	1,432	48	3%
Research and development	17,013	13,264	3,749	28%
General and administrative	5,412	3,691	1,721	47%
Total operating expenses	23,905	21,434	2,471	12%
Loss from operations	(22,438)	(5,068)	(17,370)	343%
Interest and other income (expense), net	—	1,015	(1,015)	(100)%
Net loss	\$ (22,438)	\$ (4,053)	\$ (18,385)	454%

License and Collaboration Revenue

License and collaboration revenues were \$1.5 million and \$16.4 million in the three months ended March 31, 2021 and 2020, respectively. In the three months ended March 31, 2021, these consisted primarily of reimbursable collaboration expenses from our Biogen Agreement, which was entered into on December 18, 2019. In the three months ended March 31, 2020, we recorded \$15.0 million in license revenue from the Biogen Agreement upon receipt of an up-front license payment and \$1.3 million in reimbursable collaboration expenses from the Biogen Agreement.

Cost of License and Collaboration

Cost of license and collaboration were \$1.5 million and \$4.5 million during the three months ended March 31, 2021 and 2020, respectively. Cost of collaboration for the three months ended March 31, 2021 was primarily reimbursable third-party vendor and personnel costs we incurred pertaining to the Biogen Agreement. Cost of license and collaboration, in the three months ended March 31, 2020, included a \$3.0 million sublicense fee we paid to Mosaic and \$1.4 million in reimbursable third-party vendor and personnel costs related to the Biogen Agreement.

Research and Development Expenses

Research and development expenses were \$17.0 million and \$13.3 million during the three months ended March 31, 2021 and 2020, respectively, an increase of \$3.7 million, or 28%. The increase was due primarily to an increase of \$2.3 million in preclinical spend and an increase of \$1.6 million in personnel-related costs.

General and Administrative Expenses

General and administrative expenses were \$5.4 million and \$3.7 million during the three months ended March 31, 2021 and 2020, respectively, an increase of \$1.7 million, or 47%. The increase was due primarily to an increase of \$0.8 million in personnel-related costs and an increase of \$0.8 million in professional services.

Interest and Other Income (expense), Net

Interest and other income, net was \$0.0 million and \$1.0 million during the three months ended March 31, 2021 and 2020, respectively, a decrease of \$1.0 million, or 100%. The decrease was primarily due to a decreased interest rate and due to the payment received in the first quarter of 2020 under an agreement associated with neuronal nicotinic receptor asset sold in 2016.

Recent Accounting Pronouncements

Refer to “Accounting Pronouncements Recently Adopted” included in Note 2, *Summary of Significant Accounting Policies*, in the “Notes to the Condensed Consolidated Financial Statements” in this Form 10-Q.

Liquidity and Capital Resources

As of March 31, 2021, we had \$107.0 million of cash, cash equivalents and investments. For the three months ended March 31, 2021, we had a \$22.4 million net loss and \$24.4 million cash used in operating activities. We have an accumulated deficit of \$337.2 million as of March 31, 2021. Our primary uses of cash are to fund operating expenses, including research and development expenditures and general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

We believe that our existing capital resources, including cash, cash equivalents and investments will be sufficient to meet our projected operating requirements for at least the next 12 months from the date of this filing. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We plan to continue to fund losses from operations and capital funding needs through future equity and/or debt financings, as well as potential additional asset sales, licensing transactions, collaborations or strategic partnerships with other companies. As of the date of this quarterly report, we had effective registration statements on Form S-3 that enable us to sell up to \$232.0 million in securities. The sale of additional equity or convertible debt could result in additional dilution to our stockholders. The incurrence of indebtedness would result in debt service obligations and could result in operating and financing covenants that would restrict our operations. Licensing transactions, collaborations or strategic partnerships may result in us relinquishing valuable rights. We can provide no assurance that financing will be available in the amounts we need or on terms acceptable to us, if at all. If we are not able to secure adequate additional funding we may be forced to delay, make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially harm our business.

During the first quarter 2021, we received approximately \$49.3 million in cash proceeds from the sale of equity securities. See Note 9.

The following table summarizes our cash flows for the periods presented (*in thousands*):

	Three Months Ended March 31,	
	2021	2020
Cash used in operating activities	\$ (24,356)	\$ (4,790)
Cash provided by investing activities	27,581	27,421
Cash provided by financing activities	49,459	32,364
Net increase in cash and cash equivalents	<u>\$ 52,684</u>	<u>\$ 54,995</u>

Cash Flows from Operating Activities

Cash used in operating activities for the three months ended March 31, 2021 was \$24.4 million, due primarily to a net loss of \$22.4 million, and the change in our net operating assets and liabilities of \$3.0 million. The change in our net operating assets and liabilities is due primarily to a \$1.7 million increase in prepaid and other assets, a \$3.0 million decrease in accounts payable, and a \$0.7 million decrease in deferred revenue related to the Biogen Agreement, offset by a \$2.3 million decrease in accounts receivable. Non-cash charges of \$1.0 million were recorded for stock-based compensation.

Cash used in operating activities for the three months ended March 31, 2020 was \$4.8 million, due primarily to a net loss of \$4.1 million, and the change in our net operating assets and liabilities of \$1.6 million, due primarily to a \$13.6 million decrease in accounts receivable offset by a \$15.0 million decrease in deferred revenue related to the Biogen Agreement. Non-cash charges of \$0.8 million were recorded for stock-based compensation.

Cash Flows from Investing Activities

Cash provided by investing activities for the three months ended March 31, 2021 was \$27.6 million, due primarily to proceeds from maturities of investments.

Cash provided by investing activities for the three months ended March 31, 2020 was \$27.4 million, due primarily to \$33.5 million in proceeds from maturities of investments, partially offset by \$6.0 million used in purchases of investments.

Cash Flows from Financing Activities

Cash provided by financing activities for the three months ended March 31, 2021 was \$49.5 million, due to \$49.3 million in net proceeds from the issuance of common stock related to our public offering in the first quarter of 2021 and \$0.2 million in stock grants.

Cash provided by financing activities for the three months ended March 31, 2020 was \$32.4 million, due to \$32.0 million in net proceeds from the issuance of common stock related to our public offering in February 2020 and \$0.3 million in stock grants and option exercises.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

Except for the new equity awards with performance conditions mentioned below, there have been no significant changes to our critical accounting policies since December 31, 2020. For a description of critical accounting policies that affect our significant judgments and estimates used in the preparation of our unaudited condensed consolidated financial statements, refer to Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” contained in our Annual Report on Form 10-K.

Stock-based Compensation

We measure the cost of employee and director services received in exchange for an award of equity instruments based on the fair value-based measurement of the award on the date of grant and recognize the related expense over the period during which an employee or director is required to provide service in exchange for the award on a straight-line basis. The estimated fair value of equity awards that contain performance conditions is expensed over the term of the award once we have determined that it is probable that performance conditions will be satisfied.

Determining the fair value of stock-based awards at the grant date requires judgment. We use the Black-Scholes option-pricing model to determine the fair value of stock options. The determination of the grant date fair value of options using an option-pricing model is affected by our assumptions regarding a number of variables including the fair value of our common stock, our expected common stock price volatility over the expected life of the options, expected term of the stock option, risk-free interest rates and expected dividends. We record stock-based compensation as a compensation expense, net of the forfeited awards. We elected to account for forfeitures when they occur. As such, we recognize stock-based compensation expense only for those stock-based awards that are expected to vest, over their requisite service period, based on the vesting provisions of the individual grants. See Note 6, to our unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for more information.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2021. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

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. Based on the evaluation of our disclosure controls and procedures as of March 31, 2021, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

As of March 31, 2021, we have not experienced any significant impact to our internal controls over financial reporting despite the fact that most of our employees who are involved in our financial reporting processes and controls are working remotely due to the COVID-19 pandemic. The design of our processes and controls allow for remote execution with accessibility to secure data. We are continually monitoring and assessing the COVID-19 situation on our internal controls to minimize the impact on their design and operating effectiveness.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) identified during the quarter ended March 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings.

ITEM 1A. RISK FACTORS

The risk factors disclosed in “*Part I - Item 1A - Risk Factors*” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, filed with the Securities and Exchange Commission on March 4, 2021, disclose risk and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our common stock.

You should carefully consider the risks and uncertainties disclosed as “*Risk Factors*” in our Annual Report, together with all of the other information in this Report, including the section titled “*Part I - Financial Information - Item 2 - Management’s Discussion and Analysis of Financial Condition and Results of Operations*” and the condensed consolidated financial statements and related notes.

The risk factors below modify the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2020:

The outbreak of the novel coronavirus disease, COVID-19, has and may continue to adversely impact our business, including our preclinical studies and clinical trials.

The global coronavirus pandemic has resulted in widespread requirements for individuals to work from their homes, strained medical facilities worldwide and is causing disruptions to certain pharmaceutical manufacturing and product supply chains. We are experiencing operational and other challenges as a result of the COVID-19 global pandemic, which have delayed our enrollment in MAA-304 and MAA-202, and which may delay or halt our development in these or other programs. The pandemic has had a particularly pronounced impact in some of the countries where we are seeking to enroll a significant number of patients. As a result of the COVID-19 pandemic, we have experienced delays in enrollment in MAA-304 and MAA-202, and we may experience disruptions that could severely impact our business, preclinical studies, drug manufacturing and clinical trials including:

- additional delays or difficulties in enrolling potential trial participants in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- delays in manufacturing of our product candidates as third-party manufacturing capacity is shifted towards the production of COVID-19 vaccines;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA, European Medicines Agency (the “EMA”) or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in preclinical studies due to restricted or limited operations at laboratory facilities;
- suspension or termination of our clinical trials for various reasons, such as a finding that the participants are being exposed to infectious diseases like COVID-19 or the participants involved in our clinical trials have become infected with COVID-19;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- material delays and complications with respect to our research and development programs.

In addition, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. Furthermore, a recession or market correction resulting from the spread of COVID-19 could materially affect our operations and the value of our common stock.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our regulatory approvals could be delayed or prevented, or we could cease development of certain product candidates.

We or our collaborators may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate, enroll and maintain enrollment of a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In particular, there is a relatively small number of individuals with hemophilia, which may cause delays in enrollment of clinical trials of MarzAA in individuals with hemophilia A and B with an inhibitor, and there are a limited number of individuals with CFI deficiency for whom CB 4332 can be used in clinical trials. Competitive products or products that reduce the frequency of bleeding among patients treated with our drugs have reduced the likelihood that patients will enroll in our clinical trials for MarzAA. Some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates and thus compete with us to enroll patients in their clinical trials. The availability of other approved products and other products in clinical trials may limit the number of patients willing to participate in our clinical trials.

Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the availability of competitive products;
- the efforts to facilitate timely enrollment in clinical trials;
- laboratory testing and turnaround time for samples needed for eligibility assessments;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials will result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in clinical trials conducted by us may also result in increased development costs for our product candidates, which would cause the value of the Company to decline and limit our ability to obtain additional financing.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Unregistered Sales of Equity Securities

None.

Issuer Repurchase of Equity Securities

None.

Use of Proceeds

In the first quarter of 2021, we sold 9,185,000 shares of our common stock, which included the partial exercise by the underwriters of their option to purchase additional shares, at the public offering price of \$5.75 per share and received net proceeds of approximately \$49.3 million, after deducting underwriting discounts and commissions of approximately \$3.2 million and offering-related transaction costs of approximately \$0.4 million. None of the expenses associated with the offering were paid to directors, officers, persons owning ten percent or more of any class of equity securities, or to their associates, or to our affiliates. Piper, Sandler & Co., acted as sole lead active bookrunner and Raymond James & Associates, Inc. acted as a bookrunner for the offering.

There has been no material change in the planned use of proceeds from our public offering from that described in the prospectus filed by us with the SEC on January 26, 2021.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

See Index to Exhibits at the end of this Report, which is incorporated by reference here. The Exhibits listed in the accompanying Index to Exhibits are filed as part of this Report.

EXHIBIT INDEX

Exhibit Number	Description
31.1	<u>Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2	<u>Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
32.1	<u>Certification of the Chief Executive Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
32.2	<u>Certification of the Chief Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets as of March 31, 2021 (unaudited) and December 31, 2020; (ii) the Condensed Consolidated Statements of Operations for the three months ended March 31, 2021 and 2020 (unaudited); (iii) the Condensed Consolidated Statements of Comprehensive Income for the three months ended March 31, 2021 and 2020 (unaudited); (iv) the Condensed Consolidated Statement of Stockholders' Equity as of March 31, 2021 and March 31, 2020 (unaudited); (v) the Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2021 and 2020 (unaudited); and (vi) the Notes to Unaudited Interim Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

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.

CATALYST BIOSCIENCES, INC.

Date: May 6, 2021

/s/ Nassim Usman, Ph.D.

Nassim Usman, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 6, 2021

/s/ Clinton Musil

Clinton Musil
Chief Financial Officer
(Principal Financial and Accounting Officer)

CERTIFICATION PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT
OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Nassim Usman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Catalyst Biosciences, Inc. for the quarter ended March 31, 2021;
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;

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 6, 2021

/s/ Nassim Usman, Ph.D.

Nassim Usman, Ph.D.

President and Chief Executive Officer

(Principal Executive Officer)

CERTIFICATION PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT
OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Clinton Musil, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Catalyst Biosciences, Inc. for the period ended March 31, 2021;
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;

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 6, 2021

/s/ Clinton Musil

Clinton Musil
Chief Financial Officer
(Principal Financial Officer)

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

In connection with the Quarterly Report on Form 10-Q of Catalyst Biosciences, Inc. (the "Company") for the quarterly period ended March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Nassim Usman, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; 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 6, 2021

/s/ Nassim Usman, Ph.D.

Nassim Usman, 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 Catalyst Biosciences, Inc. (the "Company") for the quarterly period ended March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Clinton Musil, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; 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 6, 2021

/s/ Clinton Musil

Clinton Musil
Chief Financial Officer
(Principal Financial Officer)