

**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, 2019

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)

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 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 (Check one):

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 30, 2019, the number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 11,980,103.

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

CATALYST BIOSCIENCES, INC.
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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, 2019</u> (Unaudited)	<u>December 31, 2018</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 25,024	\$ 31,213
Short-term investments	80,253	88,914
Restricted cash	50	50
Prepaid and other current assets	3,675	3,814
Total current assets	<u>109,002</u>	<u>123,991</u>
Other assets, noncurrent	197	543
Right-of-use assets	2,315	—
Property and equipment, net	356	386
Total assets	<u>\$ 111,870</u>	<u>\$ 124,920</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 282	\$ 1,248
Accrued compensation	876	1,495
Other accrued liabilities	2,762	2,043
Deferred rent, current portion	—	15
Operating lease liability	450	—
Total current liabilities	<u>4,370</u>	<u>4,801</u>
Operating lease liability, noncurrent	1,686	—
Deferred rent, noncurrent portion	—	174
Total liabilities	<u>6,056</u>	<u>4,975</u>
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; 11,974,104 and 11,954,528 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	12	12
Additional paid-in capital	324,214	323,279
Accumulated other comprehensive income (loss)	13	(4)
Accumulated deficit	(218,425)	(203,342)
Total stockholders' equity	<u>105,814</u>	<u>119,945</u>
Total liabilities and stockholders' equity	<u>\$ 111,870</u>	<u>\$ 124,920</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,	
	2019	2018
Contract revenue	\$ —	\$ 6
Operating expenses:		
Research and development	12,027	3,771
General and administrative	3,687	2,914
Total operating expenses	<u>15,714</u>	<u>6,685</u>
Loss from operations	(15,714)	(6,679)
Interest and other income, net	631	1,637
Net loss	<u>\$ (15,083)</u>	<u>\$ (5,042)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (1.26)</u>	<u>\$ (0.56)</u>
Shares used to compute net loss per share attributable to common stockholders, basic and diluted	<u>11,963,586</u>	<u>8,989,669</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 March 31,</u>	
	<u>2019</u>	<u>2018</u>
Net loss	\$ (15,083)	\$ (5,042)
Other comprehensive income (loss):		
Unrealized gain (loss) on available-for-sale securities	17	(4)
Total comprehensive loss	<u>\$ (15,066)</u>	<u>\$ (5,046)</u>

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance at December 31, 2018	—	\$ —	11,954,528	\$ 12	\$ 323,279	\$ (4)	\$ (203,342)	\$ 119,945
Stock-based compensation expense	—	—	—	—	829	—	—	829
Issuance of common stock from stock grants and option exercises	—	—	19,576	—	106	—	—	106
Unrealized gain on available-for-sale securities	—	—	—	—	—	17	—	17
Net loss	—	—	—	—	—	—	(15,083)	(15,083)
Balance at March 31, 2019	—	\$ —	11,974,104	\$ 12	\$ 324,214	\$ 13	\$ (218,425)	\$ 105,814
	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance at December 31, 2017	3,680	\$ —	6,081,230	\$ 6	\$ 204,262	\$ —	\$ (173,494)	\$ 30,774
Opening balance adjustment - adoption of ASC 606	—	—	—	—	—	—	207	207
Balance at January 1, 2018	3,680	\$ —	6,081,230	\$ 6	\$ 204,262	\$ —	\$ (173,287)	30,981
Stock-based compensation expense	—	—	—	—	606	—	—	606
Issuance of common stock for secondary public offering, net of issuance costs	—	—	3,382,352	4	106,758	—	—	106,762
Issuance of common stock upon exercise of warrants	—	—	1,735,419	2	9,543	—	—	9,545
Conversion of preferred stock to common stock	(3,680)	—	736,000	—	—	—	—	—
Issuance of common stock from stock grants and option exercises	—	—	59	—	—	—	—	—
Conversion of redeemable convertible notes to common stock	—	—	21	—	3	—	—	3
Unrealized gain on available-for-sale securities	—	—	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	—	—	(5,042)	(5,042)
Balance at March 31, 2018	—	\$ —	11,935,081	\$ 12	\$ 321,172	\$ (4)	\$ (178,329)	\$ 142,851

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,	
	2019	2018
Operating Activities		
Net loss	\$ (15,083)	\$ (5,042)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	829	606
Depreciation and amortization	45	33
Loss on disposal of property and equipment	—	116
Changes in operating assets and liabilities:		
Prepaid and other current assets	96	(407)
Accounts payable	(966)	690
Accrued compensation and other accrued liabilities	100	(1,225)
Change in operating lease liability and right-of-use asset	21	
Deferred rent	—	128
Deferred revenue	—	(6)
Net cash flows used in operating activities	<u>(14,958)</u>	<u>(5,107)</u>
Investing Activities		
Proceeds from maturities of short-term investments	48,274	13,937
Purchase of investments	(39,596)	(12,936)
Purchases of property and equipment	(15)	(198)
Net cash flows provided by investing activities	<u>8,663</u>	<u>803</u>
Financing Activities		
Payments for the redemption of redeemable convertible notes	—	(5,082)
Issuance of common stock for secondary public offering, net of issuance costs	—	106,761
Issuance of common stock from stock grants and option exercises	106	—
Proceeds from exercise of warrants	—	9,545
Net cash flow provided by financing activities	<u>106</u>	<u>111,224</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	(6,189)	106,920
Cash, cash equivalents and restricted cash at beginning of the period	31,263	19,805
Cash, cash equivalents and restricted cash at end of the period ^(a)	<u>\$ 25,074</u>	<u>\$ 126,725</u>
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Adoption of ASC 606	\$ —	\$ 207
Conversion of redeemable convertible notes to common stock	\$ —	\$ 3
Unrealized gain on investments	\$ 17	\$ 4
Right-of-use asset and operating lease liability recorded upon the adoption of ASC 842, net	\$ 2,052	\$ —

(a) The following table provides a reconciliation of cash and restricted cash to amounts reported within the condensed consolidated balance sheets:

Cash and cash equivalents	\$ 25,024	\$ 126,550
Restricted cash	50	175
Total cash and restricted cash	<u>\$ 25,074</u>	<u>\$ 126,725</u>

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

1. Nature of Operations and Liquidity

Catalyst Biosciences, Inc. and its subsidiary (the “Company” or “Catalyst”) is a clinical-stage biopharmaceutical company focused on developing novel treatments for hemophilia and other rare bleeding disorders using our engineered subcutaneous (SQ) coagulation factors that promote blood clotting. Our facilities are located in South San Francisco, California and we operate in one segment. Prior to August 20, 2015, the name of the Company was Targacept, Inc. (“Targacept”). On August 20, 2015, Targacept completed its business combination with Catalyst.

The Company had a net loss of \$15.1 million for the quarter ended March 31, 2019 and an accumulated deficit of \$218.4 million as of March 31, 2019 and expects to continue to incur losses for the next several years. As of March 31, 2019, we had \$105.3 million of cash, cash equivalents and short-term investments. Our 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, 2019 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 U.S. 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 full year.

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, 2018 (“Annual Report”).

Accounting Pronouncements Recently Adopted

The Company’s significant accounting policies are included in “Part II - Item 8 - Financial Statements and Supplementary Data - Note 3 – Summary of Significant Accounting Policies” in the Company’s Annual Report. In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), to enhance the transparency and comparability of financial reporting related to leasing arrangements. The Company adopted the standard effective January 1, 2019. As discussed in our Annual Report, the Company adopted the new lease standards in the first quarter of 2019. There have been no other significant changes to these accounting policies during the first three months of 2019.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes its incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received.

The Company has elected to combine lease and non-lease components as a single component. The lease expense is recognized over the expected term on a straight-line basis. Operating leases are recognized on the balance sheet as right-of-use assets, operating lease liabilities, current and operating lease liabilities, non-current. As a result, the Company no longer recognizes deferred rent on the balance sheet.

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

On January 1, 2019, the Company adopted the new lease accounting standard using the optional transition method under which comparative financial information is not restated and continues to apply the provisions of the previous lease accounting standard in its financial disclosures for the comparative periods. The Company also elected relevant optional practical expedients including 1) did not reassess whether expired or existing contracts are or contain a lease, 2) did not reassess the lease classifications or reassess the initial direct costs associated with expired or existing leases, and 3) did not separate lease and non-lease components of its operating leases in which it is the lessee.

The adoption of the new lease accounting standard had an impact of approximately \$2.1 million on the Company's assets and liabilities and had no impact on cash provided by or used in operating, investing or financing activities on the Company's condensed consolidated statements of cash flows. The adoption of the new lease accounting standard did not impact previously reported financial results.

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 2 – 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, 2019.

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, 2019 and December 31, 2018 (*in thousands*):

	March 31, 2019			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds ⁽¹⁾	\$ 23,475	\$ —	\$ —	\$ 23,475
U.S. government agency securities ⁽²⁾	65,653	—	—	65,653
Federal agency securities ⁽²⁾	—	14,600	—	14,600
Restricted cash (money market funds)	50	—	—	50
Total financial assets	\$ 89,178	\$ 14,600	\$ —	\$ 103,778

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

(2) Included in short-term investments on accompanying condensed consolidated balance sheets and are classified as available-for-sale securities.

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds ⁽¹⁾	\$ 29,090	\$ —	\$ —	\$ 29,090
Federal agency securities ⁽¹⁾	—	999	—	999
U.S. Treasury securities ⁽²⁾	74,139	—	—	74,139
Federal agency securities ⁽²⁾	—	14,775	—	14,775
Restricted cash (money market funds)	50	—	—	50
Total financial assets	\$ 103,279	\$ 15,774	\$ —	\$ 119,053

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

(2) Included in short-term investments on accompanying condensed consolidated balance sheets and are classified as available-for-sale securities.

4. Financial Instruments

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

March 31, 2019	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds (cash equivalents)	\$ 23,475	\$ —	\$ —	\$ 23,475
U.S. government agency securities	65,645	9	(1)	65,653
Federal agency securities	14,595	5	—	14,600
Restricted cash (money market funds)	50	—	—	50
Total financial assets	\$ 103,765	\$ 14	\$ (1)	\$ 103,778

Classified as:

Cash and cash equivalents	\$ 23,475
Short-term investments	80,253
Restricted cash (money market funds)	50
	\$ 103,778

December 31, 2018	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds (cash equivalents)	\$ 29,090	\$ —	\$ —	\$ 29,090
Federal agency securities (cash equivalents)	999	—	—	999
Restricted cash (money market funds)	50	—	—	50
U.S. government agency securities	74,144	1	(6)	74,139
Agency securities	14,774	1	—	14,775
Total financial assets	\$ 119,057	\$ 2	\$ (6)	\$ 119,053

Classified as:

Cash and cash equivalents	\$ 30,089
Short-term investments	88,914
Restricted cash (money market funds)	50
	\$ 119,053

There have been no material realized gains or losses on available-for-sale securities for the periods presented. The carrying amounts of cash, accounts payable, and other payables approximate their fair values due to the short-term maturity of these instruments. As of March 31, 2019, the remaining contractual maturities of available-for-sale securities was less than one year.

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 liability but are reflected as an expense in the period incurred.

For the three months ended March 31, 2019, the Company's operating lease expense was \$0.2 million. The present value assumptions used in calculating the present value of the lease payments were as follows:

Weighted-average remaining lease term	4.1 years
Weighted-average discount rate	6.0%

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

Future lease payments under non-cancelable leases as of March 31, 2019 were as follows:

Remaining in 2019	\$	423
2020		578
2021		596
2022		613
2023		209
Total future minimum lease payments		2,419
Less imputed interest		(283)
Total lease liability	\$	<u>2,136</u>

6. Stock Based Compensation

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, 2018	1,361,977	\$ 12.04	8.71
Options granted	309,300	\$ 8.12	
Options exercised	(12,794)	\$ 4.60	
Options forfeited	(39,971)	\$ 7.60	
Options Expired	(5,641)	\$ 91.79	
Outstanding — March 31, 2019	<u>1,612,871</u>	\$ 11.17	8.77
Exercisable — March 31, 2019	<u>468,193</u>	\$ 16.19	8.03
Vested and expected to vest — March 31, 2019	<u>1,612,871</u>	\$ 11.17	8.77

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 and is 6.03 years based on the average between the vesting period and the contractual life of the option. 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, 2019 and 2018:

	Three Months Ended March 31,	
	2019	2018
Employee Stock Options:		
Risk-free interest rate	2.56%	2.40%
Expected term (in years)	6.03	6.01
Dividend yield	—	—
Volatility	82.91%	109.32%
Weighted-average fair value of stock options granted	\$ 5.80	\$ 12.34

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

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

	Three Months Ended March 31,	
	2019	2018
Research and development	\$ 238	\$ 115
General and administrative ⁽¹⁾	591	491
Total stock-based compensation	<u>\$ 829</u>	<u>\$ 606</u>

(1) 2018 includes \$0.1 million in modification stock-based compensation expense related to a Board member's departure.

As of March 31, 2019, 1,031,456 shares of common stock were available for future grant and 1,612,871 options to purchase shares of common stock were outstanding. As of March 31, 2019, the Company had unrecognized employee stock-based compensation expense of \$7.4 million, related to unvested stock awards, which is expected to be recognized over an estimated weighted-average period of 2.93 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 equal to up to \$17.5 million, payable upon the achievement of 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 million milestone payment based on the dosing of the first patient in its ongoing Phase 2 study; the amount was recorded as a research and development expense. No payments were made to Pfizer in the first quarter of 2019.

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 our 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 million in commercial milestone payments, if the applicable milestones are met.

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, 2019 and 2018 (*in thousands, except share and per share data*):

	Three Months Ended March 31,	
	2019	2018
Net loss attributable to common stockholders	\$ (15,083)	\$ (5,042)
Weighted-average number of shares used in computing net loss per share, basic and diluted	11,963,586	8,989,669
Net loss available for common stockholders per share, basic and diluted	<u>\$ (1.26)</u>	<u>\$ (0.56)</u>

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

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,	
	2019	2018
Options to purchase common stock	1,612,871	1,026,393
Common stock warrants	10,194	12,039
Redeemable convertible notes	—	—
Total	1,623,065	1,038,432

9. Stockholders' Equity

February 2018 Underwritten Public Offering — On February 13, 2018, the Company entered into an underwriting agreement with JonesTrading, in connection with a registered firm commitment underwritten public offering of 2,941,176 shares of common stock, pursuant to a shelf registration statement that was declared effective by the SEC on February 6, 2018. On February 15, 2018, the Company sold 3,382,352 shares of common stock (including 441,176 shares of common stock sold pursuant to the exercise of the underwriters' overallotment option) at a price to the public of \$34.00 per share. The net proceeds to the Company, after deducting the underwriting discounts and commissions and offering expenses payable by the Company were approximately \$106.8 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 \$9.4 million and the payment obligations remaining at March 31, 2019 was \$4.6 million.

11. Related Parties

On October 24, 2017 the Company announced a strategic research collaboration with Mosaic Biosciences, Inc. ("Mosaic") to develop intravitreal anti-complement factor 3 products for the treatment of dry age-related macular degeneration and other retinal diseases. According to the agreement the Company and Mosaic will co-fund the research. Dr. Usman, our Chief Executive Officer and a member of our board of directors, and Mr. Lawlor, the chairman of our board of directors, were also members of the board of directors of Mosaic when this agreement was entered in to, and the agreement was reviewed by disinterested members of our board of directors and approved by our audit committee. Expenses related to the collaboration were \$0.3 and \$0.2 million for the three months ended March 31, 2019 and 2018, respectively.

12. Interest and Other Income

The following table shows the detail of interest and other income/(expense), net for the three-month periods ended March 31, 2019 and 2018 (*in thousands*):

	Three Months Ended March 31,	
	2019	2018
Interest income	\$ 631	\$ 285
Loss on disposal of fixed assets	—	(116)
Other income, net	—	1,468
Total other income/(expense), net	\$ 631	\$ 1,637

Other income of \$1.5 million for the three months ended March 31, 2018, reflects milestone payments received under an agreement associated with neuronal nicotinic receptor assets sold in 2016.

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, (i) references to "Catalyst," "we," "us," "our" or the "Company" mean Catalyst Biosciences, Inc. and our subsidiaries. The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and related notes that appear in this Quarterly Report on Form 10-Q ("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 Company's Annual Report on Form 10-K for the year ended December 31, 2018 ("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 clinical-stage biopharmaceutical company focused on developing novel treatments for hemophilia and other rare bleeding disorders using our potent, subcutaneous (SQ) coagulation factors that promote blood clotting. Our engineered coagulation factors are designed to overcome the significant limitations of current intravenous (IV) treatment options, facilitate prophylaxis, and ultimately deliver substantially better outcomes for patients using SQ dosing.

Hemophilia is a rare but serious bleeding disorder that results from a genetic or an acquired deficiency of a factor required for normal blood coagulation. There are two major types of hemophilia, A and B, that are caused by alterations in Factor VIII or Factor IX genes, respectively, with a corresponding reduction in the ability to generate a blood clot. The disease is X chromosome-linked, meaning that most people who inherit the disorder and suffer from symptoms are male; however, female carriers of mutations in Factor VIII or Factor IX can also have reduced coagulation factor levels and resultant bleeding. Hemophilia A occurs in approximately 1 in 5,000 male births, and hemophilia B in approximately 1 in 20,000 male births. The prevalence of hemophilia A and B in the United States is approximately 20,000 individuals out of an estimated 400,000 individuals worldwide. Currently there is no cure for hemophilia. Individuals with hemophilia suffer from spontaneous bleeding episodes and substantially prolonged bleeding times that can become limb- or life-threatening following injury or trauma. In cases of severe hemophilia, spontaneous bleeding into muscles or joints is frequent and often results in disabling joint damage.

The New Standard in Hemophilia Management

Patients with hemophilia either do not generate sufficient levels of a coagulation factor or a functional coagulation factor. Current treatment involves management of acute bleeding episodes or prophylactic treatment through factor replacement therapy by IV infusion of the individuals' missing Factor VIII or IX. Intravenous infusion is difficult, time consuming and particularly challenging to administer to children. Another significant challenge in managing patients with hemophilia is the risk for development of inhibitors, which reduce the efficacy of the Factor replacement. This occurs in approximately 30% of hemophilia A and 5-10% of hemophilia B patients. Inhibitor patients are treated with an IV treatment of either NovoSeven RT® or FEIBA; more recently, SQ Hemlibra® has been approved for hemophilia A inhibitor patients.

We are focused on the clinical development of our subcutaneously dosed, next-generation Factor VIIa (marzeptacog alfa (activated) – MarzAA) for the treatment of hemophilia A and B inhibitor patients, and Factor IX (dalcinonacog alfa – DalcA) for hemophilia B patients. We believe that SQ prophylaxis will provide effective and convenient protection from spontaneous bleeds. Preclinical and Phase 1 clinical studies showed that MarzAA is nine-fold more potent than NovoSeven RT, the current leading Factor VIIa bypass therapy, and that DalcA is 22-fold more potent than BeneFIX, the current leading Factor IX replacement therapy. The enhanced potency of both products allows for SQ dosing using a small volume. We believe dosing of our novel factors for prophylaxis is potentially more efficacious because of prolongation of half-life and greater convenience, especially for children. We currently control worldwide development, manufacturing and commercialization rights of our product candidates. DalcA commercialization rights in Korea are assigned to ISU Abxis, our collaborator who performed development through Phase 1/2. Both MarzAA and DalcA have received orphan drug designation in the U.S. and in the E.U.

We estimate the global market opportunity for MarzAA and DalcA to be approximately \$3.7 billion: \$2.2 billion for the Factor VIIa market and \$1.5 billion for the Factor IX market.

Recent Program Updates

MarzAA

We have completed enrollment and dosing of our Phase 2 open-label SQ efficacy trial. The Phase 2 trial demonstrated the ability of MarzAA substantially to eliminate spontaneous bleeding at the final dose level and to minimize traumatic bleeding episodes in individuals with hemophilia A or B with inhibitors. The primary endpoint was reduction in annualized bleed rate (“ABR”) at an individualized final dose level and secondary endpoints included safety, tolerability and lack of neutralizing antibody (nAb) formation. We recently reported at the European Alliance for Hemophilia and Allied Disorders (EAHAD) meeting on February 8th 2019 that seven subjects who completed dosing had a pre-dose mean ABR of 18.2 (range of 12.2-26.7) that was reduced to 2.1 (>90% reduction); and five of the seven had no bleeds for 50 days at the lowest dose (30 µg/kg). No anti-drug antibodies or nAbs to MarzAA or thrombotic events have been observed to date, and only six injection site reactions have been reported after more than 450 injections. Final results from all nine subjects that completed dosing in the Phase 2 open-label trial will be presented at the International Society for Thrombosis & Hemostasis (ISTH) meeting in July 2019. We plan to initiate a Phase 3 registration study in 2020. We will initiate a SQ Phase 1 pharmacokinetic and pharmacodynamic study in the second quarter of 2019 and expect that study to conclude in the fourth quarter of 2019. We have also completed an IV Phase 1 clinical trial evaluating the pharmacokinetics, pharmacodynamics and coagulation activity of MarzAA in individuals with severe hemophilia A and B with and without an inhibitor.

DalcA

We have completed a Phase 1/2 subcutaneous dosing trial that evaluated the safety and efficacy of DalcA in individuals with severe hemophilia B. The objective of the Phase 1/2 trial was to demonstrate the feasibility of increasing Factor IX activity trough levels from approximately 1% (severe hemophilia) to greater than 12% (mild hemophilia corresponding to a reduced chance of spontaneous joint bleeds) with daily SQ injections. Data from the study demonstrated that DalcA maintained protective Factor IX activity levels of 12 – 30%. Two subjects in the Phase 1/2 SQ dosing trial developed nAbs, one transiently. The nAbs were specific to DalcA and did not interfere with the patients’ ability to resume use of their prior FIX therapy so are not referred to as inhibitors. We completed a comprehensive investigation of the cause of the nAbs in 2018 and concluded that the immunogenic potential of DalcA was low and similar to that of commercial Factor IX products and that drug product quality is comparable to commercial Factor IX products. Based on the results of the investigation, and discussions with clinicians and regulatory experts, we have initiated a Phase 2b trial to assess safety and efficacy of DalcA, that will include 28 days of daily SQ dosing in six subjects, and we expect the trial to be completed in the second half of 2019.

Pipeline Assets

We have three additional drug candidates: a Factor IX gene therapy construct CB 2679d-GT; a novel anti-C3 protease program for the treatment of dry AMD, CB 2782 for which we have a strategic research collaboration with Mosaic Biosciences; and a Factor Xa pro-coagulant molecule.

The Factor IX gene therapy construct CB 2679d-GT has demonstrated 3-fold higher activity and 4-5-fold faster clotting time in a preclinical hemophilia B mouse model compared with the Padua variant of Factor IX that is in clinical development by others. Pfizer/Spark (fidanacogene elaparovec) and uniQure (AMT-061) use the Padua variant as the transgene in their AAV based gene therapy clinical programs and both have demonstrated encouraging Factor IX levels in their respective Phase 1/2 and Phase 2/3 studies with median Factor IX levels of approximately 30%. We are currently optimizing the construct and will make a strategic decision on its future development at the end of this year.

We have created a modified version of our anti-C3 protease CB 2782, CB 2782-PEG, that is designed to have an extended half-life. Complement factor 3 (C3) is the central regulator of the complement cascade and C3 is a clinically validated target for geographic atrophy in age-related macular degeneration. CB 2782-PEG has indistinguishable enzymatic activity from CB 2782, inactivating C3 at the same rate as unmodified CB 2782. We have completed an intravitreal rabbit pharmacokinetics study and an intravitreal non-human primate pharmacokinetics, pharmacodynamics study comparing CB 2782-PEG with CB 2782. A single intravitreal injection of 125µg of CB 2782-PEG had a greater than 99% elimination of C3 in non-human primate for at least 28 days. Data from these studies indicate CB 2782-PEG is potentially a best-in-class anti-complement factor 3 therapy, with an intravitreal administration frequency of three to four times a year.

We have delayed initiating further work on our Factor Xa therapeutic program at this time to focus our efforts on the MarzAA and DalcA clinical programs.

Summary of Our Pipeline



We have no products approved for commercial sale and have not generated any revenue from product sales. From inception to March 31, 2019, we have raised net cash proceeds of approximately \$373.0 million, primarily from private placements of convertible preferred stock and the proceeds from our merger with Targacept in addition to issuances of shares of common stock and warrants, and payments received from collaboration agreements.

We have never been profitable and have incurred significant operating losses in each year since inception. Our net losses were \$15.1 million and \$5.0 million for the three months ended March 31, 2019 and 2018, respectively. As of March 31, 2019, we had an accumulated deficit of \$218.4 million. As of March 31, 2019, our cash, cash equivalents and short-term investments balance is \$105.3 million. Substantially all our operating losses resulted from manufacturing expenses and losses incurred in our research and development programs and from general and administrative costs associated with our 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. In addition, our expenses have increased due to hiring additional financial personnel, upgrading our financial information systems and incurring costs associated with being a public company. In addition, our operating losses may fluctuate significantly from quarter to quarter and year to year due to timing of preclinical, clinical development programs and regulatory approval.

Financial Operations Overview

Contract Revenue

We did not generate any revenue in the first quarter of 2019 and do not expect to generate revenue in the next three quarters of 2019. Revenue generated in 2018 was from our collaboration with ISU Abxis which was effectively terminated through an amendment in December 2018.

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.

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, 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 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 during the three months ended March 31, 2019 and 2018 (*in thousands*):

	Three Months Ended March 31,	
	2019	2018
Personnel costs	\$ 2,045	\$ 713
Preclinical research	845	448
Clinical manufacturing	8,911	2,399
Facility and overhead	226	211
Total research and development expenses	<u>\$ 12,027</u>	<u>\$ 3,771</u>

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 DalcA. Our internal resources, employees and infrastructure are 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 MarzAA and DalcA. While ISU Abxis has previously been responsible for clinical and development expenses for DalcA under our agreement with them, their funding obligations have expired, and we have assumed responsibility for these expenses.

On May 20, 2016, we 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. 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. In 2016 we commenced manufacturing activities for MarzAA, and successfully manufactured MarzAA for the Phase 2 portion of a planned Phase 2/3 clinical trial. In February 2018 we entered into a statement of work for AGC for process transfer and clinical scale manufacturing of DalcA.

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 committed to a total of \$9.4 million in payments to AGC pursuant to the statements of work for MarzAA and DalcA and \$4.6 million of those payments are outstanding at March 31, 2019.

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 make determinations as to 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 continue.

Interest and Other Income, Net

Interest and other income consist primarily of interest income on our investment portfolio and milestone payments received under an agreement associated with neuronal nicotinic receptor assets sold in 2016.

Results of Operations

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

	Three Months Ended March 31,		Change (\$)	Change (%)
	2019	2018		
Contract revenue	\$ —	\$ 6	\$ (6)	(100)%
Operating expenses:				
Research and development	12,027	3,771	8,256	219%
General and administrative	3,687	2,914	773	27%
Total operating expenses	15,714	6,685	9,029	135%
Loss from operations	(15,714)	(6,679)	(9,035)	135%
Interest and other income	631	1,637	(1,006)	(61)%
Net loss	\$ (15,083)	\$ (5,042)	\$ (10,041)	199%

Contract Revenue

Contract revenue was \$0 and \$0.01 million during the three months ended March 31, 2019 and 2018, respectively. Revenue generated in 2018 was from our collaboration with ISU Abxis which was effectively terminated through an amendment in December 2018.

Research and Development Expenses

Research and development expenses were \$12.0 million and \$3.8 million during the three months ended March 31, 2019 and 2018, respectively, an increase of \$8.3 million, or 219%. The increase was due primarily to an increase of \$6.5 million in manufacturing development as we continued to advance the development of the MarzAA and DalcA product candidates, an increase of \$1.3 million in personnel-related costs and an increase of \$0.4 million in preclinical third-party research and development service contracts.

General and Administrative Expenses

General and administrative expenses was \$3.7 million and \$2.9 million during the three months ended March 31, 2019 and 2018, respectively, an increase of \$0.8 million, or 27%. The increase was due primarily to an increase of \$0.3 million in personnel-related costs and an increase of \$0.4 million in several professional services costs including patent legal services and commercial market assessment.

Interest and Other Income

Interest and other income was \$0.6 million and \$1.6 million during the three months ended March 31, 2019 and 2018, respectively, a decrease of \$1.0 million, or 61%. The decrease was due primarily to a contingent milestone payment of \$1.5 million received in 2018, partially offset by higher interest income in 2019 of \$0.3 million due to higher cash equivalent and short-term investments balance in 2019.

Recent Accounting Pronouncements

Accounting Pronouncements Recently Adopted

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which replaces the existing guidance for leases. The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Disclosure requirements have been enhanced with the objective of enabling financial statement users to assess the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 became effective for us beginning in the first quarter of 2019. We have implemented the standard using the modified retrospective method that allows us to initially apply the new leases standard as of the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. In connection with the adoption, we have elected to utilize the package of practical expedients, including: (1) not reassess the lease classification for any expired or existing leases, (2) not reassess the treatment of initial direct costs as they related to existing leases, and (3) not reassess whether expired or existing contracts are or contain leases. We also elected the practical expedient to not separate lease and non-lease components of its operating leases in which it is the lessee.

The adoption of the new lease accounting standard had an impact of approximately \$2.1 million on the Company's assets and liabilities and had no impact on cash provided by or used in operating, investing or financing activities on the Company's condensed consolidated statements of cash flows. The adoption of the new lease accounting standard did not impact previously reported financial results.

Liquidity and Capital Resources

As of March 31, 2019, we had \$105.3 million of cash, cash equivalents and short-term investments and a \$15.1 million net loss and \$15.0 million cash used in operating activities for the three months ended March 31, 2019. We have an accumulated deficit of \$218.4 million as of March 31, 2019. 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 short-term 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. We have effective registration statements on Form S-3 that enable us to sell up to \$268 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.

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

	Three Months Ended March 31,	
	2019	2018
Cash used in operating activities	\$ (14,958)	\$ (5,107)
Cash provided by investing activities	8,663	803
Cash provided by financing activities	106	111,224
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ (6,189)</u>	<u>\$ 106,920</u>

Cash Flows from Operating Activities

Cash used in operating activities for the three months ended March 31, 2019 was \$15.0 million, due primarily to a net loss of \$15.1 million, and the change in our net operating assets and liabilities of \$0.8 million due primarily to a \$1.0 million decrease in accounts payable offset by a \$0.2 million decrease in the prepaid and other current assets net of the release of prepaid rent and the related liability upon the adoption of Topic 842. Non-cash charges of \$0.8 million were recorded for stock-based compensation.

Cash used in operating activities for the three months ended March 31, 2018 was \$5.1 million, due primarily to a net loss of \$5.0 million, the change in our net operating assets and liabilities of \$0.8 million due primarily to a \$1.2 million decrease in accrued compensation and other accrued liabilities and a \$0.4 million increase in prepaid expenses, partially offset by a \$0.7 million increase in accounts payable and a \$0.1 million increase in deferred rent. Non-cash charges of \$0.6 million were recorded for stock-based compensation, and a \$0.1 million for loss on the disposal of property and equipment.

Cash Flows from Investing Activities

Cash provided by investing activities for the three months ended March 31, 2019 was \$8.7 million, due primarily to \$48.3 million in proceeds from maturities of investments, partially offset by \$39.6 million in purchases of investments and \$0.02 million in purchase of assets.

Cash provided by investing activities for the three months ended March 31, 2018 was \$0.8 million, due primarily to \$13.9 million in proceeds from maturities of investments, partially offset by \$12.9 million in purchases of investments and \$0.2 million in purchase of assets.

Cash Flows from Financing Activities

Cash provided by financing activities for the three months ended March 31, 2019 was \$0.1 million, due entirely to proceeds from issuance of common stock related to our Employee Stock Purchase Plan and stock option exercises.

Cash provided by financing activities for the three months ended March 31, 2018 was \$111.2 million, due primarily to net proceeds from the issuance of common stock related to our secondary public offering in February 2018, \$9.5 million in proceeds from the exercise of common stock warrants, partially offset by payments of \$5.1 million related to the maturity and redemption of the remaining redeemable notes.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

The Company's significant accounting policies are included in "Part II - Item 8 - Financial Statements and Supplementary Data - Note 3 – Summary of Significant Accounting Policies" in the Company's Annual Report. As discussed in our Annual Report, the Company adopted the new leases standards in the first quarter of 2019 and otherwise, there have been no other significant changes to our accounting policies during the first three months of 2019.

See Recent Accounting Pronouncements above for effects of adoption on our condensed consolidated statement of operations for the three months ended March 31, 2019 and on our condensed consolidated balance sheet as of January 1, 2019.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and interest rates. We are exposed to market risks in the ordinary course of our business. Our primary exposure to market risk is interest income sensitivity in our investment portfolio. Fixed rate securities and borrowings may have their fair market value adversely impacted due to fluctuations in interest rates, while floating rate securities may produce less income than expected if interest rates fall and floating rate borrowings may lead to additional interest expense if interest rates increase. Due in part to these factors, our future investment income may fall short of expectations due to changes in interest rates or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates.

However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on the fair market value of our investment portfolio. As of March 31, 2019, we had cash and cash equivalents and short-term investments of \$105.3 million, which included bank deposits and money market funds and short-term investments of \$80.3 million. Accordingly, we do not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our investment portfolio.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2019. 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, 2019, 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.

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 first three months of 2019 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

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. Our risk factors have not changed materially from those described in “*Part I - Item 1A - Risk Factors*” in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the Securities and Exchange Commission on March 8, 2019.

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.

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

None.

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 Principal 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 Principal 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 Principal Executive Officer pursuant to 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 Principal Financial Officer pursuant to 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, 2019, formatted in XBRL (eXtensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets as of March 31, 2019 (unaudited) and December 31, 2018; (ii) the Condensed Consolidated Statements of Comprehensive Income for the three months ended March 31, 2019 and 2018 (unaudited); (iii) the Condensed Consolidated Statement of Stockholders' Equity as of March 31, 2019 (unaudited); (iv) the Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2019 and 2018 (unaudited); and (v) the Notes to Unaudited Interim Condensed Consolidated Financial Statements.

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 2, 2019

/s/ Nassim Usman, Ph.D.

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

Date: May 2, 2019

/s/ Fletcher Payne

Fletcher Payne
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.;
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 2, 2019

/s/ Nassim Usman, Ph.D.

Nassim Usman, Ph.D.

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, Fletcher Payne, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Catalyst Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

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 2, 2019

/s/ Fletcher Payne

Fletcher Payne

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 period ended March 31, 2019 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 2, 2019

/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 period ended March 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Fletcher Payne, 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 2, 2019

/s/ Fletcher Payne

Fletcher Payne

Chief Financial Officer

(Principal Financial and Accounting Officer)