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, 2020

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	**56-2020050**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
611 Gateway Blvd., Suite 710 South San Francisco, California	**94080**
(Address of Principal Executive Offices)	**(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	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock	CBIO	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	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
Emerging growth 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 May 1, 2020, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 17,435,361.

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)

	March 31, 2020 (Unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 70,364	$ 15,369
Short-term investments	34,164	61,496
Accounts receivable	1,366	15,000
Prepaid and other current assets	2,381	4,201
Total current assets	108,275	96,066
Other assets, noncurrent	197	257
Right-of-use assets	1,795	1,927
Property and equipment, net	296	304
Total assets	$ 110,563	$ 98,554
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,316	$ 4,279
Accrued compensation	1,268	2,106
Deferred revenue	—	15,000
Other accrued liabilities	8,774	7,031
Operating lease liability	495	483
Total current liabilities	11,853	28,899
Operating lease liability, noncurrent	1,191	1,319
Total liabilities	13,044	30,218
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; 17,419,313 and 12,040,835 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	17	12
Additional paid-in capital	359,935	326,810
Accumulated other comprehensive income	140	34
Accumulated deficit	(262,573)	(258,520)
Total stockholders' equity	97,519	68,336
Total liabilities and stockholders' equity	$ 110,563	$ 98,554

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, 2020	Three Months Ended March 31, 2019
License	$ 15,045	$ —
Collaboration	1,321	—
License and collaboration revenue	16,366	—
Operating expenses:		
Cost of license	3,047	—
Cost of collaboration	1,432	—
Research and development	13,264	12,027
General and administrative	3,691	3,687
Total operating expenses	21,434	15,714
Loss from operations	(5,068)	(15,714)
Interest and other income, net	1,015	631
Net loss	$ (4,053)	$ (15,083)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.28)	$ (1.26)
Shares used to compute net loss per share attributable to common stockholders, basic and diluted	14,592,451	11,963,586

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)

	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019
Net loss	$ (4,053)	$ (15,083)
Other comprehensive income:		
Unrealized gain on available-for-sale debt securities	106	17
Total comprehensive loss	$ (3,947)	$ (15,066)

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, 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

	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, 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 debt 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

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,	
	2020	2019
Operating Activities		
Net loss	$ (4,053)	$ (15,083)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	805	829
Depreciation and amortization	25	45
Changes in operating assets and liabilities:		
Accounts receivable	13,634	—
Prepaid and other current assets	1,880	96
Accounts payable	(2,963)	(966)
Accrued compensation and other accrued liabilities	866	100
Operating lease liability and right-of-use asset	16	21
Deferred revenue	(15,000)	—
Net cash flows used in operating activities	(4,790)	(14,958)
Investing Activities		
Proceeds from maturities of short-term investments	33,457	48,274
Purchase of short-term investments	(6,019)	(39,596)
Purchases of property and equipment	(17)	(15)
Net cash flows provided by investing activities	27,421	8,663
Financing Activities		
Issuance of common stock for public offering, net of issuance costs	32,025	—
Issuance of common stock from stock grants and option exercises	339	106
Net cash flow provided by financing activities	32,364	106
Net increase (decrease) in cash, cash equivalents and restricted cash	54,995	(6,189)
Cash, cash equivalents and restricted cash at beginning of the period	15,369	31,263
Cash, cash equivalents and restricted cash at end of the period[a]	$ 70,364	$ 25,074
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
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, cash equivalents and restricted cash to amounts reported within the condensed consolidated balance sheets:

Cash and cash equivalents	$ 70,364	$ 25,024
Restricted cash	—	50
Total cash, cash equivalents and restricted cash	$ 70,364	$ 25,074

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 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 $4.1 million for the three months ended March 31, 2020 and an accumulated deficit of $262.6 million as of March 31, 2020. The Company expects to continue to incur losses for the next several years. As of March 31, 2020, the Company had $104.5 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, 2020 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 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, 2019 ("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 November 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606 ("ASU 2018-18"). The amended guidance precludes presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. The new guidance is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted. The Company adopted ASU 2018-18 as of January 1, 2020. The adoption of ASU 2018-18 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.

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. ASU 2019-12 is effective for the Company beginning January 1, 2021 with early adoption permitted. The Company is evaluating the impact of adopting this new accounting guidance on its consolidated financial statements.

Cost of License and Collaboration Revenue

Cost of license revenue includes sublicense fees paid or payable to Mosaic Biosciences, Inc. (“Mosaic”), incurred in the period, under the terms of the Mosaic collaboration agreement, and fees for patent development and protection paid or payable to other third-party vendors corresponding to the recognition of license revenue from the Biogen Agreement. See Notes 7 and 11. Cost of license revenue does not include any allocated overhead costs.

Cost of collaboration revenue includes fees for research and development services paid or payable to Mosaic and other third-party vendors and personnel cost, incurred in the period pertaining to the Biogen Agreement. See Notes 7 and 11. Cost of collaboration revenue does not include any allocated overhead costs.

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, 2020.

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, 2020 and December 31, 2019 (*in thousands*):

	March 31, 2020			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds(1)	$ 70,364	$ —	$ —	$ 70,364
U.S. government agency securities(2)	28,146	—	—	28,146
Federal agency securities(2)	—	6,018	—	6,018
Total financial assets	$ 98,510	$ 6,018	$ —	$ 104,528

(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.

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds(1)	$ 15,369	$ —	$ —	$ 15,369
U.S. government agency securities(2)	51,490	—	—	51,490
Federal agency securities(2)	—	10,006	—	10,006
Total financial assets	$ 66,859	$ 10,006	$ —	$ 76,865

(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.

4. Financial Instruments

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

March 31, 2020	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds (cash equivalents)	$ 70,364	$ —	$ —	$ 70,364
U.S. government agency securities	28,026	120	—	28,146
Federal agency securities	5,998	20	—	6,018
Total financial assets	$ 104,388	$ 140	$ —	$ 104,528
Classified as:				
Cash and cash equivalents				$ 70,364
Short-term investments				34,164
				$ 104,528

December 31, 2019	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds (cash equivalents)	$ 15,369	$ —	$ —	$ 15,369
U.S. government agency securities	51,467	23	—	51,490
Federal agency securities	9,995	11	—	10,006
Total financial assets	$ 76,831	$ 34	$ —	$ 76,865
Classified as:				
Cash and cash equivalents				$ 15,369
Short-term investments				61,496
				$ 76,865

There have been no material realized gains or losses on available-for-sale debt securities for the periods presented. As of March 31, 2020, the remaining contractual maturities of available-for-sale debt securities was less than one year.

The carrying amounts of cash, 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, 2020 and 2019, 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, 2020	December 31, 2019
Weighted-average remaining lease term	3.08 years	3.33 years
Weighted-average discount rate	6.0%	6.0%

The maturity of the Company's operating lease liabilities as of March 31, 2020 were as follows *(in thousands)*:

Remaining in 2020	$ 435
2021	596
2022	613
2023	209
Total undiscounted lease payments	1,853
Less imputed interest	(167)
Total operating lease liability	$ 1,686

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

	Three Months Ended March 31,	
	2020	2019
Cash paid for leases that were included in operating cash outflows	$ 142	$ 138

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, 2019	1,577,541	$ 10.85	8.15
Options granted	469,750	$ 6.87	
Options exercised	(44,605)	$ 5.04	
Options forfeited	(26,116)	$ 16.04	
Options expired	(3,918)	$ 67.12	
Outstanding — March 31, 2020	1,972,652	$ 9.86	8.13
Exercisable — March 31, 2020	808,220	$ 12.50	

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 5.53 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, 2020 and 2019:

	Three Months Ended March 31,	
	2020	2019
Employee Stock Options:		
Risk-free interest rate	1.57%	2.56%
Expected term (in years)	5.53	6.03
Dividend yield	—	—
Volatility	110.00%	82.91%
Weighted-average fair value of stock options granted	$ 5.58	$ 5.80

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

	Three Months Ended March 31,	
	2020	2019
Research and development	$ 344	$ 238
General and administrative(1)	461	591
Total stock-based compensation	$ 805	$ 829

(1) Included in general and administrative stock-based compensation for the three months ended March 31, 2020 is expense related to 7,817 shares of common stock issued to certain board members in lieu of their cash compensation.

As of March 31, 2020, 276,043 shares of common stock were available for future grant and 1,972,652 options to purchase shares of common stock were outstanding. As of March 31, 2020, the Company had unrecognized employee stock-based compensation expense of $7.1 million, related to unvested stock awards, which is expected to be recognized over an estimated weighted-average period of 2.62 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, 2020.

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, 2020, 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, 2020, the Company recognized the $15.0 million in license revenue upon the transfer of the Exclusive License and the related know-how, and less than $0.1 million in license revenue for reimbursable out-of-pocket costs incurred.

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

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, 2020 and 2019 (*in thousands, except share and per share data*):

	Three Months Ended March 31,	
	2020	2019
Net loss attributable to common stockholders	$ (4,053)	$ (15,083)
Weighted-average number of shares used in computing net loss per share, basic and diluted	14,592,451	11,963,586
Net loss available for common stockholders per share, basic and diluted	$ (0.28)	$ (1.26)

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,	
	2020	2019
Options to purchase common stock	1,972,652	1,612,871
Common stock warrants	7,857	10,194
Total	1,980,509	1,623,065

9. Stockholders' Equity

In February 2020, the Company completed an underwritten public offering of 5,307,692 shares of its common stock (including 692,307 shares sold pursuant to the exercise of the underwriters' overallotment option) at a price of $6.50 per share. The net proceeds to the Company, after deducting $2.5 million in underwriting discounts and commissions and offering expenses payable by the Company, were approximately $32.0 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 $10.7 million and the payment obligations remaining at March 31, 2020 were $3.4 million.

On October 9, 2019, the Company and Catalent Indiana, LLC ("Catalent") signed a clinical supply services agreement, effective October 4, 2019, pursuant to which Catalent will conduct drug product development of agreed upon product candidates. The Company currently has firm work orders with Catalent to manufacture DalcA to support its clinical trial totaling $0.5 million and the payment obligations remaining at March 31, 2020 were $0.4 million.

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.

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, are 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. Expenses related to the collaboration were $0.7 million and $0.3 million for the three months ended March 31, 2020 and 2019, respectively. The amount incurred in 2020 is fully reimbursable under the Biogen Agreement, see Note 7.

In consideration for its co-funded research, Mosaic is entitled to a low double-digit percentage of funds the Company receives from any C3 collaboration. Mosaic is also entitled to sublicense fees and/or research and development and commercial milestones and royalties on one non-C3 complement product. 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. The Company paid Mosaic a $3.0 million sublicense fee and recorded such payment as cost of license revenue.

12. Interest and Other Income, Net

The following table shows the detail of interest and other income, net for the three months ended March 31, 2020 and 2019 (*in thousands*):

	Three Months Ended March 31,	
	2020	2019
Interest income	$ 334	$ 631
Miscellaneous income	679	—
Other	2	—
Total interest and other income, net	$ 1,015	$ 631

13. Subsequent Event

On May 8, 2020, the Company further amended and restated the Mosaic collaboration agreement to provide for a one-time payment of $750,000, plus up to $4.0 million in future milestone payments related to regulatory and clinical development events for CB 2782-PEG and an additional anti-complement product candidate, in lieu of Catalyst's obligations to pay Mosaic a double-digit percentage of funds the Company receives from Biogen or any other amounts related to sublicense fees, research and development payments, or any other commercial milestones and royalties on any other development candidates. Catalyst will own one hundred percent of all future payment streams related to these product candidates.

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

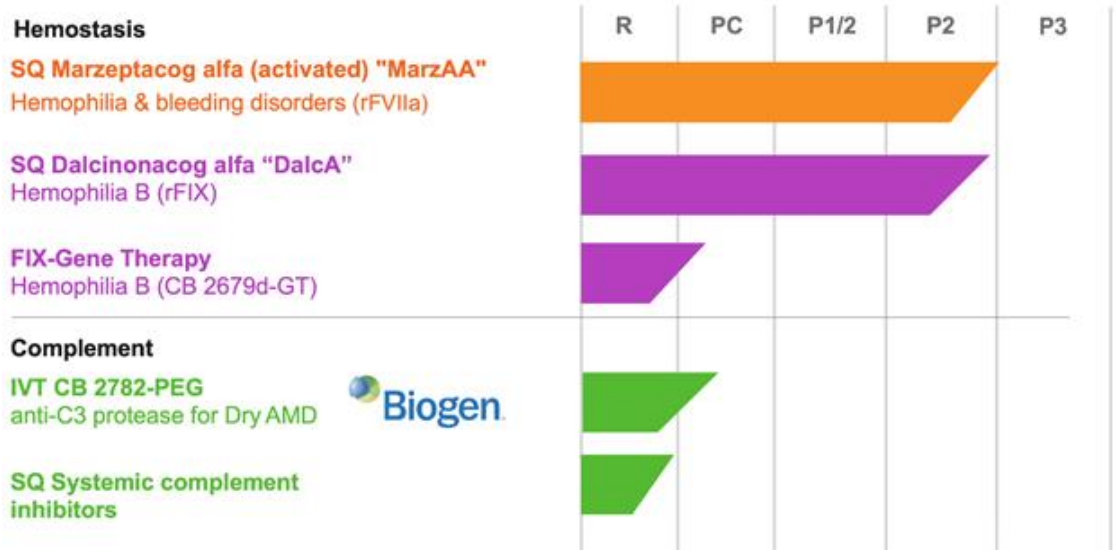
Unless otherwise indicated, in this Quarterly Report on Form 10-Q, references to "Catalyst," "we," "us," "our" or the "Company" mean Catalyst Biosciences, Inc. and our subsidiary. The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and related notes that appear in this Quarterly Report on Form 10-Q (this "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, 2019 ("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 fully integrated research and clinical development biopharmaceutical company with expertise in protease engineering, discovery, translational research, clinical development, and manufacturing. Currently, we are focused on advancing our protease product candidates in the fields of hemostasis and complement regulation. One of our key competitive advantages is that our systemically dosed product candidates can be delivered subcutaneously ("SQ") due to the improvements we have made using our protease engineering platform. SQ dosing is less invasive, more convenient and potentially more efficacious than intravenous ("IV") drugs currently on the market. Our SQ product candidates demonstrate prolonged duration of effect enabling them to provide protracted therapeutic levels. In addition, these improvements we have made to our protease drug candidates allows them to be dosed less frequently in ocular indications and at lower viral dose levels for gene therapy applications.

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 halt our development programs. See Recent Other 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

Our most advanced product candidate is MarzAA, a potent, subcutaneously administered, next-generation recombinant Factor VIIa variant. We are initiating a Phase 3 clinical trial to evaluate the safety and efficacy of MarzAA for on-demand treatment and control of episodic bleeding in subjects with Hemophilia A or Hemophilia B with inhibitors in 2020. The Phase 3 study will be an open-label global trial, evaluating the safety and efficacy of SQ MarzAA in the treatment of approximately 230 bleeding episodes in approximately 75 patients, compared with their prior standard of care in a similar number of bleeding episodes. The study will assess the effectiveness of SQ MarzAA, using up to 3 doses to treat a bleeding episode. The primary endpoint will be hemostatic efficacy using a standard 4-point assessment scale.

We completed a Phase 2 open-label SQ prophylaxis trial in 2019 that met all primary and secondary end points. The Phase 2 trial was designed to evaluate the efficacy of MarzAA in preventing bleeding episodes. The primary endpoint was to assess the effect of MarzAA on the annualized bleed rate (ABR) at a subject's final dose level, with each patient's prior 6-month ABR serving as his own control. The secondary endpoints included safety, tolerability and lack of anti-drug-antibody (ADA) as well as neutralizing antibody formation.

Our preclinical data suggest that MarzAA has the potential to be used for treatment of episodic bleeding and supports further clinical testing in individuals with hemophilia with inhibitors or for other conditions, such as Factor VII deficiency and Glanzmann thrombasthenia.

We are completing a Phase 1/2 PK/PD study to evaluate the pharmacokinetics and pharmacodynamics of ascending single dose levels of MarzAA and twice and thrice dosing of 60 µg/kg at 3-hourly intervals in individuals with Hemophilia A or B with or without inhibitors. The purpose of the trial is to determine if the timing and peak levels achieved will be sufficient to treat episodic or breakthrough bleeding with SQ dosing and determine if increasing dose levels result in dose proportional pharmacokinetics. This trial will confirm the dose we have selected for the MarzAA Phase 3 study. We reported interim data from this trial at the 13th Annual Congress of the European Association of Haemophilia and Allied Disorders (EAHAD) on February 5, 2020, which demonstrated MarzAA reaches target levels we believe are required to effectively treat episodic and breakthrough bleeds.

NovoSeven is the primary therapy used in combination with Hemlibra in Hemophilia A inhibitor patients to stop breakthrough bleeding. Our preclinical data also indicates that MarzAA can potentially have a safety profile comparable to that of NovoSeven when used in combination with Hemlibra. Specifically, as tested *in vitro* using a thrombin-generation assay with Hemophilia A plasma, both MarzAA and NovoSeven, when combined with Hemlibra, were equally effective at triggering blood coagulation at their respective clinically relevant concentrations without generation of excessive thrombin levels. The concurrent administration of FEIBA with Hemlibra has been associated with thrombotic events (when a blood clot forms inside a blood vessel), requiring a boxed warning in the package insert. While NovoSeven is safe in patients on Hemlibra prophylaxis, it must be administered through an IV infusion to treat a bleed. Ideally, an add-on therapy for patients on SQ Hemlibra would also be given subcutaneously. We believe MarzAA provides a potential solution as a SQ rescue therapy for Hemophilia A patients with inhibitors who experience breakthrough bleeds while being treated prophylactically with Hemlibra.

DalcA

Our next most advanced product candidate is DalcA, a next-generation SQ Factor IX drug for the prophylactic treatment of individuals with Hemophilia B. We have completed a Phase 2b study and, subject to potential delays from the impact of COVID-19, expect to report final data in the second quarter of 2020.

The open-label Phase 2b study was designed to evaluate the ability of DalcA to maintain steady state protective FIX levels above 12% in six individuals with severe Hemophilia B. Each subject received a single intravenous dose, followed by daily SQ doses of DalcA for 28 days. Data presented at EAHAD in February showed that daily SQ dosing of DalcA achieved effective prophylaxis with FIX activity levels ranging from 14 to 28% and zero bleeds. No neutralizing antibodies were detected and the treatment was well tolerated. The half-life of SQ DalcA ranged from 70 to 112 hours, suggesting the potential for lower or less frequent dosing.

Factor IX Gene Therapy

Our Factor IX gene therapy construct CB 2679d-GT has demonstrated 2-fold to 3-fold higher activity compared with the Padua variant of Factor IX resulting in improved clotting time in a preclinical Hemophilia B mouse model. Fidanacogene elaparvovec (Pfizer/Spark), AMT-061 (uniQure) and FLT180A (Freeline) use the Padua variant as the transgene in their AAV-based gene therapy clinical programs. Fidanacogene elaparvovec, 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 of approximately 30-45%. 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. The Company recently presented preclinical data at EAHAD in February 2020 demonstrating that a proprietary chimeric AAV capsid licensed from Stanford expressing CB 2679d-GT FIX variant may significantly reduce the vector dose required of a gene therapy treatment while maintaining high factor activity levels. We expect to report data from this construct in a nonhuman primate efficacy study in Q2 2020.

Recent Collaborations

On December 18, 2019, we entered into a license and collaboration agreement with Biogen to develop and commercialize CB 2782-PEG and our other anti-C3 proteases for the potential treatment of dry age-related macular degeneration (“AMD”) and other disorders. Under the collaboration agreement, we will perform pre-clinical and manufacturing activities, and Biogen is solely responsible for funding the pre-clinical and manufacturing activities and performing IND-enabling activities, worldwide clinical development, and commercialization. We received a $15.0 million upfront payment from Biogen in January 2020 for the grant of an exclusive license and the related know-how, and we are eligible to receive up to $340.0 million in milestone payments, along with tiered royalties for worldwide net sales of this product candidate up to low double-digits. As of March 31, 2020, we recorded the $15.0 million upfront payment in collaboration revenue. Unless earlier terminated, the agreement will remain in effect until the expiry of all royalty obligations. Biogen has the right to terminate the agreement at will, on a product-by-product basis or in its entirety at any time upon 60 days’ prior written notice. In addition, either party has the right to terminate the agreement following a material breach that remains uncured for 90 days, or in connection with an insolvency event involving the other party.

We also collaborated with Mosaic in the development of our Complement product candidates including CB 2782-PEG. Under the collaboration agreement, as amended in December 2019, Mosaic will perform all future services for a fee. Mosaic was entitled to a double-digit percentage of funds we receive from Biogen. Mosaic was also entitled to sublicense fees and/or research and development and commercial milestones and royalties on one non-C3 complement product.

On May 8, 2020, we further amended and restated the Mosaic collaboration agreement to provide for a one-time payment of $750,000, plus up to $4.0 million in future milestone payments related to regulatory and clinical development events for CB 2782-PEG and an additional anti-complement product candidate, in lieu of our obligations to pay Mosaic a double-digit percentage of funds we receive from Biogen or any other amounts we receive related to sublicense fees, research and development payments, or any other commercial milestones and royalties on any other development candidates. We will own one hundred percent of all future payment streams related to these product candidates.

Dr. Usman, our Chief Executive Officer and a member of our board of directors, and Mr. Lawlor, a member of our board of directors, are also members of the board of directors of Mosaic. Transactions with related parties, including the transaction referred above, are reviewed and approved by independent members of our Board of Directors in accordance with our Code of Business Conduct and Ethics.

Recent Manufacturing Updates

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 and DalcA. We also have long-term clinical supply services agreements with Symbiosis Pharmaceutical Services ("Symbiosis") and Catalent Indiana, LLC ("Catalent"). Symbiosis has facilities in Europe and conducts drug product manufacturing for MarzAA. Catalent has facilities in the U.S. and Europe and conducts drug product development, manufacturing and packaging for MarzAA and DalcA.

MarzAA

We have successfully manufactured MarzAA to support our global Phase 3 clinical trial to evaluate the safety and efficacy of MarzAA for on-demand treatment and control of bleeding episodes in subjects with Hemophilia A or Hemophilia B with inhibitors. At the end of 2019, we successfully completed development work for a variety of vial sizes which will support flexible dosing. As of March 31, 2020, 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.

In January 2020, we completed a successful CMC Scientific Advice meeting with the Paul Ehrlich Institute (PEI) in the EU which endorsed our current CMC activities and plans required for registration filing.

DalcA

We have completed the transfer of manufacturing technology of the drug substance for DalcA from ISU Abxis to AGC, including the associated development activities and our first large-scale GMP batch of DalcA that will support the initiation of further clinical trials. At the end of 2019, we successfully completed development work for a variety of vial sizes which will support flexible dosing in future clinical trials. As of March 31, 2020, we have successfully manufactured a large-scale drug product engineering batch for DalcA and plan to initiate a GMP large scale drug product manufacturing batch in the third quarter of 2020, subject to potential delays resulting from the impact of COVID-19.

Recent Other Developments

COVID-19 business impact

In light of recent developments relating to the COVID-19 global pandemic, we have instructed our employees to stay at home except as needed to ensure continuity of our operations. At this stage of the COVID-19 pandemic we cannot rule out future impact on our business. We have completed subject dosing and all participant activities in our DalcA Phase 2b trial and dosing of all subjects in the MarzAA Phase 1/2 PK/PD trial. As we continue to actively advance our clinical programs, we are in close contact with our principal investigators, clinical sites and contractors, including manufacturers, and are assessing the impact of COVID-19 on our current and planned trials, expected timelines and costs on an ongoing basis. We are continuing study start-up activities where possible to allow rapid site activation and enrollment of our Phase 3 MarzAA trial at the appropriate time.

Given the focus of healthcare providers and hospitals on fighting the virus, we may experience delays in the enrollment of patients in our upcoming clinical trials as well as delays in the analysis of data from our trials that have completed. We will continue to evaluate the impact of the COVID-19 pandemic on our business and will reevaluate the timing of our anticipated clinical milestones as we learn more and the impact of COVID-19 on our industry becomes clearer.

Financing

In February 2020, we sold an aggregate of 5,307,692 registered shares of common stock at $6.50 per share, for net proceeds, after deducting underwriting discounts and offering expenses of $2.5 million, of approximately $32.0 million.

We have no products approved for commercial sale and have not generated any revenue from product sales. From inception to March 31, 2020, we have raised net cash proceeds of approximately $405.0 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.

We have never been profitable and have incurred significant operating losses in each year since inception. Our net losses were $4.1 million and $15.1 million for the three months ended March 31, 2020 and 2019, respectively. As of March 31, 2020, we had an accumulated deficit of $262.6 million. As of March 31, 2020, our cash, cash equivalents and short-term investments balance were $104.5 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 Biogen Agreement. In December 2019, we entered into a license and collaboration agreement with Biogen. In consideration for the grant of an Exclusive License and related know-how, we received an up-front payment of $15.0 million in January 2020 which was recorded in license revenue during the three months ended March 31, 2020. We also incurred reimbursable out-of-pocket and personnel costs pertaining to the Biogen Agreement of approximately $1.4 million in the first quarter of 2020. 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 until we obtain regulatory approval of and commercialize our product candidates.

Cost of License and Collaboration

Cost of license and collaboration revenue consists of sublicense fees and fees for research and development services payable to Mosaic, 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, we paid Mosaic a $3.0 million sublicense fee and recorded such payment as cost of license revenue. We also incurred reimbursable out-of-pocket and personnel costs pertaining to the Biogen Agreement of approximately $1.4 million 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.

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, 2020 and 2019 (*in thousands*):

	Three Months Ended March 31,	
	2020	2019
Personnel costs	$ 2,265	$ 2,045
Preclinical research(1)	2,286	1,428
Clinical and manufacturing(1)	8,477	8,336
Facility and overhead(1)	236	218
Total research and development expenses	$ 13,264	$ 12,027

(1) Prior year numbers have been reclassified to conform with the current year presentation.

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, DalcA and our anti-complement program. 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. 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. 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.

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 $10.7 million in payments to AGC pursuant to the statements of work for MarzAA and DalcA and $3.4 million of those payments are outstanding at March 31, 2020.

On October 9, 2019, we signed a clinical supply services agreement with Catalent, effective Oct 4, 2019, pursuant to which Catalent will conduct drug product development of agreed upon product candidates. We will own, and Catalent assigns to us, the intellectual property that is specifically related to our products including the products' composition and use, and Catalent will own, and we assign to Catalent, the intellectual property that result from Catalent's performance of its services under the clinical supply agreement.

The initial term of the clinical supply agreement is three years, although the term may be extended for successive twelve-month periods, unless either party gives the other party written notice of its intent not to extend the term at least ninety (90) days prior to the expiration of the initial term or the then-current extension. Either party may terminate the clinical supply agreement in its entirety upon written notice of a material uncured breach or upon the other party's bankruptcy, and we may terminate the clinical supply agreement for its convenience upon thirty (30) days prior written notice. In addition, each party may terminate the clinical supply agreement in the event that the other party fails to perform its obligations under the agreement for reasons beyond the reasonable control of such party, such as technical or scientific reasons. If we cancel or reschedule a project plan or purchase order outside the parameters set in the clinical supply agreement, we would be obligated to pay for a portion of Catalent's costs less certain fees that Catalent is able to mitigate. We have committed to a total of $0.5 million in payments to Catalent pursuant to the statements of work for DalcA and $0.4 million of those payments are outstanding at March 31, 2020.

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 increase as we advance our programs.

Interest and Other Income, Net

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

Results of Operations

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

	Three Months Ended March 31,			
	2020	2019	Change ($)	Change (%)
License	$ 15,045	$ —	$ 15,045	100%
Collaboration	1,321	—	1,321	100%
License and collaboration revenue	16,366	—	16,366	100%
Operating expenses:				
Cost of license	3,047	—	3,047	100%
Cost of collaboration	1,432	—	1,432	100%
Research and development	13,264	12,027	1,237	10%
General and administrative	3,691	3,687	4	0%
Total operating expenses	21,434	15,714	5,720	36%
Loss from operations	(5,068)	(15,714)	10,646	(68)%
Interest and other income, net	1,015	631	384	61%
Net loss	$ (4,053)	$ (15,083)	$ 11,030	(73)%

License and Collaboration Revenue

License and collaboration revenue of $16.4 million generated in the three months ended March 31, 2020 was from our Biogen Agreement, which was entered into on December 18, 2019.

Cost of License and Collaboration

Cost of license in the three months ended March 31, 2020 was primarily the $3.0 million sublicense fee we paid to Mosaic in connection with the recognition of the license revenue from Biogen. Cost of collaboration in the three months ended March 31, 2020 was reimbursable third-party vendor and personnel costs we incurred pertaining to the Biogen Agreement.

Research and Development Expenses

Research and development expenses were $13.3 million and $12.0 million during the three months ended March 31, 2020 and 2019, respectively, an increase of $1.3 million, or 10%. The increase was due primarily to an increase of $0.9 million in preclinical spend and an increase of $0.2 million in personnel costs.

General and Administrative Expenses

General and administrative expenses were $3.7 million and $3.7 million during the three months ended March 31, 2020 and 2019, respectively, with no significant changes period over period.

Interest and Other Income, Net

Interest and other income, net was $1.0 million and $0.6 million during the three months ended March 31, 2020 and 2019, respectively. The increase was primarily due to a $0.7 million final contingent payment from a prior asset sale partially offset by a decrease in interest income of approximately $0.3 million.

Recent Accounting Pronouncements

Refer to "Recently Adopted Accounting Pronouncements" 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, 2020, we had $104.5 million of cash, cash equivalents and short-term investments. For the three months ended March 31, 2020, we had a $4.1 million net loss and $4.8 million cash used in operating activities. We have an accumulated deficit of $262.6 million as of March 31, 2020. 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 $200.0 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.

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

	Three Months Ended March 31,	
	2020	2019
Cash used in operating activities	$ (4,790)	$ (14,958)
Cash provided by investing activities	27,421	8,663
Cash provided by financing activities	32,364	106
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 54,995	$ (6,189)

Cash Flows from Operating Activities

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 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 Flows from Investing Activities

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 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 Flows from Financing Activities

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.

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.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Critical Accounting Polices and Estimates

There have been no significant changes to our critical accounting policies since December 31, 2019. For a description of critical accounting policies that affect our significant judgments and estimates used in the preparation of our unaudited condensed 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.

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, 2020, we had cash and cash equivalents and short-term investments of $104.5 million, which included bank deposits and money market funds and short-term investments of $34.2 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 (also Principal Financial Officer), evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2020. 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, 2020, our Chief Executive Officer (also Principal 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 quarter ended March 31, 2020 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. The disclosure below modifies the risk factors previously disclosed in *"Part I - Item 1A - Risk Factors"* of our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the Securities and Exchange Commission on February 20, 2020.

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 included in our Annual Report on Form 10-K for the year ended December 31, 2019 have expanded to include the following additional risk factor:

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

The global coronavirus pandemic has resulted in widespread requirements for individuals to stay in their homes and strained medical facilities worldwide. It is too early to assess the full impact of the coronavirus outbreak on our business, including our trials for MarzAA and DalcA and our development activities in our anti-complement program but coronavirus may affect our ability to complete recruitment and data analysis for our clinical trials and our ability to conduct research and development of our complement programs- in our planned timeframe. The extent to which the coronavirus impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration and severity of the outbreak, and the actions that may be required to contain the coronavirus or treat its impact. In particular, as a result of the COVID-19 pandemic, we may experience disruptions that could severely impact our business, preclinical studies, drug manufacturing and clinical trials including:

- delays or difficulties in enrolling patients 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;
- 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 Food and Drug Administration, European Medicines Agency 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;
- 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. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms.

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

On May 8, 2020, the Company amended and restated its research collaboration with Mosaic Biosciences, Inc. ("Mosaic") to develop intravitreal anti-complement factor C3 products for the treatment of dry AMD and other retinal diseases, as amended. Pursuant to the amended and restated agreement, Catalyst may engage Mosaic for future work on a fee-for-service basis. Catalyst also agreed to a one-time payment of $750,000, plus up to $4.0 million in future milestone payments related to regulatory and clinical development events for CB 2782-PEG and an additional product candidate, in lieu of Catalyst's prior obligations to pay Mosaic a double-digit percentage of funds Catalyst receives from Biogen or any other amounts Catalyst receives related to sublicense fees, research and development payments, or any other commercial milestones and royalties on any other development candidates. Catalyst will own one hundred percent of all future payment streams related to these product candidates.

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	Certification of the Principal Executive and 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.
32.1	Certification of the Principal Executive and Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, formatted in XBRL (eXtensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets as of March 31, 2020 (unaudited) and December 31, 2019; (ii) the Condensed Consolidated Statements of Operations for the three months ended March 31, 2020 and 2019 (unaudited); (iii) the Condensed Consolidated Statements of Comprehensive Income for the three months ended March 31, 2020 and 2019 (unaudited); (iv) the Condensed Consolidated Statement of Stockholders' Equity as of March 31, 2020 and March 31, 2019 (unaudited); (v) the Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2020 and 2019 (unaudited); and (vi) 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 11, 2020

/s/ Nassim Usman, Ph.D.

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

Exhibit 31.1

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, 2020;

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 11, 2020

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

Exhibit 32.1

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, 2020 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 11, 2020

/s/ Nassim Usman, Ph.D.

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