# 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 June 30, 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** | **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)**

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 July 26, 2019, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 12,015,921.

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 |

**CATALYST BIOSCIENCES, INC.**
**TABLE OF CONTENTS**

**PART I. FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

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

| | June 30, 2019 (Unaudited) | December 31, 2018 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 17,348 | $ 31,213 |
| Short-term investments | 76,587 | 88,914 |
| Restricted cash | 50 | 50 |
| Prepaid and other current assets | 4,072 | 3,814 |
| Total current assets | 98,057 | 123,991 |
| Other assets, noncurrent | 257 | 543 |
| Right-of-use assets | 2,188 | — |
| Property and equipment, net | 371 | 386 |
| **Total assets** | $ 100,873 | $ 124,920 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 393 | $ 1,248 |
| Accrued compensation | 1,410 | 1,495 |
| Other accrued liabilities | 3,932 | 2,043 |
| Deferred rent, current portion | — | 15 |
| Operating lease liability | 461 | — |
| Total current liabilities | 6,196 | 4,801 |
| Operating lease liability, noncurrent | 1,566 | — |
| Deferred rent, noncurrent portion | — | 174 |
| Total liabilities | 7,762 | 4,975 |
| 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; 12,008,528 and 11,954,528 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively | 12 | 12 |
| Additional paid-in capital | 325,246 | 323,279 |
| Accumulated other comprehensive income (loss) | 57 | (4) |
| Accumulated deficit | (232,204) | (203,342) |
| Total stockholders' equity | 93,111 | 119,945 |
| **Total liabilities and stockholders' equity** | $ 100,873 | $ 124,920 |

*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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Contract revenue | $ — | $ — | $ — | $ 6 |
| Operating expenses: | | | | |
| Research and development | 11,111 | 3,889 | 23,138 | 7,660 |
| General and administrative | 3,270 | 3,225 | 6,956 | 6,139 |
| Total operating expenses | 14,381 | 7,114 | 30,094 | 13,799 |
| Loss from operations | (14,381) | (7,114) | (30,094) | (13,793) |
| Interest and other income, net | 601 | 632 | 1,232 | 2,269 |
| Net loss | $ (13,780) | $ (6,482) | (28,862) | (11,524) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (1.15) | $ (0.54) | $ (2.41) | $ (1.10) |
| Shares used to compute net loss per share attributable to common stockholders, basic and diluted | 11,989,866 | 11,938,401 | 11,976,799 | 10,472,180 |

*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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Net loss | $ (13,780) | $ (6,482) | $ (28,862) | $ (11,524) |
| Other comprehensive income (loss): | | | | |
| Unrealized gain on available-for-sale securities | 44 | 8 | 61 | 4 |
| Total comprehensive loss | $ (13,736) | $ (6,474) | $ (28,801) | $ (11,520) |

*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 | Accumulated Other Comprehensive | Accumulated | Total Stockholders' Equity |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Capital | Income (Loss) | Deficit | (Deficit) |
| 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 | — | — | — | — | — | — | (15,082) | (15,082) |
| Balance at March 31, 2019 | — | — | 11,974,104 | 12 | 324,214 | 13 | (218,424) | 105,815 |
| Stock-based compensation expense | — | — | 5,999 | — | 903 | — | — | 903 |
| Issuance of common stock from option exercises | — | — | 28,425 | — | 129 | — | — | 129 |
| Unrealized gain on available-for-sale securities | — | — | — | — | — | 44 | — | 44 |
| Net loss | — | — | — | — | — | — | (13,780) | (13,780) |
| Balance at June 30, 2019 | — | $ — | 12,008,528 | $ 12 | $325,246 | $ 57 | $ (232,204) | $ 93,111 |

| | Convertible Preferred Stock | | Common Stock | | Additional Paid-In | Accumulated Other Comprehensive | Accumulated | Total Stockholders' Equity |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Capital | Income (Loss) | Deficit | (Deficit) |
| 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 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 |
| Stock-based compensation expense | — | — | — | — | 550 | — | — | 550 |
| Issuance of common stock from option exercises | — | — | 7,648 | — | 36 | — | — | 36 |
| Unrealized gain on available-for-sale securities | — | — | — | — | — | 8 | — | 8 |
| Net loss | — | — | — | — | — | — | (6,482) | (6,482) |
| Balance at June 30, 2018 | — | $ — | 11,942,729 | $ 12 | $321,758 | $ 4 | $ (184,811) | $ 136,963 |

*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)

| | Six Months Ended June 30, | |
|---|---|---|
| | 2019 | 2018 |
| **Operating Activities** | | |
| Net loss | $ (28,862) | $ (11,524) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation expense | 1,732 | 1,156 |
| Depreciation and amortization | 79 | 70 |
| Loss on disposal of property and equipment | — | 116 |
| Changes in operating assets and liabilities: | | |
| Prepaid and other current assets | (361) | (1,469) |
| Accounts payable | (855) | (613) |
| Accrued compensation and other accrued liabilities | 1,803 | (393) |
| Operating lease liability and right-of-use assets | 40 | — |
| Deferred rent | — | 143 |
| Deferred revenue | — | (6) |
| Net cash flows used in operating activities | (26,424) | (12,520) |
| | | |
| **Investing Activities** | | |
| Proceeds from maturities of short-term investments | 89,005 | 30,693 |
| Purchase of short-term investments | (76,617) | (102,330) |
| Purchases of property and equipment | (64) | (201) |
| Net cash flows provided by (used in) investing activities | 12,324 | (71,838) |
| | | |
| **Financing Activities** | | |
| Payments for the redemption of redeemable convertible notes | — | (5,082) |
| Issuance of common stock for secondary public offering, net of issuance costs | — | 106,762 |
| Issuance of common stock from stock grants and option exercises | 235 | 36 |
| Proceeds from exercise of warrants | — | 9,545 |
| Net cash flow provided by financing activities | 235 | 111,261 |
| Net (decrease) increase in cash, cash equivalents and restricted cash | (13,865) | 26,903 |
| 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)] | $ 17,398 | $ 46,708 |
| | | |
| **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 | $ 61 | $ 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, cash equivalents and restricted cash to amounts reported within the condensed consolidated balance sheets:

| | | |
|---|---|---|
| Cash and cash equivalents | $ 17,348 | $ 46,533 |
| Restricted cash | 50 | 175 |
| Total cash and restricted cash | $ 17,398 | $ 46,708 |

*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 its engineered subcutaneous (SC) coagulation factors that promote blood clotting. The Company is located in South San Francisco, California and it operates in one segment.

The Company had a net loss of $28.9 million for the six months ended June 30, 2019 and an accumulated deficit of $232.2 million as of June 30, 2019 and expects to continue to incur losses for the next several years. As of June 30, 2019, the Company had $94.0 million of cash, cash equivalents and short-term investments. Its primary uses of cash are to fund operating expenses, including research and development expenditures and general and administrative expenditures. Based on the current status of its research and development plans, the Company believes that its existing cash, cash equivalents and short-term investments as of June 30, 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 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. There have been no other significant changes to these accounting policies during the first six 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.

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 six months ended June 30, 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 June 30, 2019 and December 31, 2018 (*in thousands*):

| | June 30, 2019 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Financial assets: | | | | |
| Money market funds(1) | $ 16,858 | $ — | $ — | $ 16,858 |
| U.S. government agency securities(2) | 57,904 | | — | 57,904 |
| Federal agency securities(2) | — | 18,683 | — | 18,683 |
| Restricted cash (money market funds) | 50 | — | — | 50 |
| Total financial assets | $ 74,812 | $ 18,683 | $ — | $ 93,495 |

(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*):

| June 30, 2019 | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
|---|---|---|---|---|
| Money market funds (cash equivalents) | $ 16,858 | $ — | $ — | $ 16,858 |
| U.S. government agency securities | 57,870 | 34 | — | 57,904 |
| Federal agency securities | 18,660 | 23 | — | 18,683 |
| Restricted cash (money market funds) | 50 | — | — | 50 |
| Total financial assets | $ 93,438 | $ 57 | $ — | $ 93,495 |
| Classified as: | | | | |
| Cash and cash equivalents | | | | $ 16,858 |
| Short-term investments | | | | 76,587 |
| Restricted cash (money market funds) | | | | 50 |
| | | | | $ 93,495 |

| 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. As of June 30, 2019, the remaining contractual maturities of available-for-sale debt securities was less than one year.

The carrying amounts of cash, accounts payable, and other payables 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 liability but are reflected as an expense in the period incurred.

For the six months ended June 30, 2019, the Company's operating lease expense was $0.3 million. The present value assumptions used in calculating the present value of the lease payments were as follows:

| | |
|---|---|
| Weighted-average remaining lease term | 3.8 years |
| Weighted-average discount rate | 6.0% |

Future lease payments under non-cancelable leases as of June 30, 2019 were as follows:

| | |
|---|---|
| Remaining in 2019 | $ 282 |
| 2020 | 578 |
| 2021 | 596 |
| 2022 | 613 |
| 2023 | 209 |
| Total future minimum lease payments | 2,278 |
| Less imputed interest | (251) |
| Total lease liability | $ 2,027 |

## 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 | 395,300 | $ 8.10 | |
| Options exercised | (41,219) | $ 4.57 | |
| Options forfeited | (60,290) | $ 8.14 | |
| Options expired | (7,474) | $ 74.90 | |
| Outstanding — June 30, 2019 | 1,648,294 | $ 11.14 | 8.60 |
| Exercisable — June 30, 2019 | 547,822 | $ 15.74 | 7.95 |
| Vested and expected to vest — June 30, 2019 | 1,648,294 | $ 11.14 | 8.60 |

**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 5.98 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 six months ended June 30, 2019 and 2018:

| | Six Months Ended June 30, | |
|---|---|---|
| | 2019 | 2018 |
| Employee Stock Options: | | |
| Risk-free interest rate | 2.44% | 2.48% |
| Expected term (in years) | 5.98 | 5.93 |
| Dividend yield | — | — |
| Volatility | 88.21% | 104.37% |
| Weighted-average fair value of stock options granted | $ 5.96 | $ 13.38 |

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Research and development | $ 284 | $ 137 | $ 522 | $ 252 |
| General and administrative(1) | 619 | 414 | 1,210 | 904 |
| Total stock-based compensation | $ 903 | $ 551 | $ 1,732 | $ 1,156 |

(1) Included $0.03 and $0.1 million in modifications related to certain Board member stock options in the three and six months ended June 30, 2019 and for the six months ended June 30, 2018, respectively.

Also included in total stock-based compensation for the three and six months ended June 30, 2019 is expense related to 5,999 shares of common stock issued to certain board members in lieu of their cash compensation.

As of June 30, 2019, 961,609 shares of common stock were available for future grant and 1,648,294 options to purchase shares of common stock were outstanding. As of June 30, 2019, 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 2.78 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 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 six months 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 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 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 six months ended June 30, 2019 and 2018 (*in thousands, except share and per share data*):

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Net loss attributable to common stockholders | $ (13,780) | $ (6,482) | $ (28,862) | $ (11,524) |
| Weighted-average number of shares used in computing net loss per share, basic and diluted | 11,989,866 | 11,938,401 | 11,976,799 | 10,472,180 |
| Net loss available for common stockholders per share, basic and diluted | $ (1.15) | $ (0.54) | $ (2.41) | $ (1.10) |

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:

| | Six Months Ended June 30, | |
|---|---|---|
| | 2019 | 2018 |
| Options to purchase common stock | 1,648,294 | 1,071,899 |
| Common stock warrants | 7,857 | 12,039 |
| Redeemable convertible notes | — | — |
| Total | 1,656,151 | 1,083,938 |

## 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 $12.4 million and the payment obligations remaining at June 30, 2019 was $5.4 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, the Company's Chief Executive Officer and a member of the Company's board of directors, and Mr. Lawlor, the chairman of the Company's 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 the Company's board of directors and approved by the Company's audit committee. Expenses related to the collaboration were $0.3 and $0.3 million for the three months ended June 30, 2019 and 2018, respectively. Expenses related to the collaboration were $0.7 and $0.5 million for the six months ended June 30, 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-and six-months ended June 30, 2019 and 2018 (*in thousands*):

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Interest income | $ 601 | $ 602 | $ 1,262 | $ 887 |
| Loss on disposal of fixed assets | — | — | — | (116) |
| Other income/(expense), net | — | 30 | (30) | 1,498 |
| Total other income/(expense), net | $ 601 | $ 632 | $ 1,232 | $ 2,269 |

Other income of $1.5 million for the six months ended June 30, 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, 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 (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, 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 (SC) 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 SC dosing.

Hemophilia is a rare and 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 clot blood. 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 patients with an estimated 400,000 patients worldwide. Currently there is no cure for hemophilia. Patients with hemophilia suffer from spontaneous and traumatic bleeding episodes and substantially prolonged bleeding times that can become limb- or life-threatening. 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 have insufficient functional coagulation factor in their blood. Current treatment involves management of acute bleeding episodes or prophylactic treatment through factor replacement or bypass therapy. Replacement therapy comprises IV infusion of the missing Factor VIII or IX. Intravenous infusion is invasive, 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 are anti-drug-antibodies that 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 bypass agents. Currently, two types of bypass treatment exist: recombinant activated coagulation factor VII (NovoSeven RT) and activated prothrombin complex concentrates (e.g., FEIBA). More recently, a bispecific antibody mimicking FVIIIa activity (Hemlibra®) has been approved for prophylaxis in hemophilia A patients with or without inhibitors. Both NovoSeven and FEIBA are administered IV while Hemlibra is administered SC.

We are currently focused on the clinical development of our subcutaneously dosed, next-generation Factor VIIa (marzeptacog alfa (activated) – MarzAA) for hemophilia A and B inhibitor patients and Factor IX (dalcinonacog alfa – DalcA) for hemophilia B patients. Our 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 MarzAA and DalcA allows for SC dosing using a small volume, which we believe will provide for more effective and convenient treatments of spontaneous bleeds and prophylactic protection, especially for children. In addition to our current development focus areas, we believe MarzAA has the potential to treat bleeds in several disease settings and manage severe Factor VII deficiency and Glanzmann thrombasthenia.

We currently control worldwide development, manufacturing and commercialization rights of our product candidates. DalcA commercialization rights in South 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 a Phase 2 open-label SC efficacy and safety trial and met all our primary and secondary end points. The Phase 2 trial in patients with hemophilia A or B with inhibitors was designed to evaluate the efficacy of MarzAA in reducing total bleeding episodes. The primary endpoint was to assess the effect of MarzAA on annualized bleed rate (ABR) at a subject's final dose level, with each patient's historic annualized bleeding rate serving as his own control. The secondary endpoints included safety, tolerability and lack of anti-drug-antibody (ADA) and neutralizing antibody (nAb) formation.

We reported at the International Society for Thrombosis & Hemostasis 2019 Congress on July 8, 2019 that daily SC administration of MarzAA for 50 days significantly reduced the subject group's 6-month pre-study mean ABR from 19.8 to 1.6 at the subjects' final individual dose levels ($p<0.01$). Additionally, the Proportion of Days with Bleeding (PDB) was significantly reduced from the subject group's 6-month pre-treatment mean of 12.3% to 0.8% at the subjects' final individual dose levels ($p<0.01$). The median ABR and PDB were both reduced to zero during treatment, with seven of nine subjects experiencing no bleeds, either traumatic or spontaneous, at their final individual dose levels. Only 2 subjects required dose escalation from 30 mg/kg/day to 60 mg/kg/day per protocol. Subcutaneous treatment with MarzAA was safe and well-tolerated. Six mild to moderate localized skin reactions were observed in 2 subjects. No ADAs nor nAbs to MarzAA were detected after administration of a total of 517 SC doses. SC dosing prolonged the half-life of MarzAA to 16.6 hours so that trough levels of MarzAA before the next SC dose were sufficient to provide bleed prevention.

We plan to initiate a Phase 3 registration study of MarzAA in 2020. We have initiated a SC Phase 1 study to evaluate the pharmacokinetics and pharmacodynamics in patients with hemophilia A or B with or without inhibitors to determine if the timing of the peak levels achieved are sufficient to treat a breakthrough bleed with subcutaneous dosing and expect to report data in 2020. We previously completed an IV Phase 1 clinical trial evaluating the pharmacokinetics, pharmacodynamics and coagulation activity of MarzAA in patients with severe hemophilia A and B with and without an inhibitor. In this study we demonstrated that single IV doses ranging from 0.5 mg/kg/day to 30 mg/kg/day were safe and well tolerated in patients with severe hemophilia A and B. Pharmacokinetic and pharmacodynamic results showed a dose dependent increase in antigen and activity with good correction of coagulation parameters and normalization at the higher dose levels.

In the second quarter of 2019, we received agreement from the FDA that we have demonstrated comparability of the clinical drug substance and drug product between our previously manufactured batches and those recently manufactured at AGC.

***DalcA***

We have completed a Phase 1/2 subcutaneous dosing trial that evaluated the safety and efficacy of DalcA in patients 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 risk of spontaneous joint bleeds) with daily SC injections. Data from the study demonstrated that DalcA maintained protective Factor IX activity levels of 12 – 30%. Two subjects in the Phase 1/2 SC 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. Thus, the nAbs to DalcA 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 SC dosing in six subjects, and we expect to report the topline data in the fourth quarter of 2019 and final data in 2020.

***Pipeline Assets***

We have three additional drug candidates: a Factor IX gene therapy construct CB 2679d-GT; a novel anti-C3 protease CB 2782-PEG for the treatment of dry age-related macular degeneration (dry AMD); and a Factor Xa pro-coagulant molecule, CB 1965a.

*Factor IX Gene Therapy*

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 for gene therapy by others. Pfizer/Spark (fidanacogene elaparvovec) and uniQure (AMT-061) use the Padua variant as the transgene in their AAV based gene therapy clinical programs. Both programs 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%. CB 2679d-GT's potential for higher activity levels and lower vector dose could improve efficacy, safety and lower manufacturing cost. 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.

*Complement Factor 3*

Geographic atrophy is an advanced stage of Dry AMD that results in the irreversible loss of retina and leads to blindness. Dry AMD affects approximately a million people in the United States and approximately over five million people worldwide. The global market is estimated at $5 billion with no approved drugs. Complement factor 3 (C3) is the central regulator of the complement cascade and C3 is the only clinically validated target for geographic atrophy in age-related macular degeneration. We have created a modified version of our anti-C3 protease CB 2782 through site-specific PEGylation, CB 2782-PEG, that is designed to have an extended half-life. 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 and 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 vitreous 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 a projected human intravitreal administration frequency of three to four times a year. We are developing CB 2782-PEG in collaboration with Mosaic Biosciences.

*Factor Xa*

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 June 30, 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 $13.8 million and $6.5 million for the three months ended June 30, 2019 and 2018, respectively, and $28.9 million and $11.5 million for the six months ended June 30, 2019 and 2018, respectively. As of June 30, 2019, we had an accumulated deficit of $232.2 million. As of June 30, 2019, our cash, cash equivalents and short-term investments balance was $94.0 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 six months of 2019 and do not expect to generate revenue in the remainder of 2019. Revenue generated in 2018 was from our collaboration with ISU Abxis, continuing collaboration revenues have ceased as a result of 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 and six months ended June 30, 2019 and 2018 (*in thousands*):

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Personnel costs | $ 1,791 | $ 1,074 | $ 3,836 | $ 1,787 |
| Preclinical research(1) | 1,809 | 679 | 3,237 | 2,104 |
| Clinical and manufacturing(1) | 7,288 | 2,080 | 15,624 | 3,568 |
| Facility and overhead(1) | 223 | 56 | 441 | 201 |
| Total research and development expenses | $ 11,111 | $ 3,889 | $ 23,138 | $ 7,660 |

(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 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 $12.4 million in payments to AGC pursuant to the statements of work for MarzAA and DalcA and $5.4 million of those payments are outstanding at June 30, 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 June 30, | | | |
|---|---|---|---|---|
| | 2019 | 2018 | Change ($) | Change (%) |
| Contract revenue | $ — | $ — | $ — | — |
| Operating expenses: | | | | |
| Research and development | 11,111 | 3,889 | 7,222 | 186% |
| General and administrative | 3,270 | 3,225 | 45 | 1% |
| Total operating expenses | 14,381 | 7,114 | 7,267 | 102% |
| Loss from operations | (14,381) | (7,114) | (7,267) | 102% |
| Interest and other income | 601 | 632 | (31) | (5)% |
| Net loss | $ (13,780) | $ (6,482) | $ (7,298) | 113% |

| | Six Months Ended June 30, | | | |
|---|---|---|---|---|
| | 2019 | 2018 | Change ($) | Change (%) |
| Contract revenue | $ — | $ 6 | $ (6) | (100)% |
| Operating expenses: | | | | |
| Research and development | 23,138 | 7,660 | 15,478 | 202% |
| General and administrative | 6,956 | 6,139 | 817 | 13% |
| Total operating expenses | 30,094 | 13,799 | 16,295 | 118% |
| Loss from operations | (30,094) | (13,793) | (16,301) | 118% |
| Interest and other income | 1,232 | 2,269 | (1,037) | (46)% |
| Net loss | $ (28,862) | $ (11,524) | $ (17,338) | 150% |

***Contract Revenue***

Contract revenue was $0 million during the three and six months ended June 30, 2019. Revenue of $0.01 million generated in the six months ended June 30, 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 $11.1 million and $3.9 million during the three months ended June 30, 2019 and 2018, respectively, an increase of $7.2 million, or 186%. The increase was due primarily to an increase of $5.2 million in clinical and manufacturing development as we continued to advance the development of the MarzAA and DalcA product candidates, an increase of $1.1 million in preclinical research inclusive of projects supportive of the product candidates, and an increase of 0.7 million in personnel-related costs.

Research and development expenses were $23.1 million and $7.7 million during the six months ended June 30, 2019 and 2018, respectively, an increase of $15.5 million, or 202%. The increase was due primarily to an increase of $12.1 million in clinical and manufacturing development as we continued to advance the development of the MarzAA and DalcA product candidates, an increase of $2.0 million in personnel-related costs and an increase of $1.1 million in preclinical research inclusive of projects supportive of the product candidates.

***General and Administrative Expenses***

General and administrative expenses were $3.3 million and $3.2 million during the three months ended June 30, 2019 and 2018, respectively, an increase of $0.1 million, or 1%.

General and administrative expenses were $6.9 million and $6.1 million during the six months ended June 30, 2019 and 2018, respectively, an increase of $0.8 million, or 13%. The increase was due primarily to personnel-related costs.

***Interest and Other Income***

Interest and other income was $0.6 million and $0.6 million during the three months ended June 30, 2019 and 2018, respectively.

Interest and other income was $1.2 million and $2.2 million during the six months ended June 30, 2019 and 2018, respectively, a decrease of $1.0 million, or 46%. 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 $0.4 million due to higher average cash equivalent and short-term investments balance in first six months of 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 statement of cash flows. The adoption of the new lease accounting standard did not impact previously reported financial results.

**Liquidity and Capital Resources**

As of June 30, 2019, we had $94.0 million of cash, cash equivalents and short-term investments. For the six months ended June 30, 2019, we had a $28.9 million net loss and $26.5 million cash used in operating activities. We have an accumulated deficit of $232.2 million as of June 30, 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*):

| | Six Months Ended June 30, | |
|---|---|---|
| | 2019 | 2018 |
| Cash used in operating activities | $ (26,424) | $ (12,520) |
| Cash provided by (used in) investing activities | 12,324 | (71,838) |
| Cash provided by financing activities | 235 | 111,261 |
| Net (decrease) increase in cash, cash equivalents and restricted cash | $ (13,865) | $ 26,903 |

***Cash Flows from Operating Activities***

Cash used in operating activities for the six months ended June 30, 2019 was $26.4 million, due primarily to a net loss of $28.9 million, and the change in our net operating assets and liabilities of $0.6 million, due primarily to a $1.8 million increase in accrued compensation and vendor payments, offset by a $1.2 million decrease in accounts payable and increase in prepaid and other current assets. Non-cash charges of $1.7 million were recorded for stock-based compensation.

Cash used in operating activities for the six months ended June 30, 2018 was $12.5 million, due primarily to a net loss of $11.5 million, the change in our net operating assets and liabilities of $2.3 million due primarily to a $1.5 million increase in prepaid expenses, $0.6 million decrease in accounts payable and $0.4 million decrease in accrued compensation and other accrued liabilities, partially offset by a $0.2 million increase in deferred rent. Non-cash charges of $1.2 million were recorded for stock-based compensation, and a $0.1 million for loss on the disposal of assets.

***Cash Flows from Investing Activities***

Cash provided by investing activities for the six months ended June 30, 2019 was $12.3 million, due primarily to $89.0 million in proceeds from maturities of investments, offset by $76.7 million in purchases of investments.

Cash used in investing activities for the six months ended June 30, 2018 was $71.8 million, due primarily to $102.3 million in purchases of investments and $0.2 million in purchases of property and equipment, offset by $30.7 million in proceeds from maturities of investments.

***Cash Flows from Financing Activities***

Cash provided by financing activities for the six months ended June 30, 2019 was $0.2 million, due primarily to proceeds from issuance of common stock related to stock option exercises.

Cash provided by financing activities for the six months ended June 30, 2018 was $111.3 million, due primarily to $106.8 million in net proceeds from the issuance of common stock related to our underwritten public offering in February 2018, $9.5 million in proceeds from the exercise of common stock warrants and $0.1 million in proceeds from the exercise of stock options, partially offset by payments of $5.1 million related to the maturity and redemption of the remaining redeemable convertible notes.

**Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements.

**Critical Accounting Polices 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 six months of 2019.

See Recent Accounting Pronouncements above for effects of adoption on our condensed consolidated statement of operations for the six months ended June 30, 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 June 30, 2019, we had cash and cash equivalents and short-term investments of $94.0 million, which included bank deposits and money market funds and short-term investments of $76.6 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 June 30, 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 June 30, 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 six 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 | 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. |
| 31.2 | 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. |
| 32.1 | 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. |
| 32.2 | 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. |
| 101 | The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, formatted in XBRL (eXtensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets as of June 30, 2019 (unaudited) and December 31, 2018; (ii) the Condensed Consolidated Statements of Comprehensive Income for the three and six months ended June 30, 2019 and 2018 (unaudited); (iii) the Condensed Consolidated Statement of Stockholders' Equity as of June 30, 2019 (unaudited); (iv) the Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 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: August 1, 2019

/s/ Nassim Usman, Ph.D.

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

Date: August 1, 2019

/s/ Fletcher Payne

Fletcher Payne
Chief Financial Officer
(*Principal Financial and Accounting 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.;

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: August 1, 2019

/s/ Nassim Usman, Ph.D.
Nassim Usman, Ph.D.

**Exhibit 31.2**

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: August 1, 2019

/s/ Fletcher Payne
Fletcher Payne

**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 period ended June 30, 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: August 1, 2019

/s/ Nassim Usman, Ph.D.

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

**Exhibit 32.2**

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 June 30, 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: August 1, 2019

/s/

Fletcher Payne
Chief Financial Officer
(*Principal Financial and Accounting Officer)*