

**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 September 30, 2016

OR

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

For the transition period from _____ to _____

Commission file number: 000-51173

Catalyst Biosciences, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

260 Littlefield Ave.
South San Francisco, California
(Address of Principal Executive Offices)

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

94080
(Zip Code)

(650) 266-8674

(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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post 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. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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 October 31, 2016, the number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 12,026,297.

CATALYST BIOSCIENCES, INC.
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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	<u>September 30, 2016</u> (Unaudited)	<u>December 31,</u> <u>2015</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 9,317	\$ 29,096
Short-term investments	10,208	3,402
Restricted cash	29,719	33,794
Deposits	5	133
Accounts receivable	101	492
Prepaid and other current assets	1,425	1,781
Total current assets	<u>50,775</u>	<u>68,698</u>
Restricted cash, noncurrent	125	125
Property and equipment, net	716	698
Total assets	<u>\$ 51,616</u>	<u>\$ 69,521</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 529	\$ 939
Accrued compensation	682	926
Other accrued liabilities	652	535
Deferred revenue, current portion	401	438
Deferred rent, current portion	35	19
Redeemable convertible notes	29,667	33,743
Derivative liability	28	1,156
Total current liabilities	<u>31,994</u>	<u>37,756</u>
Deferred revenue, noncurrent portion	—	292
Deferred rent, noncurrent portion	18	48
Total liabilities	<u>32,012</u>	<u>38,096</u>
Stockholders' equity:		
Preferred stock, \$0.001 par value, 5,000,000 shares and 0 shares authorized and outstanding at September 30, 2016 and December 31, 2015	—	—
Common stock, \$0.001 par value, 100,000,000 shares authorized at September 30, 2016 and December 31, 2015; 11,935,981 and 11,430,085 shares issued and outstanding at September 30, 2016 and December 31, 2015	12	11
Additional paid-in capital	163,820	162,450
Accumulated other comprehensive income	4	1
Accumulated deficit	(144,232)	(131,037)
Total stockholders' equity	<u>19,604</u>	<u>31,425</u>
Total liabilities and stockholders' equity	<u>\$ 51,616</u>	<u>\$ 69,521</u>

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

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	2016	2015	2016	2015
Contract revenue	\$ 109	\$ 109	\$ 328	\$ 1,641
Operating expenses:				
Research and development	3,396	1,486	8,443	4,192
General and administrative	2,425	2,508	7,083	6,567
Total operating expenses	<u>5,821</u>	<u>3,994</u>	<u>15,526</u>	<u>10,759</u>
Loss from operations	(5,712)	(3,885)	(15,198)	(9,118)
Interest and other income, net	941	273	2,003	964
Interest Expense	—	(1,439)	—	(1,478)
Net loss	<u>\$ (4,771)</u>	<u>\$ (5,051)</u>	<u>\$ (13,195)</u>	<u>\$ (9,632)</u>
Net loss per common share, basic and diluted	<u>\$ (0.40)</u>	<u>\$ (0.93)</u>	<u>\$ (1.14)</u>	<u>\$ (4.65)</u>
Shares used to compute net loss per common share, basic and diluted	<u>11,846,947</u>	<u>5,410,864</u>	<u>11,575,701</u>	<u>2,071,161</u>

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

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	2016	2015	2016	2015
Net loss	\$ (4,771)	\$ (5,051)	\$ (13,195)	\$ (9,632)
Other comprehensive income (loss):				
Unrealized gain on available-for-sale securities	3	16	3	16
Total comprehensive loss	<u>\$ (4,768)</u>	<u>\$ (5,035)</u>	<u>\$ (13,192)</u>	<u>\$ (9,616)</u>

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance at December 31, 2015	11,430,085	\$ 11	\$ 162,450	\$ 1	\$ (131,037)	\$ 31,425
Stock-based compensation expense	—	—	505	—	—	505
Issuance of common stock, net of issuance costs	505,826	—	865	—	—	865
Conversion of redeemable convertible notes to common stock	70	1	—	—	—	1
Unrealized gain on available-for-sale securities	—	—	—	3	—	3
Net loss	—	—	—	—	(13,195)	(13,195)
Balance at September 30, 2016	<u>11,935,981</u>	<u>\$ 12</u>	<u>\$ 163,820</u>	<u>\$ 4</u>	<u>\$ (144,232)</u>	<u>\$ 19,604</u>

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)

	Nine Months Ended September 30,	
	2016	2015
Operating Activities		
Net loss	\$ (13,195)	\$ (9,632)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	505	135
Depreciation and amortization	328	365
Non-cash interest expense	—	1,478
Loss on disposal of fixed assets	—	11
Gain on extinguishment of redeemable convertible notes	(92)	(39)
Change in fair value of warrant liability	—	(91)
Change in fair value of derivative liability	(1,036)	(740)
Changes in operating assets and liabilities:		
Accounts receivable	391	(235)
Prepaid and other current assets	484	(56)
Accounts payable	(410)	(4,543)
Accrued compensation and other accrued liabilities	(127)	1,029
Deferred rent	(14)	(18)
Deferred revenue	(329)	(1,640)
Net cash flows used in operating activities	<u>(13,495)</u>	<u>(13,976)</u>
Investing Activities		
Proceeds from the reverse merger	—	23,931
Proceeds from maturities of investments	6,601	2,750
Purchase of investments	(13,404)	—
Change in restricted cash	—	(125)
Purchases of property and equipment	(346)	(174)
Net cash flows (used in) provided by investing activities	<u>(7,149)</u>	<u>26,382</u>
Financing Activities		
Release of restricted cash due to conversion and redemption of redeemable convertible notes	4,075	2,225
Payments for the redemption of redeemable convertible notes	(4,075)	(2,157)
Proceeds from issuance of common stock, net of issuance costs	865	—
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	7,259
Proceeds from issuance of convertible notes to related parties	—	1,888
Repurchase of common stock in connection with equity award assumed	—	(82)
Proceeds from the exercise of common stock options	—	13
Net cash flows provided by financing activities	<u>865</u>	<u>9,146</u>
Net (decrease) increase in cash and cash equivalents	<u>(19,779)</u>	<u>21,552</u>
Cash and cash equivalents at beginning of period	29,096	1,544
Cash and equivalents at end of period	<u>\$ 9,317</u>	<u>\$ 23,096</u>

Supplemental Disclosure of Non-Cash Investing and Financing Information:

Conversion of convertible notes to Series F convertible preferred stock	—	1,511
Conversion of preferred stock warrant liabilities to equity upon reverse merger	—	774
Conversion of preferred stock and warrant liabilities to equity upon reverse merger	—	117,647
Investment securities received from the reverse merger	—	17,223
Redeemable convertible notes assumed upon reverse merger	—	37,073
Conversion of convertible notes to common stock	1	68
Embedded derivative related to redeemable convertible notes	—	1,455

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

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

1. Nature of Operations

Catalyst Biosciences, Inc. (the “Company” or “Catalyst”), is a clinical-stage biotechnology company focused on developing novel medicines to address hematology indications, including the treatment of hemophilia and surgical bleeding. Its facilities are located in South San Francisco, California and it operates in one segment.

Prior to August 20, 2015, the name of the Company was Targacept, Inc. On August 20, 2015, Targacept completed its business combination with “Old Catalyst” in accordance with the terms of an Agreement and Plan of Merger, dated as of March 5, 2015, as amended on May 6 and May 13, 2015, by and among Targacept, Talos Merger Sub, Inc. (“Merger Sub”) and Old Catalyst, pursuant to which Merger Sub merged with and into Old Catalyst, with Old Catalyst surviving as a wholly-owned subsidiary of Targacept (the “Merger”). Also on August 20, 2015, in connection with, and prior to the completion of, the Merger, Targacept effected a 7-for-1 reverse stock split of its common stock (the “Reverse Stock Split”) and changed its name from Targacept, Inc. to Catalyst Biosciences, Inc. Following the completion of the Merger, the business conducted by the Company became primarily the business conducted by Old Catalyst described in the paragraph above. We refer in this Quarterly Report on Form 10-Q to the business combination as the “Merger,” to the Company prior to the Merger as “Targacept” and to our subsidiary as “Old Catalyst,” and discussions of historical results reflect the results of Old Catalyst prior to the completion of the Merger and do not include the historical results of Targacept prior to the completion of the Merger.

On August 19, 2015, prior to and in connection with the Merger, the Company paid a dividend to the Targacept holders consisting of cash and non-interest bearing redeemable convertible notes (the “Pre-Closing Dividend”), see *Note 6* for further detail. In connection with the Pre-Closing Dividend and the reverse-stock split, the Company adjusted the number of shares subject to each outstanding option to purchase its common stock. On August 20, 2015, upon the completion of the Merger, the Company issued shares of its common stock to Old Catalyst stockholders in exchange for each share of Old Catalyst common stock outstanding immediately prior to the Merger and assumed all of the outstanding options and warrants of Old Catalyst, with such options and warrants henceforth representing the right to purchase a number of shares of the Company’s common stock. All preferred stock and warrants were converted to common stock and warrants to purchase common stock upon the closing of the Merger.

2. Summary of Significant Accounting Policies

Basis of Presentation

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

The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with the consolidated financial statements filed with the Company’s Annual Report on Form 10-K for the year ended December 31, 2015 (“Annual Report”).

The Company’s significant accounting policies are included in “*Part II - Item 8 - Financial Statements and Supplementary Data - Note 2 – Summary of Significant Accounting Policies*” in the Company’s Annual Report. There have been no significant changes to these accounting policies during the first nine months of 2016.

3. Fair Value Measurements

For a description of the fair value hierarchy and our 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 nine months ended September 30, 2016. As of September 30, 2016 and December 31, 2015, the Company’s highly liquid money market funds included within cash equivalents and restricted cash including deposit in an escrow account are financial assets that are valued using Level 1 inputs. The Company classifies its municipal bonds and corporate notes as Level 2.

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

Level 2 inputs for the valuations are limited to quoted prices for similar assets or liabilities in active markets and inputs other than quoted prices that are observable for the asset or liability. There were no transfers in or out of Level 1 and Level 2 during the periods presented.

Liabilities that are measured at fair value consist of the derivative liability that utilize Level 3 inputs. There were no transfers in or out of Level 3 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 September 30, 2016 and December 31, 2015 (*in thousands*):

	September 30, 2016			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds ⁽¹⁾	\$ 8,980	—	—	\$ 8,980
Restricted cash (money market funds) ⁽²⁾	29,844	—	—	29,844
U.S. government agency securities ⁽³⁾	10,208	—	—	10,208
Total financial assets	\$ 49,032	\$ —	\$ —	\$ 49,032
Financial liabilities:				
Derivative liability	—	—	\$ 28	\$ 28
Total financial liabilities	\$ —	\$ —	\$ 28	\$ 28

- (1) Included in Cash and Cash Equivalents on accompanying condensed consolidated balance sheets.
- (2) \$29.7 million of restricted cash in the Indenture serves as full collateral for the redeemable convertible notes and \$125,000 of restricted cash serves as collateral for the Company's corporate credit card and deposit for its facility lease.
- (3) Included in Short Term Investments on accompanying condensed consolidated balance sheets.

	December 31, 2015			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds ⁽¹⁾	\$ 28,927	\$ —	\$ —	\$ 28,927
Restricted cash (money market funds) ⁽²⁾	33,919	—	—	33,919
Municipal bonds ⁽³⁾	—	296	—	296
Corporate notes ⁽³⁾	—	3,106	—	3,106
Total financial assets	\$ 62,846	\$ 3,402	\$ —	\$ 66,248
Financial liabilities:				
Derivative liability	\$ —	\$ —	\$ 1,156	\$ 1,156
Total financial liabilities	\$ —	\$ —	\$ 1,156	\$ 1,156

- (1) Included in Cash and Cash Equivalents on accompanying condensed consolidated balance sheets.
- (2) \$33.8 million of restricted cash in the Indenture serves as full collateral for the redeemable convertible notes and \$125,000 of restricted cash serves as collateral for the Company's corporate credit card and deposit for its facility lease.
- (3) Included in Short Term Investments on accompanying condensed consolidated balance sheets.

The fair value of the derivative liability is measured using the Black-Scholes option-pricing valuation model. Inputs used to determine the estimated fair value of the conversion option include the fair value of the underlying common stock at the valuation measurement date, the remaining contractual term of the conversion option, risk-free interest rates, and expected dividends on and expected volatility of the price of the underlying common stock. In addition, the Company estimated the convertible redeemable note exchange rate based on an analysis of its actual exchange of notes for cash redemption or exchange of notes for conversion to common stock. See *Note 6* for further detail.

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

The following table presents the activity for the derivative liability measured at estimated fair value using unobservable inputs as of September 30, 2016 (*in thousands*):

	Derivative Liability
Balance as of December 31, 2015	\$ 1,156
Change in fair value included in interest and other income	(1,036)
Gain on extinguishment of redeemable convertible notes	(92)
Balance as of September 30, 2016	<u>\$ 28</u>

The estimated reporting date fair value-based measurement of the derivative liability was calculated using the Black-Scholes valuation model, based on the following weighted-average assumptions for the nine months ended September 30, 2016:

	Nine Months Ended September 30, 2016
Expected term	1.26
Expected volatility	79.8%
Risk-free interest rate	0.77%
Expected dividend yield	0%

4. Financial Instruments

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

September 30, 2016	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	\$ 8,980	\$ —	\$ —	\$ 8,980
Restricted cash (money market funds)	29,844	—	—	29,844
U.S. government agency securities	10,205	3	—	10,208
Total financial assets	<u>\$ 49,029</u>	<u>\$ 3</u>	<u>\$ —</u>	<u>\$ 49,032</u>
Classified as:				
Cash and cash equivalents				\$ 8,980
Restricted cash (money market funds)				29,844
Short-term investments				10,208
				<u>\$ 49,032</u>
December 31, 2015	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	\$ 28,927	\$ —	\$ —	\$ 28,927
Restricted cash (money market funds)	33,919	—	—	33,919
Municipal bonds	295	1	—	296
Corporate notes	3,106	1	(1)	3,106
Total financial assets	<u>\$ 66,247</u>	<u>\$ 2</u>	<u>\$ (1)</u>	<u>\$ 66,248</u>
Classified as:				
Cash and cash equivalents				\$ 28,927
Restricted cash (money market funds)				33,919
Short-term investments				3,402
				<u>\$ 66,248</u>

As of September 30, 2016, the remaining contractual maturities of available-for-sale securities were less than one year. There have been no significant realized gains or losses on available-for-sale securities for the periods presented.

5. Convertible Notes – Related Parties

In May and June 2015, Old Catalyst issued and sold convertible promissory notes in a series of closings in the aggregate principal amount of \$1.9 million to existing stockholders, together with warrants to purchase shares of either the Old Catalyst's Series E preferred stock or the capital stock issued during the next financing. The convertible promissory notes accrued interest at a rate of 12% per annum and were to mature one year from the date of issuance.

In connection with the debt financing, Old Catalyst also issued and sold to each investor purchasing a convertible promissory note a warrant to purchase equity securities of the same type that the principal amount of the convertible promissory note issued to such investor converts into.

In conjunction with the second closing in June 2015 of the Series F convertible preferred stock financing, Old Catalyst and the majority holders of the notes amended the notes such that the closing constituted a qualified financing and, accordingly, the total outstanding principal amount of the notes of \$1.9 million and all unpaid accrued interest of \$0.03 million, were converted into 1,511,723 shares of Series F convertible preferred stock and warrants for the purchase of 372,045 shares of Series F convertible preferred stock were issued to the note holders in connection with the conversion of the notes to Series F convertible preferred stock. All preferred stock and warrants were converted to common stock and warrants to purchase common stock upon the closing of the Merger.

The Company recognized interest expense of \$0 for both the three months ended September 30, 2016 and 2015, and \$0 and \$0.1 million for the nine months ended September 30, 2016 and 2015, related to the accrued interest and amortization of the debt discount.

All outstanding shares of Old Catalyst's convertible preferred stock and warrants to purchase convertible preferred stock were converted into shares of the Company's common stock and warrants to purchase common stock upon completion of the Merger.

6. Redeemable Convertible Notes

On August 19, 2015, immediately prior to the Merger, the Company issued to Targacept stockholders non-interest bearing redeemable convertible notes (the "Notes") in the aggregate principal amount of \$37.0 million. The Notes do not bear interest. The principal amount of the Notes are convertible, at the option of each noteholder, into cash or into shares of the Company's common stock at a conversion rate of \$9.19 per share (after taking into account the Reverse Stock Split), and are payable in cash, if not previously redeemed or converted, at maturity on February 19, 2018, the 30-month anniversary of the closing of the issuance of the Notes.

In connection with the Pre-Closing Dividend, on August 19, 2015, Targacept entered into an indenture (the "Indenture") with American Stock Transfer & Trust Company, LLC, as trustee, and an escrow agreement with American Stock Transfer & Trust Company, LLC and Delaware Trust Company, LLC, as escrow agent, under which \$37.0 million, which represented the initial principal amount of the convertible notes, was deposited in a segregated escrow account for the benefit of the holders of the notes in order to facilitate the payment of the notes upon redemption or at maturity (the amount of such deposit together with interest accrued and capitalized thereon, the "Escrow Funds"). The Notes are the Company's secured obligation, and the Indenture does not limit its other indebtedness, secured or unsecured.

Holders of the Notes may submit conversion notices, which are irrevocable, instructing the trustee to convert such the Notes into shares of the common stock at a conversion price of \$9.19 per share. Following each conversion date, the Company will issue the number of whole shares of common stock issuable upon conversion as promptly as practicable (and in any event within 10 business days). The trustee will in turn release to the Company the respective amount of restricted cash to cover the stock issuance.

The conversion to common stock feature of the Notes was determined to be a derivative liability requiring bifurcation and separate accounting. The fair value of such conversion feature at issuance was determined to be \$1.5 million. The bifurcation of the derivative liability from the estimated fair value of the Notes of \$37.1 million at issuance resulted in a debt discount of \$1.4 million. The Company elected to accrete the entire debt discount as interest expense immediately subsequent to the Merger. In addition, changes in the fair value of the derivative liability are being recorded within interest and other income in the consolidated statements of operations. The Company remeasures the derivative liability to fair value until the earlier of the conversion, redemption or maturity of the redeemable convertible notes.

For the three and nine months ended September 30, 2016 and 2015, the Company did not recognize interest expense related to the amortization of the debt discount within interest expense on the Company's consolidated statement of operations as the redeemable convertible notes are immediately fully redeemable at the option of the holders.

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

As of September 30, 2016, \$7.1 million of the Notes were redeemed and \$0.2 million of the Notes were converted into common stock since the Merger took effect. \$4.1 million of the Notes were redeemed during the nine months ended September 2016. For the three and nine months ended September 30, 2016, the Company recognized \$0 million and \$0.1 million of gain on the extinguishment of Notes upon the redemption of the Notes.

7. Stock Based Compensation

The Company assumed all of the outstanding options under Old Catalyst's 2004 Stock Plan (the "Catalyst Plan") and all of the standalone options of Old Catalyst that were not issued under the Catalyst Plan, in each case whether or not vested, outstanding immediately prior to the Merger, with such options henceforth representing the right to purchase that number of shares of the Company's common stock equal to 0.0382 multiplied by the number of shares of Old Catalyst common stock previously represented by such options. For accounting purposes, however, the Company is instead deemed to have assumed all of the options under the Targacept, Inc. 2000 Equity Incentive Plan and the 2006 Stock Incentive Plan and all of the standalone options of Targacept that were not issued under such plans outstanding immediately prior to the Merger (such plans and options, together with the Catalyst Plan and the standalone Catalyst options, the "Plans"), in addition to the Company's 2015 Stock Incentive Plan (as subsequently amended and restated).

The following table summarizes stock option activity under the Plans including stock options granted to non-employees, and related information:

	Number of Shares Underlying Outstanding Options	Weighted- Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)
Outstanding — December 31, 2015	2,199,509	\$ 9.84	4.51
Options granted	192,600	\$ 1.64	
Options forfeited	(199,238)	\$ 12.27	
Outstanding — September 30, 2016	2,192,871	\$ 8.90	3.94
Exercisable — September 30, 2016	1,651,916	\$ 10.65	2.22
Vested and expected to vest — September 30, 2016	2,141,143	\$ 9.02	3.81

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. 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 nine months ended September 30, 2016 and 2015:

	<u>Nine Months Ended September 30, 2016</u>	
	2016	2015
Employee Stock Options:		
Risk-free interest rate	1.41%	2.32%
Expected term (in years)	5.92	6.28
Dividend yield	—	—
Volatility	75.04%	76.34%
Weighted-average fair value of stock options granted	\$ 1.07	\$ 0.18

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	2016	2015	2016	2015
Research and development	\$ 68	\$ 13	\$ 172	\$ 37
General and administrative	120	39	333	98
Total stock-based compensation	\$ 188	\$ 52	\$ 505	\$ 135

As of September 30, 2016, the Company had unrecognized employee stock-based compensation expense of \$1.0 million, related to unvested stock awards, which is expected to be recognized over an estimated weighted-average period of 3.0 years.

8. Collaborations

Pfizer

On August 20, 2013 the Company and Pfizer entered into an amendment to the Factor VIIa marzeptacog alfa (activated) (formerly CB 813d) collaboration agreement whereby the companies agreed to provide specific mutual releases and covenants and modify certain milestone payment schedules in the agreement. Per the amendment, Pfizer agreed to make two non-refundable \$1.5 million annual license maintenance payments to the Company, payable on August 1, 2014 and August 1, 2013. The annual license maintenance payments received were being amortized to contract revenue over the estimated expected performance period under the arrangement, which the Company estimated was to the end August 1, 2015.

On April 2, 2015, Pfizer notified the Company that it was exercising its right to terminate in its entirety the collaboration agreement. The termination became effective 60 days after the Company's receipt of the termination notice. On June 1, 2015, the license and certain rights under the research and license agreement terminated and reverted back to the Company. Pfizer is in the process of transferring clinical trial data, regulatory documentation and related technology under the research and license agreement to the Company. The Company plans to continue clinical development of this product candidate. The Company revised the expected period of performance to end on June 1, 2015, which was the effective termination of all performance obligations of the Company under the research and license agreement. Accordingly, all deferred revenue was recognized through June 1, 2015.

Contract revenue related to the agreement with Pfizer was \$0 and \$0.8 million during the three months ended September 30, 2016 and 2015 and \$0 and \$1.3 million during the nine months ended September 30, 2016 and 2015, respectively.

ISU Abxis

On June 16, 2013, the Company entered into a license and collaboration agreement with ISU Abxis, whereby the Company licensed its proprietary human Factor IX products to ISU Abxis for initial development in South Korea. Under the terms of the agreement, ISU Abxis is responsible for development and manufacturing of the licensed products through Phase 1 clinical trials. Until the completion of Phase 1 development, ISU Abxis also has a right of first refusal with respect to commercialization rights for the licensed products in South Korea. The Company has the sole rights and responsibility for worldwide development, manufacture and commercialization of Factor IX products after Phase 1 development, unless ISU Abxis has exercised its right of first refusal regarding commercialization rights in South Korea, in which case the Company's rights are in the entire world excluding South Korea. ISU Abxis' rights will also terminate in the event that the Company enters into a license agreement with another party to develop, manufacture and commercialize Factor IX products in at least two major market territories.

ISU Abxis paid the Company an up-front signing fee of \$1.75 million and is obligated to pay to the Company contingent milestone-based payments on the occurrence of certain defined development events, and reimbursement for a portion of the Company's costs relating to intellectual property filings and maintenance thereof on products. The Company is obligated to pay ISU Abxis a percentage of all net profits it receives from collaboration products.

Contract revenue of \$0.1 million for both the three months ended September 30, 2016 and 2015 and \$0.3 million for both of the nine months ended September 30, 2016 and 2015, reflected the amortization of the up-front fee over the estimated period of the Company's performance obligations under the agreement, which was assessed to be four years beginning in September 2013 when the agreement was executed. The deferred revenue balance related to the ISU Abxis collaboration was \$0.4 million and \$0.7 million as of September 30, 2016, and December 31, 2015, respectively.

9. Net Loss per Share

The following table sets forth the computation of the basic and diluted net loss per share during the three and nine months ended September 30, 2016 and 2015 (in thousands, except share and per share data):

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	2016	2015	2016	2015
Net loss, basic and diluted	\$ (4,771)	\$ (5,051)	\$ (13,195)	\$ (9,632)
Weighted-average number of shares used in computing net loss per share, basic and diluted	11,846,947	5,410,864	11,575,701	2,071,161
Net loss per share, basic and diluted	\$ (0.40)	\$ (0.93)	\$ (1.14)	\$ (4.65)

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:

	<u>September 30,</u>	<u>December 31,</u>
	2016	2015
Options to purchase common stock	2,194,252	2,200,890
Common stock warrants	180,954	180,954
Redeemable convertible notes	3,228,237	3,671,745
Total	5,603,443	6,053,589

10. Common Stock

On March 16, 2016, the Company entered into a Capital on Demand™ Sales Agreement with JonesTrading Institutional Services LLC (“JonesTrading”). In accordance with the terms of the sales agreement, the Company may offer and sell shares of its common stock having an aggregate offering price up to \$6.5 million, subject to certain limitations, from time to time in one or more public offerings of the Company’s common stock, with JonesTrading acting as agent, in transactions pursuant to a shelf registration statement that was declared effective by the SEC on April 28, 2016.

The Company sold 432,367 shares of common stock in the open market at a weighted-average selling price of \$1.69 per share, for net proceeds (net of commissions) of \$0.7 million during the three months ended September 30, 2016, and 505,826 shares of common stock in the open market at a weighted-average selling price of \$1.76 per share, for net proceeds (net of commissions) of \$0.9 million during the nine months ended September 30, 2016 in the Capital on Demand™ program. The Company expensed approximately \$0.1 million of costs for the offering, excluding JonesTrading commissions. The Company charged \$0.02 million of these costs against additional paid-in capital for the three months ended September 30, 2016, and \$0.03 million for the nine months ended September 30, 2016, respectively. As of October 31, 2016 the Company had up to \$5.5 million of common stock available for sale under the Controlled Equity Offering™ program.

11. Commitments and Contingencies

Operating Leases

Future minimum lease payments under all non-cancelable operating leases as of September 30, 2016, were as follows (in thousands):

	<u>Minimum Lease Payments</u>
2016	181
2017	745
2018	125
Total future minimum lease payments	1,051

Manufacturing Agreements

On May 20, 2016, the Company entered into a development and manufacturing services agreement with CMC ICOS Biologics, Inc. (“CMC”), pursuant to which CMC will conduct manufacturing development and, upon successful development of the manufacturing process, manufacture the Company’s next-generation Factor VIIa variant marzeptacog alfa (activated) that the Company intends to use in its clinical trials. The Company has agreed to a total of \$3.8 million in payments to CMC pursuant to the initial statement of work under the Agreement, subject to completion of applicable work stages. As of September 30, 2016 the Company is obligated to \$3.5 million in payments to CMC remaining under the agreement.

12. Other Income (Expense)

The following table shows the detail of other income/(expense), net for the three and nine month periods ended September 30, 2016 and 2015 (*in thousands*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
NNR Asset Sale	\$ 804	\$ —	\$ 804	\$ —
Derivative Liability	99	740	1,036	740
Other Income/(Expense), net	38	(467)	163	224
Total Other Income/(expense), net	<u>\$ 941</u>	<u>\$ 273</u>	<u>\$ 2,003</u>	<u>\$ 964</u>

13. Restructuring Actions

In September 2016, the Company announced a reduction in workforce of 10 employees, or approximately 50% of the company’s workforce, in connection with a strategic plan to reallocate the Company’s resources to its hemostasis programs. As a result of the workforce reduction, the Company estimated one-time severance and related costs relating to the restructuring of approximately \$1.0 million recorded in research and development expense. Of these one-time severance and related costs, approximately \$0.7 million was paid through the three and nine months ended September 30, 2016. The remaining liability is recorded within accrued expenses as of September 30, 2016 and the restructuring balance will be fully paid by the end of 2016.

14. Subsequent events

On October 12, 2016, the Company entered into a definitive sales agreement on the sale of TC-6499, a neural nicotinic receptor asset acquired from Targacept in the Merger, for approximately \$0.8 million in up-front payments and the potential for future milestones and royalties.

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

Unless otherwise indicated, in this Quarterly Report on Form 10-Q, (i) references to “Catalyst,” “we,” “us,” “our” or the “Company” mean Catalyst Biosciences, Inc. and our subsidiaries. The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and related notes that appear in this Quarterly Report on Form 10-Q (“Report”).

In addition to historical information, this Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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, 2015 (“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 medicines to address serious medical conditions. We are focusing our product development efforts in the fields of hemostasis, including the treatment of hemophilia and surgical bleeding. Our most advanced program is a highly potent next-generation coagulation Factor VIIa variant, marzeptacog alfa (activated) (formerly CB 813d), which has successfully completed an intravenous Phase 1 clinical trial evaluating safety and tolerability as well as pharmacokinetics, pharmacodynamics and coagulation activity in severe hemophilia A and B individuals. We expect to advance marzeptacog alfa (activated) into a subcutaneous prophylaxis dosing trial in 2017, to be followed if successful by a pivotal clinical efficacy trial in individuals with hemophilia A or B with an inhibitor. Based on our research, we estimate annual worldwide sales in 2015 for FDA-approved recombinant Factor VIIa products were approximately \$1.6 billion. In addition to our lead Factor VIIa program, our Factor IX variant, CB 2679d/ISU304, has completed advanced preclinical IND-enabling development. We expect to initiate a subcutaneous prophylaxis dosing trial for CB 2679d/ISU304 in the first quarter 2017. The substantially enhanced potency of marzeptacog alfa (activated) and CB 2679d/ISU304 may allow for efficacious and convenient subcutaneous prophylaxis for individuals with hemophilia A or B with an inhibitor (marzeptacog alfa (activated)) or individuals with hemophilia B (CB 2679d/ISU304), thereby achieving significant differentiation versus competing intravenous therapeutics, particularly for pediatric individuals. Based on our research, we estimate annual worldwide sales in 2015 for FDA-approved Factor IX containing products were approximately \$0.8 billion. We also have several Factor Xa variants, for which we have delayed initiating further research studies and we continue to explore licensing opportunities for our anti-complement programs in delayed graft function (“DGF”) and dry age-related macular degeneration (“Dry AMD”), so that we can focus our efforts and resources on advancing marzeptacog alfa (activated), our highly potent next generation Factor VIIa, and CB 2679d/ISU304, our highly potent next-generation FIX, through Phase 2/3 and Phase 1/2 clinical trials, respectively.

On June 29, 2009, we entered into a research and license agreement with Wyeth Pharmaceuticals, Inc., subsequently acquired by Pfizer, whereby we and Pfizer collaborated on the development of novel human Factor VIIa products, and we granted Pfizer the exclusive rights to develop and commercialize the licensed products on a worldwide basis. As a result of this agreement, Pfizer paid us an up-front non-refundable signing fee of \$21.0 million, which was initially recognized as revenue ratably over the term of our continuing involvement in the research and development of products with Pfizer, which was determined to be five years (covering the initial two-year research term plus potential extensions permitted under the applicable agreement).

During the initial two-years of the collaboration period, Pfizer reimbursed us for certain costs incurred in the development of the licensed products, including FTE-based research payments. Following the conclusion of the initial collaboration, without extension by

Pfizer, we had no further substantive performance obligations to Pfizer under the agreement, and we recognized the remaining \$12.6 million of deferred revenue related to the up-front fee in June 2011. Subsequently, in August 2013, we entered into an amendment to the Pfizer agreement, in accordance with which Pfizer made two \$1.5 million non-refundable annual license maintenance payments to us in August 2013 and August 2014 and we agreed to certain performance obligations to Pfizer for the period starting from the effective date of the amendment. Pfizer was also obligated to pay to us contingent milestone-based payments upon the occurrence of certain defined development, commercialization, and sales-based milestones.

On April 2, 2015, Pfizer notified us that it was exercising its right to terminate the research and license agreement effective June 1, 2015. Accordingly, we revised the expected period of performance to end on June 1, 2015, and the deferred revenue balance was fully amortized as of that date. We are currently negotiating with Pfizer regarding rights to use certain manufacturing materials and the amount and timing of payments to Pfizer.

In September 2013, we entered into a license and collaboration agreement with ISU Abxis pursuant to which we licensed our proprietary human Factor IX products to ISU Abxis for initial development in South Korea. Under the agreement, ISU Abxis is responsible for development and manufacturing of the licensed products through Phase 1 clinical trials. Until the completion of Phase 1 development, ISU Abxis also has a right of first refusal with respect to commercialization rights for the licensed products in South Korea. ISU Abxis paid us an up-front signing fee of \$1.75 million and is obligated to pay to us contingent milestone-based payments on the occurrence of certain defined development events, none of which have been achieved as of September 30, 2016. Collaboration and license revenue related to the ISU Abxis agreement during both the three months ended September 30, 2016 and 2015 was \$0.1 million and \$0.3 million for both of the nine months ended September 30, 2016 and 2015, which reflects the amortization of the up-front fee over the estimated period of our performance obligations, which are estimated to conclude in August 2017. We had a deferred revenue balance of \$0.4 million as of September 30, 2016 related to the ISU Abxis collaboration.

On August 20, 2015, we completed the business combination between Old Catalyst and Targacept in accordance with the terms of the Agreement and Plan of Merger, dated as of March 5, 2015, as amended on May 6 and May 13, 2015. Also on August 20, 2015, in connection with, and prior to the completion of, the merger, we effected a 7-for-1 reverse stock split of our common stock (the "Reverse Stock Split") and changed our name to "Catalyst Biosciences, Inc," discussed in *"Part II - Item 8 - Consolidated Notes to the Financial Statements- Note 7 - Reverse Merger"* in the Annual Report.

We have never been profitable and have incurred significant operating losses in each year since inception. Our net losses were \$4.8 million and \$5.1 million for the three months ended September 30, 2016 and 2015 and \$13.2 million and \$9.6 million during the nine months ended September 30, 2016 and 2015, respectively. As of September 30, 2016, we had an accumulated deficit of \$144.2 million. Substantially all of our operating losses resulted from expenses incurred in connection with 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, following the merger our expenses have further increased as a result of 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

Our contract revenue was generated by recognizing revenue from the amortization of up-front licensee fees for research and development services under our collaboration agreements with Pfizer and ISU Abxis. Payments made to us under these agreements are recognized over the period of performance for each arrangement. We may also be entitled to receive additional milestone payments and other contingent payments upon the occurrence of specific events. We have not generated any revenue from commercial product sales to date. As of June 2015, our deferred revenue balance from the Pfizer research and license agreement was fully amortized following the termination by Pfizer of that agreement, and ISU Abxis represents 100% of our total contract revenue for the three and nine months ending September 30, 2016.

Due to the nature of the milestone payments under the remaining collaboration agreement and the nonlinearity of the earnings process associated with certain payments and milestones, we expect that our revenue will fluctuate in future periods, as a result of the uncertainty of timing related to achievement of milestones.

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;
- 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 nine months ended September 30, 2016 and 2015 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Personnel costs	\$ 1,510	\$ 836	\$ 3,538	\$ 2,097
Preclinical research	649	342	2,006	1,046
Clinical Manufacturing	935	—	1,837	—
Facility and overhead	302	308	1,062	1,049
Total research and development expenses	\$ 3,396	\$ 1,486	\$ 8,443	\$ 4,192

The largest component of our total operating expenses has historically been our investment in research and development activities, including the clinical development of our product candidates. We are currently focusing substantially all of our resources and development efforts on our clinical and preclinical pipeline. 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.

On September 3, 2016, our Board of Directors approved reducing our workforce by 10 employees, or approximately 50% of our workforce in connection with a strategic plan to reallocate our resources to its hemostasis programs, focused primarily on our highly potent next-generation Factor VIIa variant marzeptacog alfa (activated), and our highly potent next-generation Factor IX CB 2679d/ISU304. This reduction in force is expected to cost approximately \$1.0 million and be completed by the end of 2016.

Notwithstanding the reduction in force, we expect our aggregate research and development expenses will increase during the next few quarters as we continue the preclinical, manufacturing and clinical development of our product candidates in the United States, particularly the clinical development of marzeptacog alfa (activated) and CB 2679d/ISU304. Due to the termination of the research and license agreement with Pfizer, we expect to incur costs in connection with the Factor VIIa program. However, the incurrence of

such costs are dependent on whether we will pursue the program on our own or enter into a new collaboration and license arrangement with another pharmaceutical or biotech company.

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. As a result, we cannot estimate with any degree of certainty the costs we will incur in connection with 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.

On May 20, 2016, we entered into a development and manufacturing services agreement with CMC ICOS Biologics, Inc. ("CMC"), pursuant to which CMC will conduct manufacturing development and, upon successful development of the manufacturing process, manufacture marzeptacog alfa (activated) that we intend to use in its clinical trials. We will own all intellectual property developed in such manufacturing development activities that are specifically related to marzeptacog alfa (activated) and will have a royalty free and perpetual license to use CMC's intellectual property to the extent reasonably necessary to make marzeptacog alfa (activated), including commercial manufacturing.

We have agreed to a total of \$3.8 million in payments to CMC pursuant to the initial statement of work under the Agreement, subject to completion of applicable work stages. In the event that clinical manufacturing batches need to be cancelled or rescheduled, we would be obligated to pay for a portion of CMC's manufacturing fees less certain fees that CMC is able to mitigate. 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.

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 have incurred increasing expenses associated with operating as a public company, including expenses related to new hires, compliance with the rules and regulations of the SEC and NASDAQ Stock Market LLC ("NASDAQ"), additional insurance expenses, additional audit expenses, investor relations activities, Sarbanes-Oxley "SOX" compliance expenses and other administrative expenses and professional services. We expect such expenses to continue.

Interest and Other Income, Net

Interest and other income consists primarily of the changes in fair value of the derivative liability and in 2015 the warrant liability and sub-lease income earned in connection with the sub-lease of a portion of our leased facility.

The derivative liability is associated with the redeemable convertible notes we issued immediately prior to the closing of the merger in August 2015. The accounting for the redeemable convertible notes, which are convertible into shares of our common stock, requires us to bifurcate the derivative liability and account for it as a derivative liability at its estimated fair value upon issuance. The derivative liability is remeasured to estimated fair value as of each balance sheet date. We will record adjustments to the fair value of the derivative liability at the end of each reporting period until the earlier of the conversion, redemption or maturity of the redeemable convertible notes.

We recorded adjustments to the estimated fair value of the preferred stock warrants until they converted into warrants to purchase shares of common stock upon the closing of the merger in August 2015. At that time, we reclassified the preferred stock warrant liability into additional paid-in capital and no longer recorded any related periodic fair value adjustments.

On February 23, 2015, we entered into a new lease for the portion of the space we previously occupied in our headquarters building. The initial term of the lease was set to expire on August 31, 2015. On June 8, 2015 we exercised our right to extend the lease term through February 27, 2018.

On July 27, 2016, we entered into a definitive sales agreement with Attenua, Inc. (“Attenua”), on the sale of TC-5619, TC-6987 and TC-6683, certain neural nicotinic receptor (“NNR”) assets acquired from Targacept in the Merger, for approximately \$1.0 million in upfront payments and the potential for future milestones and royalties, of which all of the net \$0.8 million was recognized into other income as of September 30, 2016, as we have no future performance obligations. Along with the upfront payment, we received a warrant to purchase shares of Attenua’s capital stock as additional consideration. The warrant is based upon a future financing and exercise price and the warrant value as of September 30, 2016 is deemed to be immaterial and is included in other current assets.

On October 12, 2016, we entered into a definitive sales agreement on the sale of TC-6499, an NNR asset acquired from Targacept in the Merger, for approximately \$0.8 million in upfront payments and the potential for future milestones and royalties of which all of the \$0.8 million was recognized into other income as of October 31, 2016.

Interest Expense

Interest expense consists of accrued interest costs related to our convertible notes and the amortization of debt discount for the warrants that were issued in connection with the redeemable convertible notes.

Results of Operations

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

	<u>Three Months Ended September 30,</u>		<u>Change (\$)</u>	<u>Change (%)</u>
	<u>2016</u>	<u>2015</u>		
Contract revenue	\$ 109	\$ 109	\$ —	—
Operating expenses:				
Research and development	3,396	1,486	1,910	129%
General and administrative	2,425	2,508	(83)	(3)%
Total operating expenses	5,821	3,994	1,827	46%
Loss from operations	(5,712)	(3,885)	(1,827)	47%
Interest and other income	941	273	668	245%
Interest expense	—	(1,439)	1,439	(100)%
Net loss	<u>\$ (4,771)</u>	<u>\$ (5,051)</u>	<u>\$ 280</u>	<u>(6)%</u>

	<u>Nine Months Ended September 30,</u>		<u>Change (\$)</u>	<u>Change (%)</u>
	<u>2016</u>	<u>2015</u>		
Contract revenue	\$ 328	\$ 1,641	\$ (1,313)	(80)%
Operating expenses:				
Research and development	8,443	4,192	4,251	101%
General and administrative	7,083	6,567	516	8%
Total operating expenses	15,526	10,759	4,767	44%
Loss from operations	(15,198)	(9,118)	(6,080)	67%
Interest and other income	2,003	964	1,039	108%
Interest expense	—	(1,478)	1,478	(100)%
Net loss	<u>\$ (13,195)</u>	<u>\$ (9,632)</u>	<u>\$ (3,563)</u>	<u>37%</u>

Contract Revenue

Contract revenue was \$0.1 million during both the three months ended September 30, 2016 and 2015, due primarily to the recognition of revenue under our collaboration agreement with ISU Abxis.

Contract revenue was \$0.3 million and \$1.6 million during the nine months ended September 30, 2016 and 2015, respectively, a decrease of \$1.3 million, or 80%. The decrease in contract revenue was due primarily to the termination of our collaboration agreement with Pfizer in June 2015.

We have recognized in revenue all amounts that had been previously deferred related to the terminated Pfizer collaboration and, therefore, in future periods, will not recognize any additional revenue under our previous collaboration agreement with Pfizer.

Research and Development Expenses

Research and development expenses were \$3.4 million and \$1.5 million during the three months ended September 30, 2016 and 2015, respectively, an increase of \$1.9 million, or 129%. The increase was due primarily to an increase of \$0.9 million related to manufacturing expenses for marzeptacog alfa (activated), \$0.7 million in personnel-related costs in connection with the reduction in workforce and an increase of \$0.4 million in lab supply costs and costs related to preclinical third-party research and development service contracts.

Research and development expenses were \$8.4 million and \$4.2 million during the nine months ended September 30, 2016 and 2015, respectively, an increase of \$4.2 million, or 101%. The increase was due primarily to an increase of \$1.8 million related to manufacturing expenses for marzeptacog alfa (activated), \$1.4 million in personnel-related costs and an increase of \$1.0 million in lab supply costs and costs related to preclinical third-party research and development service contracts.

General and Administrative Expenses

General and administrative expenses were \$2.4 million and \$2.5 million during the three months ended September 30, 2016 and 2015, respectively, a decrease of \$0.1 million, or 3%. The decrease was due primarily to a decrease of \$0.2 million in professional service costs, partially offset by an increase of \$0.1 million in personnel and other related costs as a result of increased head count (\$0.3 million in accounts receivable was written off related to patent-related reimbursements).

General and administrative expenses were \$7.1 million and \$6.6 million during the nine months ended September 30, 2016 and 2015, respectively, an increase of \$0.5 million, or 6%. The increase was due primarily to an increase of \$0.6 million in personnel-related costs as a result of increased head count and \$0.5 million in other expenses related to operating as a public company, partially offset by a decrease of \$0.6 million in professional service costs, including patent-related legal costs and legal and accounting advisory services.

Interest and Other Income

Interest and other income was \$0.9 million and \$0.3 million during the three months ended September 30, 2016 and 2015, respectively, an increase of \$0.6 million, or 245%. The increase was due primarily to a net \$0.8 million gain recognized related to the income received for the sale of NNR assets and \$0.5 million gain related to the change in estimated fair value of warrant, partially offset by a \$0.7 million loss recognized, related to the change in fair value of the derivative liability.

Interest and other income was \$2.0 million and \$1.0 million during the nine months ended September 30, 2016 and 2015, respectively, an increase of \$1.0 million, or 103%. The increase was due primarily to a net \$0.8 million gain recognized related to the income received for the sale of NNR assets and the \$0.3 million gain recognized, related to the change in fair value of the derivative liability, partially offset by \$0.1 million other.

Interest Expense

Interest expense of \$0 and \$1.4 million for the three months ended September 30, 2016 and 2015, respectively, is due primarily to \$1.4 million of immediate accretion of the debt discount for the redeemable convertible notes. Apart from our redeemable convertible notes, we did not have any debt obligations in 2016.

Interest expense of \$0 and \$1.5 million for the nine months ended September 30, 2016 and 2015, respectively, is due primarily to \$1.4 million immediate accretion of the debt discount for the redeemable convertible notes and \$0.1 million of the accrued interest and amortization of the debt discount for the convertible notes issued to related parties in May and June 2015. Apart from our redeemable convertible notes, we did not have any debt obligations in 2016.

Recent Accounting Pronouncements

In August 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. The standard provides guidance on how certain cash receipts and payments are presented and classified in the statement of cash flows, including beneficial interests in securitization. The standard is intended to reduce current diversity in practice. ASU 2016-15 will be effective for the Company beginning in its first quarter 2018, but early adoption is permitted, including adoption in an interim period. We are currently evaluating the potential impact that this standard may have on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The new standard involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. ASU 2016-09 will be effective for the Company in its first quarter of 2017. We are currently evaluating the potential impact that this standard may have on our consolidated financial statements.

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. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 will be effective for the Company beginning in its first quarter of 2019, but early adoption is permitted. We are currently evaluating the impact of adopting the new lease standard on our consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments – Overall (Topic 825-10), which updates certain aspects of recognition, measurement, presentation and disclosure of financial instruments. ASU 2016-01 will be effective for the Company beginning in its first quarter of 2018, and early adoption is not permitted. We are currently evaluating the potential impact that this standard may have on our consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which amends the existing accounting standards for revenue recognition. ASU 2014-09 is based on principles that govern the recognition of revenue at an amount an entity expects to be entitled when products are transferred to customers. ASU 2014-09 will be effective for the Company beginning in its first quarter of 2018, and early adoption is permitted beginning in the first quarter of 2017. Subsequently, the FASB has issued the following standards related to ASU 2014-09: ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations; ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing; and ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients. The Company must adopt ASU 2016-08, ASU 2016-10 and ASU 2016-12 with ASU 2014-09 (collectively, the “new revenue standards”). The new revenue standard may be applied retrospectively to each prior period presented or prospectively with the cumulative effect recognized as of the date of adoption. We are currently evaluating the timing of our adoption and the impact of adopting the new revenue standard on our consolidated financial statements.

Liquidity and Capital Resources

On August 20, 2015, we completed our merger with Targacept, which provided \$41.2 million in cash, cash equivalents and short-term investments. Prior to that time, our operations had been financed primarily by net proceeds from the sale of convertible preferred stock, and the issuance of convertible notes. As of September 30, 2016, we had \$19.5 million of cash, cash equivalents and short-term investments. We have an accumulated deficit of \$144.2 million as of September 30, 2016.

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 its outstanding accounts payable and accrued expenses.

We believe that our existing capital resources will be sufficient to meet our projected operating requirements for at least the next 12 months. 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 transaction, collaborations or strategic partnerships with other companies. 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. 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.

On March 16, 2016, we entered into a Capital on Demand™ Sales Agreement with JonesTrading Institutional Services LLC (“JonesTrading”). In accordance with the terms of the sales agreement, we may offer and sell shares of its common stock having an aggregate offering price up to \$6.5 million, subject to certain limitations, from time to time in one or more public offerings of our common stock, with JonesTrading acting as agent, in transactions pursuant to a shelf registration statement that was declared effective by the SEC on April 28, 2016. During the nine months ended September 30, 2016, we sold 505,826 shares of our common stock in the Capital on Demand™ program, in the open market at a weighted-average selling price of \$1.76 per share, for net proceeds (net of commissions) of \$0.9 million.

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

	<u>Nine Months Ended September 30,</u>	
	<u>2016</u>	<u>2015</u>
Cash used in operating activities	\$ (13,495)	\$ (13,976)
Cash provided by (used in) investing activities	(7,149)	26,382
Cash provided by financing activities	865	9,146
Net increase (decrease) in cash and cash equivalents	<u>\$ (19,779)</u>	<u>\$ 21,552</u>

Cash Flows from Operating Activities

Cash used in operating activities for the nine months ended September 30, 2016 was \$13.5 million, due primarily to a net loss of \$13.2 million. Also included are non-cash losses of \$1.0 million related to the change in fair value of the derivative liability and \$0.1 million related to extinguishment of redeemable convertible notes, partially offset by non-cash charges of \$0.5 million for stock-based compensation and \$0.3 million for depreciation and amortization.

Cash used in operating activities for the nine months ended September 30, 2015 was \$14.0 million, due primarily to a net loss of \$9.6 million, the change in our net operating assets and liabilities of \$5.5 million due primarily to a \$4.5 million decrease in accounts payable we assumed in connection with the merger with Targacept, \$1.7 million decrease in deferred revenue due to the amortization of upfront license fees from our collaborations, \$0.2 million increase in accounts receivable and \$0.1 million decrease in prepaids and other current assets, partially offset by \$1.0 million increase in accrued compensation and other accrued liabilities. Also included are non-cash gains of \$0.6 million related to the change in fair value of the warrant liability. Non-cash gains of \$1.5 million of interest expense related to accretion of debt discount of redeemable convertible notes and convertible notes to related parties, \$0.4 million for depreciation and amortization and \$0.1 million for stock-based compensation, partially offset by non-cash losses of \$0.8 million related to change in fair value of the derivative liability and \$0.1 million related to change in fair value of warrant liability.

Cash Flows from Investing Activities

Cash used in investing activities for the nine months ended September 30, 2016 was \$7.1 million, due primarily to \$13.4 million in purchases of investments and \$0.3 million related to the purchase of property and equipment, partially offset by proceeds from maturities of investments of \$6.6 million.

Cash provided by investing activities for the nine months ended September 30, 2015 was \$26.4 million, due primarily to \$23.9 million of net cash proceeds from the reverse merger and \$2.8 million of proceeds from maturities of investments, partially offset by \$0.2 million related to the purchase of property and equipment and \$0.1 million increase in restricted cash for the Company’s credit card collateral and facility lease deposit.

Cash flows from Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2016 was \$0.9 million, due primarily to \$0.9 million in net proceeds from issuance of common stock in at-the-market transactions and the release of restricted cash of \$4.1 million related to the redemption of some of the redeemable convertible notes which was offset by payments of \$4.1 million related to the redemption of some of the redeemable convertible notes.

Cash provided by financing activities for the nine months ended September 30, 2015 was \$9.1 million, due primarily to \$7.3 million proceeds received from the issuance of convertible preferred stock, \$1.9 million conversion of some of the redeemable convertible

notes and the release of restricted cash of \$2.2 million related to the redemption of some of the redeemable convertible notes which was offset by payments of \$2.2 million related to the redemption of some of the redeemable convertible notes and \$0.1 million related to repurchase of common stock in connection with equity awards assumed.

Contractual Obligations

The following table summarizes our fixed contractual obligations as of September 30, 2016 (*in thousands*):

	Payments due by period				Total
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	
Contractual Obligations:					
Operating lease obligations ⁽¹⁾	\$ 739	\$ 312	\$ —	\$ —	\$ 1,051
CMC Manufacturing obligations ⁽²⁾	3,563	—	—	—	3,563
Total contractual obligations ⁽³⁾⁽⁴⁾	\$ 4,302	\$ 312	\$ —	\$ —	\$ 4,614

- (1) Represents future minimum lease payments under the non-cancelable lease for our headquarters in South San Francisco, California. The minimum lease payments above do not include any related common area maintenance charges or real estate taxes.
- (2) Represents future payments due under our development and manufacturing services agreement initial statement of work, subject to the completion of applicable work stages, which we expect to occur in less than one year.
- (3) We may be obligated to pay ISU Abxis up to \$2.0 million in potential milestone payments. As the achievement and timing of these milestones are uncertain and not estimable, such commitments have not been included in the contractual obligation disclosed above. We may be obligated to pay Pfizer certain milestone payments. The achievement and timing of these milestones are uncertain and not estimable and have not been included in the contractual obligation disclosed above.
- (4) We had unrecognized tax benefits in the amount of \$1.3 million as of December 31, 2015 related to uncertain tax positions. However, there is uncertainty regarding when these benefits will require settlement so these amounts were not included in the contractual obligations table above.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

Certain of the Company's accounting policies that involve a higher degree of judgment and complexity are discussed in "Part II - Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operation - Critical Accounting Estimates" in the Annual Report. There have been no significant changes to these critical accounting estimates during the first nine months of 2016.

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, although currently income generated from our investment portfolio is insignificant. 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 that 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 September 30, 2016, we had cash and cash equivalents of \$19.5 million, which consisted of bank deposits and money market funds, and short-term investments of \$10.2 million. The redeemable convertible notes we issued in August 2015 in connection with the merger do not bear interest and thus a change in market interest rates would not have an impact on an interest expense related to these redeemable convertible notes. Accordingly, we would 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 September 30, 2016. 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 September 30, 2016, 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 the Company’s internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) identified during the first nine months of 2016 that has materially affected, or is reasonably likely to materially affect, the Company’s 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

Other than as described below, we have not identified any material changes to the risk factors previously disclosed in “*Part I - Item 1A - Risk Factors*” in the Company’s Annual Report. Our business, financial condition and operating results can be affected by a number of factors, whether currently known or unknown, including but not limited to those described below or in the Annual Report, any one or more of which could, directly or indirectly, cause our actual financial condition and operating results to vary materially from past, or from anticipated future, financial condition and operating results. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, operating results and stock price.

You should carefully consider the risks and uncertainties described below, 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.

We are substantially dependent upon the success of subcutaneous dosing trials of marzeptacog alfa (activated) and CB 2679d/ISU304.

We expect to commence a subcutaneous prophylaxis clinical trial of marzeptacog alfa (activated) in 2017 and for ISU Abxis to commence a subcutaneous clinical trial of CB 2679d/ISU304 in the first quarter of 2017. Neither product candidate has previously been studied in human clinical trials using subcutaneous dosing. There can be no assurance that either product will achieve efficacious levels of biological activity when administered subcutaneously. There can also be no assurance that the clinical trial results will be positive or that the clinical trials will not generate unanticipated safety concerns. The failure of either product to achieve successful clinical trial endpoints, delays in clinical trial commencement or in clinical development generally, unanticipated adverse side effects, adverse immunological responses, or any other adverse developments or information related to our product candidates would significantly harm our business, its prospects and the value of the company’s common stock.

Marzeptacog alfa (activated) and CB 2679d/ISU304 may cause the generation of antibodies, which could prevent their further development.

Both marzeptacog alfa (activated) and CB 2679d/ISU304 are protein molecules which may cause the generation of antibodies in patients who receive them. The Phase 1 clinical trial of marzeptacog alfa (activated) was a single-dose intravenous escalation trial that would not, compared to multi-dose trials, be expected to exclude the possibility of an immunological response to marzeptacog alfa (activated) in individuals who received the product candidate. One subject from the 18 µg/kg dose group developed a weak, transient and non-neutralizing anti-marzeptacog alfa (activated) antibody at a single time point of Day 60 post-dose. The positive anti-marzeptacog alfa (activated) antibody was characterized as cross-reactive with NovoSeven and native human Factor VII. Additional review of the raw data suggests that the bioanalytical result of a weak positive anti-drug antibody immune response at Day 60 may represent a false-positive test result. There were no subjects with evidence of neutralizing antibodies against marzeptacog alfa (activated), and there were no subjects with >50% depletion of Factor VII activity relative to baseline.

If subsequent multi-dose trials demonstrate a treatment-related neutralizing immunological response in individuals, development of marzeptacog alfa (activated) or of CB 2679d/ISU304 could be halted.

Our product candidates are years away from regulatory approval.

Marzeptacog alfa (activated) and CB 2679d/ISU304 are not expected to be commercially available for several years, if at all. Further, the commercial success of either product candidate will depend upon its acceptance by physicians, individuals, third-party payors and other key decision-makers as a therapeutic and cost effective alternative to products available at the time, which may include competing products currently under development by others. See “We face substantial competition that, may result in others discovering, developing or commercializing products before or more successfully than we do.” If we are unable to successfully develop, obtain regulatory approval for and commercialize marzeptacog alfa (activated) or CB 2679d/ISU304, our ability to generate revenue from product sales will be significantly delayed and our business will be materially and adversely affected, and we may not be able to earn sufficient revenues to continue as a going concern.

Even if the FDA or other regulatory agency approves marzeptacog alfa (activated) or CB 2679d/ISU304, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product and may impose ongoing commitments or requirements for post-approval studies, including additional research and development and clinical trials. The FDA and other agencies also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval. Regulatory approval from authorities in foreign countries will be needed to market marzeptacog alfa (activated) or CB 2679d/ISU304 in those countries. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. If we fail to obtain approvals from foreign jurisdictions, the geographic market for marzeptacog alfa (activated) or CB 2679d/ISU304 would be limited.

We face substantial competition that may result in others discovering, developing or commercializing products before or more successfully than we do.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. We face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies, and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Specifically, there are a large number of companies developing or marketing treatments for hemophilia, including many major pharmaceutical and biotechnology companies, including Novo Nordisk, which has developed NovoSeven, a human recombinant coagulation Factor VIIa indicated for treatment of bleeding episodes that has been approved for use in treatment of hemophilia A or B individuals with inhibitors to Factor VIII or Factor IX and in individuals with Factor VII deficiency and Glanzmann's thrombasthenia, Baxter, which has developed BAX 817, a biosimilar of NovoSeven that recently completed an intravenous Phase 3 clinical trial and has been filed for marketing approval, Roche, which is developing ACE910/Emicizumab, a recombinant humanized bispecific antibody that binds to activated Factor IX and Factor X and mimics the cofactor function of Factor VIII and has been granted breakthrough therapy designation by the FDA to potentially treat hemophilia A, and Alnylam, which is developing an investigational RNAi therapeutic targeting antithrombin for the treatment of hemophilia. We are also aware of many companies focused on developing gene therapies that may compete with our planned hemophilia B indication, as well as several companies addressing other methods for modifying genes and regulating gene expression.

Our commercial opportunity in different indications could be reduced or eliminated if competitors develop and market products or therapies that are more convenient to use, more effective, less expensive, and safer to use than our products. Furthermore, if competitors gain FDA approval faster than we do, we may be unable to establish a strong market presence or to gain market share. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition, and the availability of reimbursement from government and other third-party payors.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and individual registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Raising additional funds by issuing equity securities, taking on debt or through licensing arrangements may cause dilution to stockholders, restrict our operations or require us to relinquish proprietary rights.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, stockholders may be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of common stockholders. In March 2016, we filed a shelf registration statement on Form S-3 with the SEC, which upon being declared effective on April 28, 2016, allows us to offer up to \$50 million of securities from time to time in one or more public offerings of our common stock. In addition, in March 2016, we entered into a Capital on Demand™ Sales Agreement with JonesTrading Institutional Services LLC ("JonesTrading"). In accordance with the terms of the sales agreement, as of October 31, 2016, we may offer and sell additional shares of our common stock having an aggregate offering price of up to \$5.5 million from time to time. Any additional sales in the public market of our common stock, under the agreement with JonesTrading or otherwise under the shelf registration statement, could adversely affect prevailing market prices for our common stock.

We may also seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. In addition, debt financing, if available at all, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates or future revenue streams or grant licenses on terms that are not favorable to us. There can be no assurance that we will be able to obtain additional funding if and when necessary. If we are unable to obtain adequate financing on a timely basis, we could be required to delay, curtail or eliminate one or more, or all, of our development programs or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our failure to meet the continued listing requirements of The NASDAQ Capital Market could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of The NASDAQ Capital Market, such as the corporate governance requirements or the minimum closing bid price requirement, which requires that the closing price of our Common Stock not be below \$1.00 per share for thirty (30) consecutive days, NASDAQ may take steps to de-list our common stock. Such a delisting would likely have a negative effect on the price of our common stock and our ability to raise capital, and could impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we would expect to seek to take actions to restore our compliance with NASDAQ's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the NASDAQ minimum bid price requirement or prevent future non-compliance with NASDAQ's listing requirements.

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.

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: November 3, 2016

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

Date: November 3, 2016

/s/ Fletcher Payne
Fletcher Payne
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Description
10.1*	Separation Agreement, dated September 14, 2016, between the Company and Edwin Madison (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on September 16, 2016).
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 September 30, 2016, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets as of September 30, 2016 (unaudited) and December 31, 2015; (ii) the Consolidated Statements of Comprehensive Income for the three and nine months ended September 30, 2016 and 2015 (unaudited); (iii) the Consolidated Statement of Stockholders' Equity as of September 30, 2016 (unaudited); (iv) the Consolidated Statements of Cash Flows for the nine months ended September 30, 2016 and 2015 (unaudited); and (v) the Notes to Unaudited Interim Consolidated Financial Statements.

* Denotes management contract, compensatory plan or arrangement.

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: November 3, 2016

/s/ Nassim Usman, Ph.D.

Nassim Usman, Ph.D.

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

I, Fletcher Payne, certify that:

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

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

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

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

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

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2016

/s/ Fletcher Payne

Fletcher Payne

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

In connection with the Quarterly Report on Form 10-Q of Catalyst Biosciences, Inc. (the "Company") for the period ended September 30, 2016 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: November 3, 2016

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

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

In connection with the Quarterly Report on Form 10-Q of Catalyst Biosciences, Inc. (the "Company") for the period ended September 30, 2016 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: November 3, 2016

/s/ Fletcher Payne

Fletcher Payne

Chief Financial Officer

(Principal Financial and Accounting Officer)