# **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 X 1934

For the quarterly period ended June 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)

> > $\mathbf{X}$

(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  $\boxtimes$  No  $\Box$ 

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  $\boxtimes$  No  $\Box$ 

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

Large accelerated filer		Accelerated filer	X
Non-accelerated filer	$\Box$ (Do not check if a smaller reporting company)	Smaller reporting company	X
ndicate by check mark whethe	r the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).	Yes 🗆 No 🗵	
As of July 29, 2016, the number	er of outstanding shares of the registrant's common stock, par value \$0.001 per share	, was 11,835,864.	

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ITEM 1. FINANCIAL STATEMENTS

# Catalyst Biosciences, Inc. Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)

		June 30, 2016 Jnaudited)	E	December 31, 2015
Assets	(-	,		
Current assets:				
Cash and cash equivalents	\$	11,333	\$	29,096
Short-term investments		12,617		3,402
Restricted cash		30,395		33,794
Deposits		5		133
Accounts receivable		462		492
Prepaid and other current assets		1,479		1,781
Total current assets		56,291		68,698
Restricted cash, noncurrent		125		125
Property and equipment, net		803		698
Total assets	\$	57,219	\$	69,521
Liabilities and stockholders' equity			-	
Current liabilities:				
Accounts payable	\$	826	\$	939
Accrued compensation		682		926
Other accrued liabilities		456		535
Deposits		730		
Deferred revenue, current portion		437		438
Deferred rent, current portion		30		19
Redeemable convertible notes		30,344		33,743
Derivative liability		130		1,156
Total current liabilities		33,635		37,756
Deferred revenue, noncurrent portion		73		292
Deferred rent, noncurrent portion		29		48
Total liabilities		33,737		38,096
Stockholders' equity:				
Preferred stock, \$0.001 par value, 5,000,000 shares and 0 shares authorized and outstanding at June 30, 2016 and December 31, 2015;		_		_
Common stock, \$0.001 par value, 100,000,000 shares authorized at June 30, 2016 and December 31, 2015; 11,503,614 and 11,430,085 shares issued and				
outstanding at June 30, 2016 and December 31, 2015		12		11
Additional paid-in capital		162,924		162,450
Accumulated other comprehensive income		7		1
Accumulated deficit		(139,461)		(131,037)
Total stockholders' equity		23,482		31,425
Total liabilities and stockholders' equity	\$	57,219	\$	69,521

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

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

	Three Months Ended June 30,					Six Months Ended June 30,				
		2016	_	2015		2016		2015		
Contract revenue	\$	109	\$	859	\$	219	\$	1,531		
Operating expenses:										
Research and development		2,752		1,322		5,046		2,705		
General and administrative		2,272		1,738		4,658		4,060		
Total operating expenses		5,024		3,060		9,704		6,765		
Loss from operations		(4,915)		(2,201)		(9,485)		(5,234)		
Interest and other income, net		82		516		1,061		691		
Interest Expense				(39)		_		(39)		
Net loss	\$	(4,833)	\$	(1,724)	\$	(8,424)	\$	(4,582)		
Net loss per common share, basic and diluted	\$	(0.42)	\$	(4.60)	\$	(0.74)	\$	(12.26)		
Shares used to compute net loss per common share, basic and			_							
diluted		11,447,069	_	374,764		11,438,588		373,633		

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

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

	 Three Mon June	nded	_	Six Months Ended June 30,			
	2016		2015		2016		2015
Net loss	\$ (4,833)	\$	(1,724)	\$	(8,424)	\$	(4,582)
Other comprehensive income (loss):							
Unrealized gain on available-for-sale securities	3		—		6		—
Total comprehensive loss	\$ (4,830)	\$	(1,724)	\$	(8,418)	\$	(4,582)

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)

	Commo	n Stock			dditional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders' Equity		
	Shares	Amou	nt		nount		Capital	Income	Deficit	(Deficit)
Balance at December 31, 2015	11,430,085	\$	11	\$	162,450	\$ 1	\$ (131,037)	\$ 31,425		
Stock-based compensation expense	—		—		318	—	—	318		
Issuance of common stock, net of issuance costs	73,459		—		155	—	—	155		
Conversion of redeemable convertible notes to										
common stock	70		1		1			2		
Unrealized gain on available-for-sale securities			—		—	6	_	6		
Net loss	—		—			—	(8,424)	(8,424)		
Balance at June 30, 2016	11,503,614	\$	12	\$	162,924	\$7	\$ (139,461)	\$ 23,482		

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

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

	Six Months Ended June 30,		
	 2016	2015	
Operating Activities			
Net loss	\$ (8,424)	\$ (4	4,582
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	318		83
Depreciation and amortization	220		258
Non-cash interest expense	—		39
Gain on extinguishment of redeemable convertible notes	(89)		—
Change in fair value of warrant liability	—	(	(595
Change in fair value of derivative liability	(937)		—
Changes in operating assets and liabilities:			
Accounts receivable	30		8
Prepaid and other current assets	430		203
Accounts payable	(113)	1,	1,292
Accrued compensation and other accrued liabilities	(323)		504
Deferred rent	(8)		(26
Deferred revenue	(220)	(1,	1,531
Deposits	730		_
Net cash flows used in operating activities	 (8,386)	(4	4,347
Investing Activities	 		
Proceeds from maturities of investments	4,201		_
Purchase of investments	(13,409)		_
Change in restricted cash	_		(57
Purchases of property and equipment	(324)		_
Net cash flows used in investing activities	 (9,532)		(57
Financing Activities	 · · · · · · · · · · · · · · · · · · ·		
Release of restricted cash due to conversion and redemption of redeemable convertible			
notes	3,399		_
Payments for the redemption of redeemable convertible notes	(3,399)		_
Proceeds from issuance of common stock, net of issuance costs	155		_
Proceeds from issuance of convertible preferred stock, net of issuance costs	_	3	3,260
Proceeds from issuance of convertible notes to related parties	_	1,	1,893
Proceeds from the exercise of common stock options	_		13
Net cash flows provided by financing activities	 155	5	5,166
Net increase (decrease) in cash and cash equivalents	(17,763)		762
Cash and cash equivalents at beginning of period	29,096		1,544
Cash and equivalents at end of period	\$ 11,333		2,306

**Supplemental Disclosure of Non-Cash Investing and Financing Information:** Conversion of convertible notes to common stock

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

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#### 1. Nature of Operations

Catalyst Biosciences, Inc. (the "Company" or "Catalyst"), is a clinical-stage biotechnology company focused on engineering proteases as therapeutics for hemophilia, hemostasis and complement-mediated diseases. 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 noninterest 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 six 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 six months ended June 30, 2016. As of June 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.



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 June 30, 2016 and December 31, 2015 (*in thousands*):

 Level 1		Level 2	T	1.0		
		Level 2	1	Level 3		Total
\$ 10,922	\$	_	\$	_	\$	10,922
30,520		_		_		30,520
12,617		_		_		12,617
\$ 54,059	\$	_	\$		\$	54,059
\$ —	\$	_	\$	130	\$	130
\$ _	\$		\$	130	\$	130
\$ \$ \$ \$	30,520 12,617	30,520 12,617	30,520 — 12,617 —	30,520 — 12,617 —	$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$

(1) Included in Cash and Cash Equivalents on accompanying condensed consolidated balance sheets.

(2) \$30.4 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	vel 2		_	Total
\$ 28,927	\$		\$		\$	28,927
33,919		_		_		33,919
_		296		_		296
_		3,106		_		3,106
\$ 62,846	\$	3,402	\$	_	\$	66,248
\$ 	\$		\$	1,156	\$	1,156
\$ 	\$		\$	1,156	\$	1,156
	\$ 28,927 33,919  \$ 62,846	\$ 28,927 \$ 33,919  \$ 62,846 \$	\$ 28,927 \$ 33,919 296 3,106 \$ 62,846 \$ 3,402	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$

(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. Included in Short Term Investments on accompanying condensed consolidated balance sheets.

(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 conversion to common stock. See *Note* 6 for further detail.

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

	rivative iability
Balance as of December 31, 2015	\$ 1,156
Change in fair value included in interest and other income	(937)
Gain on extinguishment of redeemable convertible notes	(89)
Balance as of June 30, 2016	\$ 130

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 six months ended June 30, 2016:

	Six Months Ended June 30, 2016
Expected term	1.51
Expected volatility	83.9%
Risk-free interest rate	0.58%
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*):

June 30, 2016	A	mortized Cost	τ	Gross Inrealized Gains	-	Gross nrealized Losses	I	Estimated Fair Value
Money market funds	\$	10,922	\$		\$	_	\$	10,922
Restricted cash (money market funds)		30,520				_		30,520
U.S. government agency securities		12,610		7		_		12,617
Total financial assets	\$	54,052	\$	7	\$	_	\$	54,059
Classified as:					-			
Cash and cash equivalents							\$	10,922
Restricted cash (money market funds)								30,520
Short-term investments								12,617
							\$	54,059

December 31, 2015		Amortized Cost		Gross Unrealized Gains		Gross nrealized Losses	1	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	\$	66,247	\$	2	\$	(1)	\$	66,248
Classified as:	_							
Cash and cash equivalents							\$	28,927
Restricted cash (money market funds)								33,919
Short-term investments								3,402
							\$	66,248

As of June 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 and warrants were converted to common stock and warrants to purchase common stock upon the closing of the Merger.

As the recipients of the convertible promissory notes each had an equity ownership in the Company, the convertible promissory notes were considered to be a related-party transaction.

For the three and six months ended June 30, 2016 and 2015, the Company recognized interest expense of \$0 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 Company initially estimated the fair value of the conversion option using the Black-Scholes option-pricing valuation model with the following assumptions: expected term of 2.25 years, risk-free interest rate of 0.84%, expected volatility of 70.0%, anticipated future exchange rate of the Notes and a dividend yield of 0%.

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 six months ended June 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.

As of June 30, 2016, \$6.4 million of the Notes were redeemed and \$0.3 million of the Notes were converted into common stock since the Merger took effect. For the three and six months ended June 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	Av	Weighted- verage Exercise Price	Weighted-Average Remaining Contractual Term (Years)
Outstanding — December 31, 2015	2,199,509	\$	9.84	4.51
Options granted	190,500	\$	1.64	
Options forfeited	(72,608)	\$	22.69	
Outstanding — June 30, 2016	2,317,401	\$	8.76	4.60
Exercisable — June 30, 2016	1,581,243	\$	11.08	2.36
Vested and expected to vest — June 30, 2016	2,249,901	\$	8.91	4.45

#### 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 six months ended June 30, 2016 and 2015:

	 Six Months Ended June 30,						
	 2016	2015					
Employee Stock Options:							
Risk-free interest rate	1.41%	1.62%					
Expected term (in years)	5.92	6.16					
Dividend yield	_						
Volatility	75.02%	67.19%					
Weighted-average fair value of stock options granted	\$ 1.07 \$	0.16					

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

	Three Months ended June 30,			 Six Mont June	ded		
		2016		2015	2016		2015
Research and development	\$	55	\$	13	\$ 105	\$	24
General and administrative		110		28	213		61
Total stock-based compensation	\$	165	\$	41	\$ 318	\$	85

As of June 30, 2016, the Company had unrecognized employee stock-based compensation expense of \$1.5 million, related to unvested stock awards, which is expected to be recognized over an estimated weighted-average period of 2.98 years.

# 8. Collaborations

#### Pfizer

On August 20, 2013 the Company and Pfizer entered into an amendment to the Factor VIIa 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 June 30, 2016 and 2015 and \$0 and \$1.3 million during the six months ended June 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's 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 June 30, 2016 and 2015 and \$0.2 million for both of the six months ended June 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 \$0.5 million and \$0.7 million as of June 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 six months ended June 30, 2016 and 2015 (*in thousands, except share and per share data*):

	T	Three Months Ended, June 30,			hs Ended e 30,
	201	6	2015	2016	2015
Net loss, basic and diluted	\$	(4,833) \$	5 (1,724)	\$ (8,424)	\$ (4,582)
Weighted-average number of shares used in computing net					
loss per share, basic and diluted	11,44	47,069	374,764	11,438,588	373,633
Net loss per share, basic and diluted	\$	(0.42) \$	6 (4.60)	\$ (0.74)	\$ (12.26)

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

	June 30,	December 31,
	2016	2015
Options to purchase common stock	2,317,401	2,200,890
Common stock warrants	180,954	180,954
Redeemable convertible notes	3,301,846	3,671,745
Total	5,800,201	6,053,589

#### 10. Common Stock

On March 16, 2016, the Company entered into a Capital on Demand<sup>TM</sup> 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.

During the three and six months ended June 30, 2016, the Company sold 73,459 shares of common stock in the Capital on Demand<sup>TM</sup> program, in the open market at a weighted-average selling price of \$2.18 per share, for net proceeds (net of commissions) of \$0.2 million. The Company expensed approximately \$0.1 million of costs for the offering, excluding JonesTrading commissions. During the three and six months ended June 30, 2016 the Company charged \$0.004 million of these costs against additional paid-in capital, respectively. As of July 29, 2016 the Company had up to \$5.8 million of common stock available for sale under the Controlled Equity Offering<sup>TM</sup> program.

#### 11. Commitments and Contingencies

#### **Operating Leases**

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

	Minimum Lease Payments
2016	363
2017	745
2018	125
Total future minimum lease payments	1,233

#### **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 CB 813d 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 June 30, 2016 the Company is obligated to \$3.5 million in payments to CMC.

# 12. Subsequent events

On April 15, 2016, the Company 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 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 \$0.7 million was received and recorded as deposits as of June 30, 2016. Subsequently the Company amended the April 15, 2016 contract on July 27, 2016 and received the remaining \$0.3 million due thereunder together, with a warrant to purchase shares of Attenua's capital stock as additional consideration. In connection with the closing of the transaction on July 27, 2016, the Company recognized the cash deposit of \$0.7 million into other income.

#### 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 creating and developing novel medicines to address serious medical conditions. To date, we have focused our product development efforts in the fields of hemostasis, including the treatment of hemophilia and surgical bleeding, and inflammation, including the prevention of delayed graft function ("DGF") in renal transplants and the treatment of dry age-related macular degeneration ("Dry AMD"), a condition that can cause visual impairment or blindness for which there are no approved treatments. Our most advanced program is an improved next-generation coagulation Factor VIIa variant, CB 813d, which has successfully completed an intravenous Phase 1 clinical trial in severe hemophilia A and B patients. In addition to our lead Factor VIIa program, we have two other next-generation coagulation factors, a Factor IX variant, CB 2679d/ISU 304, which is in advanced preclinical development, and several Factor Xa variants that have demonstrated efficacy and safety in preclinical animal models. Proteases regulate several complex biological cascades, or sequenced biochemical reactions, including the coagulation cascade that controls bleeding (hemostasis) in hemophilia and non-hemophilia settings and the complement cascade that causes inflammation and tissue damage in certain diseases.

Our most advanced program is an improved next-generation coagulation Factor VIIa variant, CB 813d, which has 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 patients. We expect to advance CB 813d into a subcutaneous prophylaxis dosing trial in 2017, to be followed if successful by a pivotal clinical efficacy trial in hemophilia A and hemophilia B inhibitor patients. Based on our research, we estimate annual worldwide sales in 2014 for FDA-approved recombinant Factor VIIa products were approximately \$1.6 billion. In addition to our lead Factor VIIa program, we have a Factor IX variant, CB 2679d/ISU 304, which is in advanced preclinical development, and several Factor Xa variants, for which we have delayed initiating further research studies so that we can focus our efforts and resources on advancing CB 813d, our next generation Factor VIIa, and CB 2679d, our next-generation FIX, through Phase 2/3 and Phase 1/2 clinical trials, respectively. In addition to intravenous dosing, the substantially enhanced potency of CB 813d and CB 2679d/ISU 304 may allow efficacious prophylaxis for hemophilia inhibitor patients (CB 813d) or hemophilia B patients (CB 2679d/ISU 304), respectively, using subcutaneous administration, thereby achieving significant differentiation versus competing intravenous therapeutics, particularly for pediatric patients and prevention of micro bleeds. Consequently, the Company intends to evaluate subcutaneous dosing of CB 813d and CB 2679d/ISU 304 in preclinical models and, if appropriate, in clinical trials. Based on our research, we estimate annual worldwide sales in 2014 for FDA-approved Factor IX and Factor Xa-containing products were approximately \$1.8 billion.

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 June 30, 2016. Collaboration and license revenue related to the ISU Abxis agreement during both the three months ended June 30, 2016 and 2015 was \$0.1 million and \$0.2 million for both of the six months ended June 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 \$0.5 million as of June 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 \$1.7 million for the three months ended June 30, 2016 and 2015 and \$8.4 million and \$4.6 million during the six months ended June 30, 2016 and 2015, respectively. As of June 30, 2016, we had an accumulated deficit of \$139.5 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. Our operating costs have decreased since 2012 due to the termination of the research activities under the Pfizer agreement and other agreements, a restructuring of our operations that included a reduction in work force, and the focusing of our research programs.

We expect to incur significant expenses and increasing operating losses for at least the next several years as we continue the preclinical and clinical development of, 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 represents 100% of our total contract revenue for the three and six months ending June 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 six months ended June 30, 2016 and 2015 (in thousands):

	_	Three months ended June 30,			Six months ended June 30,				
		2016		2016 2015		2016			2015
Personnel costs	\$	1,099	\$	664	\$	2,027	\$	1,260	
Preclinical research		642		318		1,357		717	
Clinical Manufacturing		632		—		902		_	
Facility and overhead		379		340		760		728	
Total research and development expenses	\$	2,752	\$	1,322	\$	5,046	\$	2,705	

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.

We expect our 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. 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 our next-generation Factor VIIa variant CB 813d 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 CB 813d and will have a royalty free and perpetual license to use CMC's intellectual property to the extent reasonably necessary to make CB 813d, 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 and expect to incur additional 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.

#### 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 embedded redemption feature 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.

#### 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):

	Three Months Ended June 30,						
		2016		2015	C	hange (\$)	Change (%)
Contract revenue	\$	109	\$	859	\$	(750)	(87)%
Operating expenses:							
Research and development		2,752		1,322		1,430	108%
General and administrative		2,272		1,738		534	31%
Total operating expenses		5,024		3,060		1,964	64%
Loss from operations		(4,915)		(2,201)		(2,714)	123%
Interest and other income		82		516		(434)	(84)%
Interest expense		_		(39)		39	(100)%
Net loss	\$	(4,833)	\$	(1,724)	\$	(3,109)	180%

	Six Months Ended June 30,						
		2016		2015	(	Change (\$)	Change (%)
Contract revenue	\$	219	\$	1,531	\$	(1,312)	(86)%
Operating expenses:							
Research and development		5,046		2,705		2,341	87%
General and administrative		4,658		4,060		598	15%
Total operating expenses		9,704		6,765		2,939	43%
Loss from operations		(9,485)		(5,234)		(4,251)	81%
Interest and other income		1,061		691		370	54%
Interest expense				(39)		39	(100)%
Net loss	\$	(8,424)	\$	(4,582)	\$	(3,842)	84%

#### **Contract Revenue**

Contract revenue was \$0.1 million and \$0.9 million during the three months ended June 30, 2016 and 2015, respectively, a decrease of \$0.8 million, or 87%. The decrease in contract revenue was due primarily to the termination of our collaboration agreement with Pfizer in June 2015.

Contract revenue was \$0.2 million and \$1.5 million during the six months ended June 30, 2016 and 2015, respectively, a decrease of \$1.3 million, or 86%. 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 \$2.8 million and \$1.3 million during the three months ended June 30, 2016 and 2015, respectively, an increase of \$1.4 million, or 108%. The increase was due primarily to an increase of \$0.6 million related to manufacturing expenses for CB 813d, \$0.4 million in personnel-related costs in connection with increased development activities and hiring of additional development employees 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 \$5.0 million and \$2.7 million during the six months ended June 30, 2016 and 2015, respectively, an increase of \$2.3 million, or 87%. The increase was due primarily to an increase of \$0.9 million related to manufacturing expenses for CB 813d, \$0.8 million in personnelrelated costs in connection with increased research and development activities and hiring of additional development employees and an increase of \$0.6 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 \$2.3 million and \$1.8 million during the three months ended June 30, 2016 and 2015, respectively, an increase of \$0.5 million, or 31%. The increase was due primarily to an increase of \$0.2 million in personnel-related costs as a result of increased head count, \$0.2 million in other expenses related to operating as a public company and an increase of \$0.1 million in professional service costs, including patent-related legal costs and legal and accounting advisory services.

General and administrative expenses were \$4.7 million and \$4.1 million during the six months ended June 30, 2016 and 2015, respectively, an increase of \$0.6 million, or 15%. The increase was due primarily to an increase of \$0.6 million in personnel-related costs as a result of increased head count and \$0.4 million in other expenses related to operating as a public company, partially offset by a decrease of \$0.4 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 \$0.1 million and \$0.5 million during the three months ended June 30, 2016 and 2015, respectively, a decrease of \$0.4 million, or 84%. The decrease was due primarily to a \$0.5 million loss recognized related to the change in estimated fair value of warrant liability, partially offset by a \$0.1 million gain recognized, related to the change in fair value of the derivative liability.

Interest and other income was \$1.1 million and \$0.7 million during the six months ended June 30, 2016 and 2015, respectively, an increase of \$0.4 million, or 54%. The increase was due primarily to a \$1.0 million gain recognized, related to the change in fair value of the derivative liability, partially offset by \$0.6 million loss recognized related to the change in estimated fair value of warrant liability.

#### **Recent Accounting Pronouncements**

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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. The new standard 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. We may adopt the standard in either our first quarter of 2017 or 2018.

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 June 30, 2016, we had \$24.0 million of cash, cash equivalents and short-term investments. We have an accumulated deficit of \$139.5 million as of June 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 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<sup>TM</sup> 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 six months ended June 30, 2016, we sold 73,459 shares of our common stock in the Capital on Demand<sup>TM</sup> program, in the open market at a weighted-average selling price of \$2.18 per share, for net proceeds (net of commissions) of \$0.2 million.

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

	 Six Months Ended June 30,						
	2016		2015				
Cash used in operating activities	\$ (8,386)	\$	(4,347)				
Cash provided by (used in) investing activities	(9,532)		(57)				
Cash provided by financing activities	155		5,166				
Net increase (decrease) in cash and cash equivalents	\$ (17,763)	\$	762				

#### **Cash Flows from Operating Activities**

Cash used in operating activities for the six months ended June 30, 2016 was \$8.4 million, due primarily to a net loss of \$8.4 million, partially offset by the change in net operating assets and liabilities of \$0.5 million due primarily to a \$0.7 million increase in deposits related to a sale agreement with Attenua, Inc. relating to certain neural nicotinic receptor assets acquired from Targacept in the Merger and \$0.4 million increase in prepaid expenses and other current assets, partially offset by a \$0.3 million decrease in accrued compensation and other accrued liabilities, a \$0.2 million decrease in deferred revenue due to the recognition of revenue and a \$0.1 million decrease in accounts payable. Non-cash gains of \$0.9 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 \$0.3 million for stock-based compensation and \$0.2 million for depreciation and amortization.

Cash used in operating activities for the six months ended June 30, 2015 was \$4.3 million, due primarily to a net loss of \$4.6 million, the change in our net operating assets and liabilities of \$0.5 million due primarily to a \$1.5 million decrease in deferred revenue due to the amortization of upfront license fees from our collaborations, partially offset by a \$1.3 million increase in accounts payable, \$0.5 million increase in accrued liabilities and \$0.2 million decrease in prepaid expenses and other current assets. Non-cash gains of \$0.6 million related to the change in fair value of the warrant liability, which was offset by non-cash charges of \$0.3 million for depreciation and amortization and \$0.1 million for stock-based compensation.

#### **Cash Flows from Investing Activities**

Cash used in investing activities for the six months ended June 30, 2016 was \$9.5 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 \$4.2 million.

Cash provided from investing activities for the six months ended June 30, 2015 was \$0.1 million, due primarily to \$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 six months ended June 30, 2016 was \$0.2 million was primarily related to release of restricted cash of \$3.4 million related to the redemption of some of the redeemable convertible notes and \$0.2 million in net proceeds from issuance of common stock in at-the-market transactions, partially offset by payments of \$3.4 million related to the redeemable convertible notes.

Cash provided by financing activities for the six months ended June 30, 2015 was \$5.2 million, due primarily to proceeds received from the issuance of convertible preferred stock of \$3.3 million and convertible notes of \$1.9 million.

#### **Contractual Obligations**

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

	Payments due by period										
		Less than 1 year		1 to 3 years		3 to 5 years		More than 5 years		Total	
Contractual Obligations:											
Operating lease obligations(1)	\$	734	\$	499	\$		\$	—	\$	1,233	
CMC Manufacturing obligations <sup>(2)</sup>		3,504						—		3,504	
Total contractual obligations(3)(4)	\$	4,238	\$	499	\$		\$		\$	4,737	

<sup>(1)</sup> Represents future minimum lease payments under the non-cancelable sub-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) We are obligated to pay CMC \$3.8 million 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 not probable and 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 not probable and 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 Polices 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 six 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 June 30, 2016, we had cash and cash equivalents of \$24.0 million, which consisted of bank deposits and money market funds, and short-term investments of \$12.6 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 June 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 June 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 six 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 CB 813d, which is our only product candidate that has completed a Phase 1 clinical trial.

The failure of CB 813d to achieve successful clinical trial endpoints, delays in clinical trial commencement or in the clinical development of CB 813d generally, unanticipated adverse side effects related to CB 813d or any other adverse developments or information related to CB 813d would significantly harm our business, its prospects and the value of the company's common stock. We expect to advance CB 813d into a subcutaneous prophylaxis dosing trial during 2017, to be followed if successful by a pivotal clinical efficacy trial in hemophilia A and hemophilia B inhibitor patients. There is no guarantee that the results of this clinical trial, if it occurs, will be positive or will not generate unanticipated safety concerns. The Phase 1 clinical trial of CB 813d 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 CB 813d in patients who received the product candidate. One subject from the 18 µg/kg dose group developed a weak, transient and non-neutralizing anti-CB 813d antibody at a single time point of Day 60 post-dose. The positive anti-CB 813d 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 CB 813d, 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 patients, development of CB 813d could be halted. Even if the next trials of CB 813d are positive, CB 813d may require substantial additional trials and other testing before approving CB 813d for marketing. In addition, we anticipate, but have not yet commenced, a full evaluation of CB 813d or CB 2679d/ISU 304 for subcutaneous administration. Results from these preclinical studies may not be positive, including, for example, due to failure to achieve sufficient protective levels of CB 813d in blood circulation to prevent spontaneous bleeding or the development of inhibitory antibodies. If we move forward with subcutaneous study of CB 813d, we will have to complete an additional pharmacokinetic and pharmacodynamic subcutaneous dosing study prior to initiating the pivotal study.

Even if the FDA or other regulatory agency approves CB 813d, 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 CB 813d 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 CB 813d would be limited.

CB 813d is not expected to be commercially available in the near term, if at all. Further, the commercial success of CB 813d will depend upon its acceptance by physicians, patients, 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 CB 813d, 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.



# We are very early in our development efforts and have only one product candidate that has completed a Phase 1 clinical trial. All of our other product candidates are still in preclinical development. If we are unable to commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

We are very early in our development efforts and have only one product candidate that has completed a Phase 1 clinical trial, CB 813d. All of our other product candidates are still in preclinical development, and we have not yet commenced a full evaluation of CB 813d or CB 2679d/ISU 304 for subcutaneous administration. We expect to advance CB 813d into a subcutaneous prophylaxis clinical efficacy trial in hemophilia A and hemophilia B inhibitor patients. In addition, we expect that our collaborator ISU Abxis will initiate a Phase 1/2 subcutaneous clinical trial of CB 2679d/ISU 304, our next-generation Factor IX drug candidate for the treatment of patients with hemophilia B, in 2016. We have delayed initiating preclinical IND-enabling studies for our anti-C3 protease for the prevention of DGF and research studies for our Factor Xa, so that we can focus our efforts and resources on advancing CB 813d, our next generation Factor VIIa and CB 2679d, our next-generation FIX through Phase 2/3 and Phase 1/2 clinical trials respectively. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of these and other product candidates. The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical studies and clinical trials;
- · receipt of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities;
- · launching commercial sales of the products, if and when approved, whether alone or in collaboration with others;
- · acceptance of the products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement;
- · protecting our rights in our intellectual property portfolio; and
- maintaining a continued acceptable safety profile of the products following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

# 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 patients with inhibitors to Factor VIII or Factor IX and in patients 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 patient 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<sup>™</sup> Sales Agreement with JonesTrading Institutional Services LLC ("JonesTrading"). In accordance with the terms of the sales agreement, as of July 29, 2016, we may offer and sell additional shares of our common stock having an aggregate offering price of up to \$5.8 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.

# 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.

/s/ Nassim Usman, Ph.D.

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

/s/ Fletcher Payne

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

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Date: August 4, 2016

Date: August 4, 2016

# EXHIBIT INDEX

Exhibit Number	Description
10.1*	Development and Manufacturing Services Agreement, by and between CMC ICOS Biologics, Inc. and the Registrant, dated as of May 20, 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 June 30, 2016, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets as of June 30, 2016 (unaudited) and December 31, 2015; (ii) the Consolidated Statements of Comprehensive Income for the three and six months ended June 30, 2016 and 2015 (unaudited); (iii) the Consolidated Statement of Stockholders' Equity as of June 30, 2016 (unaudited); (iv) the Consolidated Statements of Cash Flows for the six months ended June 30, 2016 and 2015 (unaudited); and (v) the Notes to Unaudited Interim Consolidated Financial Statements.
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<sup>\*</sup> Confidential treatment has been requested with respect to certain portions of this Exhibit, which portions have been omitted and filed separately with the SEC as part of an application for confidential treatment.



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# DEVELOPMENT AND MANUFACTURING SERVICES AGREEMENT

This Development and Manufacturing Services Agreement (this "Agreement") is made as of May 20, 2016 ("Effective Date") between CMC ICOS BIOLOGICS, INC., a Washington corporation ("CMC"), and CATALYST BIOSCIENCES, INC., a Delaware Corporation ("Customer").

- CMC provides bioprocessing services to pharmaceutical and biotechnology companies;
- Customer wishes to contract with CMC for the provision of the Services pursuant to one or more Work Statements that may be entered into from time to time during the Term; and
- CMC is willing to perform the Services on the terms in this Agreement and the Quality Agreement.
- The parties have entered into a letter of agreement dated November 30, 2015 (the "LOA"), under which CMC provided certain services to the Customer, and a Confidentiality Agreement dated June 12, 2015 (the "Confidentiality Agreement"). Upon its execution, this Agreement shall supersede and replace the (i) LOA and all services performed thereunder shall be deemed to have been performed under this Agreement and (ii) Confidentiality Agreement and all disclosures thereunder shall be deemed to have been made under this Agreement.

Therefore, the parties agree as follows:

**1. DEFINITIONS.** Capitalized terms used in the main body of this Agreement but not otherwise defined in the main body are defined in Appendix I.

# 2. PERFORMANCE OF THE SERVICES

- 2.1 <u>Work Statements</u>. The Services will be described in one or more Work Statements. As of the Effective Date, the parties are entering into Work Statement No. 1 attached as Appendix III. From time to time during the Term, the parties may enter into additional Work Statements for the performance of Services. Each Work Statement will be signed by each party and will be governed by this Agreement.
- 2.2 <u>Standards</u>. CMC will use [\* \* \*] efforts to perform the Services and meet the Timeline and, where required by the Work Statements, comply with [\* \* \*]. The parties will evaluate CMC's efforts taking into account [\* \* \*].
- 2.3 <u>Totality of Services</u>. CMC will not perform any Services other than those described in the Work Statement. Due to the nature of the Services, however, changes to the Services may be necessary to achieve the Objective. If changes to the Services are necessary, the



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parties will [\* \* \*]. Changes to the Services may affect the Price and Timeline. For clarity, to the extent any Services need to be re-performed as a result of CMC's Fault, [\* \* \*].

#### 2.4 <u>Project Team</u>

- 2.4.1 Each party will name and notify the other party of its representatives who will form the project team and who will be responsible for planning, executing and discussing issues regarding the Services and communicating with the other party ("**Project Team**"). Each party will have one vote in determinations and approvals made by the Project Team. All determinations and approvals of the Project Team will require the [\* \* \*].
- 2.4.2 The Project Team will schedule meetings at regular intervals for the purpose of communicating updates on the performance of the Services and providing an initial forum for discussing and resolving any issues encountered with the Services. These meetings will be conducted by telephone or, if necessary, by face-to-face meetings. Each party is responsible for its own costs in attending these meetings.
- 2.4.3 Any decision by [\* \* \*] that amends the Services will not be binding unless it is recorded in writing and signed by [\* \* \*].
- 2.5 <u>Additional Batches of Product</u>. In the event that Customer so elects, CMC shall agree to enter into a Work Statement for the cGMP manufacture of one or more additional Batches of Product for use in Customer's clinical trials [\* \* \*].

#### CUSTOMER MATERIALS

3.

- 3.1 <u>Transfer</u>. Customer will use [\* \* \*] efforts to deliver and, with CMC's cooperation, transfer to the CMC Facility and CMC's personnel the Customer Materials and other information described in the Work Statement by the deadline in the Work Statement. To the extent relevant to the Services, that information will include[\* \* \*]. All information must be provided in written form and in English.
- 3.2 <u>Customer Assistance</u>. Customer will use [\* \* \*] efforts to promptly and, in any event, within [\* \* \*] after the request, make reasonably available to CMC suitably qualified and skilled employees or representatives to assist in the successful transfer of the Customer Know-How, Customer Materials and Process to CMC.
- 3.3 <u>MSDS</u>. At least [\* \* \*] before the delivery of the Customer Materials (including, where applicable, the Cell Line) Customer must provide to CMC an accurate and complete written risk assessment (in English) for genetically modified organisms that details the hazards, storage and handling recommendations for the Customer Materials (**"Materials and Safety Data Sheet"**).
- 3.4 <u>Return of Customer Materials</u>. Within [\* \* \*] Customer must notify CMC whether it wants CMC to return the Customer Materials to Customer or a third party storage facility or if it





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wants CMC to dispose of the Customer Materials, [\* \* \*]. If Customer fails to give the notice required by this Section 3.4 within[\* \* \*] after the completion of the relevant Services, CMC may, after providing at least [\* \* \*] prior written notification to Customer dispose of them [\* \* \*], or return them to the Customer [\* \* \*], in its sole discretion and without liability to Customer.

#### 4. TIMELINE CHANGES, SPECIFICATION AND CGMP CHANGES

#### 4.1 <u>Timeline Changes</u>

- 4.1.1. The parties may revise the Timeline [\* \* \*].
- 4.1.2 In addition, [\* \* \*].
- 4.2 Manufacturing; Specification and Quantities
  - 4.2.1 In performing the Manufacturing Services, CMC will use [\* \* \*] efforts to manufacture Product to meet the Specification then in effect where required by the Work Statement. [\* \* \*]. CMC must use [\* \* \*] efforts to manufacture Product to meet the Specification then in effect. If there is a failure of the Product to meet Specification then in effect, the parties shall investigate the reason for such failure in accordance with Section 6.10. If the investigation reveals that such failure to meet Specification arises due to CMC's Fault, [\* \* \*].
  - 4.2.2 The Specification may be revised by [\* \* \*].
  - 4.2.3 All quantities of Product are estimates only and except as expressly stated below in subsection (a) or as may be expressly stated in a Work Statement, [\* \* \*].
    - (a) [\* \* \*].
- 4.3 <u>Changes in cGMP</u>. If there are any material and unforeseen changes in cGMP or manufacturing regulations issued under law that impact the Services and:
  - 4.3.1 are specific to the Product and not of general requirement for biologics contract manufacturing services; or
  - 4.3.2 [\* \* \*];

then CMC must notify Customer and the parties must in good faith discuss ways to continue the Services [\* \* \*]. If the parties do not reach agreement [\* \* \*].





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# 5. MANUFACTURING CAPACITY AND CANCELLATION FEES

- 5.1 <u>Reservations and Scheduling</u>
  - 5.1.1 As of the Effective Date, and at the execution of each Work Statement, CMC will reserve Slots in its cGMP manufacturing suite for those cGMP Batches to be manufactured under the Manufacturing Services according to the then-current Timeline.
  - 5.1.2 If the Timeline is amended and that amendment affects the scheduled Slot for any Batch, CMC will update its manufacturing schedule and reserve a new Slot for each affected Batch. Unless otherwise requested by Customer, CMC will reserve those Slots as near in time to the existing vacated Slots as CMC's then-current schedule will permit, taking into account reserved slots under CMC's existing manufacturing schedule for its whole facility.
- 5.2 Cancellation or Delay of cGMP Batches resulting from Customer's actions or elections:
  - 5.2.1 Customer must pay CMC the Cancellation Fees stated below in Section 5.4, if [\* \* \*]
    - (a) [\* \* \*];
    - (b) [\* \* \*]
    - (C) [\* \* \*].
- 5.3 Non-Fault Delay or Cancellation of cGMP Batches:
  - 5.3.1 **Cancelled Batches**. Customer must pay CMC [\* \* \*] of the Cancellation Fees stated below in Section 5.4, if [\* \*\*];
    - (a) [\* \* \*].
  - 5.3.2 **Delayed Batches**. The parties agree that Customer will not be liable for any Cancellation Fees stated below in Section 5.4, if [\* \* \*].
- 5.4 Batch Cancellation and Delay Fees:
  - 5.4.1 CMC will use [\* \* \*] efforts [\* \* \*].
    - (a) If CMC is able to [\* \* \*].
    - (b) If CMC is able to [\* \* \*].



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5.4.2 In the event of an Affected Batch described in Section 5.2, [\* \* \*].

[\* \* \*].

#### 6. PACKAGING, DELIVERY, STORAGE, EXAMINATION, DEFECTS AND SAMPLES

6.1 <u>Packaging</u>. CMC will package all Cell Lines, Product and perishable Deliverables to be Delivered per CMC's applicable packaging SOPs, the Work Statement and Regulatory Obligations.

#### 6.2 <u>Delivery</u>.

- 6.2.1 CMC will provide Customer with [\* \* \*] of the anticipated date of Delivery of Product (which will be contemplated in the Timeline and CMC will use [\* \* \*] efforts to deliver the Product [\* \* \*] after the completion of the Batch. CMC will provide notice to Customer at least [\* \* \*] before CMC is to Deliver that Product.
- 6.2.2 Except as stated in Section 6.2.4 or in the Specifications, all Product that CMC manufactures under this Agreement will be released to Customer [\* \* \*]. Product will be considered "delivered" [\* \* \*] (**"Delivery"** or **"Delivered"**). Customer may arrange collection at any time during normal business hours on Business Days or other times as may be agreed by the parties.
- 6.2.3 CMC has no obligation to clear for export or import any Deliverables nor is CMC obligated to obtain, or assist Customer in obtaining, export or import licenses, consents or permissions.
- 6.2.4 CMC will deliver to Customer or Customer's designee by mail or electronic mail all Data, results, Batch records and Drug History Records within [\* \* \*] of the completion of the applicable Manufacturing Services.
- 6.3 <u>Release For Further Processing</u>. Subject to, and if permitted by, Regulatory Obligations, [\* \* \*] ("**Release For Further Processing**"). Any Product that is the subject of Release For Further Processing must, until the applicable Certificate of Analysis is issued by CMC:
  - 6.3.1 not be administered to any living organism;
  - 6.3.2 be handled by Customer with the utmost care as if it were an unknown substance; and
  - 6.3.3 be accepted at Customer's sole risk and liability for any use of such Product prior to delivery by CMC of the applicable Certificate of Analysis for such Product.





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CMC is not liable for any loss or damage caused by Product that is the subject of Release For Further Processing prior to the delivery by CMC of the applicable Certificate of Analysis for such Product.

- 6.4 <u>Title and Risk</u>. Title and risk of loss in the Deliverables transfers to Customer [\* \* \*].
- 6.5 <u>Storage and Transport</u>. If Customer elects to have a shipping company or other agent (**"Shipping Company"**) collect and transport the Product on Delivery, Customer must
  - 6.5.1 inform CMC of Customer's designated Shipping Company before the collection of the Product;
  - 6.5.2 coordinate with the Shipping Company for the shipment of the Product; and
  - 6.5.3 ensure that the Product is stored and transported in accordance with the Shipping Guidelines.
  - [\* \* \*]
- 6.6 <u>Storage</u>. If Customer or Customer's Shipping Company is unable to collect the Product at the time of Delivery, CMC will store the Product for a period of [\* \* \*], at Customer's request. Storage of the Product at CMC's premises after Delivery is at [\* \* \*] except that [\* \* \*]. If the Product has not been collected by Customer or Customer's Shipping Company within [\* \* \*], CMC will notify Customer. If Customer or Customer's Shipping Company fails to collect the Product within [\* \* \*] after the date of that notice, CMC may, [\* \* \*]. If CMC elects to continue to store the Product, [\* \* \*].
- 6.7 <u>Samples</u>. CMC must store samples of all cGMP Product released by CMC's quality department with a Certificate of Analysis for the period required by applicable Regulatory Obligations, which in the absence of a definitive time period is [\* \*\*] from the date of release or Delivery of the applicable Product. After the expiration of the relevant time period, [\*\*\*].
- 6.8 <u>Shipping Guidelines</u>. Customer's failure to comply with the Shipping Guidelines before or after serving a Defect notice (as defined below) shall [\* \* \*].
- 6.9 Examination of Products for Defects.
  - 6.9.1 Customer must [\* \* \*] examine and test the Products for (a) defect and non-conformity with any applicable cGMP standards that the Products are required to meet under this Agreement, and (b) in the case of Product manufactured to Specification and released with a Certificate of Analysis, the failure of the Product to meet Specification (each a "Defect"). [\* \* \*].
  - 6.9.2 Where any alleged Defect is identified, Customer must notify CMC in writing (**"Defect Notice**") within [\* \* \*] after receipt of the Certificate of Analysis applicable to such Product. To be effective, a Defect Notice must identify





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- (a) the Product;
- (b) the date of Delivery and collection;
- (c) reasonable detail of the Defect, including test results;
- (d) where applicable full disclosure of the methodology of all analytical tests performed on the Product and the results of those tests;
- (e) confirmation that the Products have been stored and transported in accordance with the applicable Shipping Guidelines or a declaration that any deviation from the Shipping Guidelines did not cause any such Defect; and
- (f) where the Customer asserts that the Defect is due to CMC, the reasons for that assertion.
- 6.9.3 In consultation with CMC, Customer must return samples of the Products that are subject to the Defect Notice in accordance with the Shipping Guidelines to CMC within [\* \* \*] after the date of the Defect Notice.
- 6.9.4 Following receipt of the Defect Notice, CMC must cooperate with Customer and [\* \* \*] investigate whether the Defect is due to CMC's Fault and must report to Customer within [\* \* \*] after receipt of the samples whether CMC accepts responsibility for the Defect.
- 6.9.5 If Customer fails to notify CMC of a Defect in any Product in accordance with the provisions and time limits stipulated in this Section 6.9, [\* \* \*].

#### 6.10 <u>Consequences of Defective Product</u>.

- 6.10.1 If Customer reasonably demonstrates that the Defect is due to CMC's Fault (including, for clarity, that the Product did not meet Specifications when delivered by CMC with a Certificate of Analysis) and not as a result of any third party or Customer action or inaction, [\* \* \*]. CMC will undertake those efforts [\* \* \*].
- 6.10.2 If there is a dispute regarding the existence or cause of a Defect ("**Disputed Product**"), [\* \* \*]. This process may involve Customer sending a representative and a sample of the Disputed Product to CMC, and the parties conducting[\* \* \*]. The parties must [\* \* \*] after completing those tests to resolve whether the Disputed Product is Defective due to CMC's Fault.
- 6.10.3 If the parties cannot resolve their dispute in the manner described above as to whether a Disputed Product meets the Specification or as to the cause of a Defective Product, [\* \* \*]



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- 6.11 <u>Rejected Product</u>. Customer must segregate and must not use any Product for any human clinical testing or trials after it becomes aware of a Defect relating to such Product. On a final determination that any Product is Defective as a result of CMC's Fault, [\* \* \*] all remaining Product to CMC, or (b) destroy all remaining Product, at CMC's election.
- 6.12 Examination and Correction of Non-Manufacturing Deliverables. Customer must, [\* \* \*] after delivery, examine and test the Deliverables (other than Products) for any non-conformity with any applicable standards that those Deliverables are required to meet under this Agreement. Where any alleged non-conformity is identified, Customer must [\* \* \*] after delivery of the Deliverable. To be effective, that notice must identify the Deliverable and provide reasonable detail of the non-conformity. From receipt of the notice, CMC must [\* \* \*] investigate whether the non-conformity is due to CMC's Fault and must report to Customer within [\* \* \*] after receipt of the notice whether it accepts responsibility for the non-conformity. If Customer reasonably demonstrates that the non-conformity is due to CMC's fault and not as a result of any third party or Customer action or inaction, then CMC will use [\* \* \*] to either [\* \* \*] replace or correct the Deliverable at [\* \* \*]; provided, that Customer has [\* \* \*] CMC of the non-conformity per this Section 6.12.
- 6.13 <u>Exclusive Remedies</u>. [\* \* \*].

#### 7. PRICE AND PAYMENT TERMS

- 7.1 <u>Amounts</u>. All amounts stated in this Agreement are denominated, and must be paid, in U.S. Dollars. Unless otherwise specifically stated in a Work Statement, the Price stated in the Work Statement is exclusive of [\* \* \*].
- 7.2 <u>Payment Schedule</u>. Unless a different payment schedule is provided in the Work Statement, CMC will issue invoices for the Price of Stages as follows:
  - 7.2.1 [\* \* \*]:
  - 7.2.2 [\* \* \*]:
- 7.3 <u>Incidental Costs</u>.
  - 7.3.1 <u>Raw Materials</u>. The costs for raw materials and handling are described in the Work Statement.
  - 7.3.2 External Analysis. The costs and handling for external analysis are described in the Work Statement.
  - 7.3.3 <u>Handling Fees</u>. [\* \* \*].
  - 7.3.4 <u>Other Fees</u>. [\* \* \*].
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7.4 <u>Payments</u>. Unless otherwise directed by CMC, all invoices must be paid by wire transfer of immediately available funds to the following account:

[\* \* \*]

Unless otherwise stated on an invoice, Customer must pay all undisputed amounts on invoices in full without any deductions within [\* \* \*] by CMC.

- 7.5 <u>Late Payments</u>. If any amount is not paid in full when due under this Agreement and such amount is not disputed in good faith by Customer, CMC may
  - 7.5.1 [\* \* \*], and
  - 7.5.2 if a payment is not received within [\* \* \*] of the applicable due date, [\* \* \*].
- 7.6 <u>Acceptance of Invoices</u>. All invoices will be considered accepted by Customer unless customer notified CMC to the contrary within [\* \* \*] after delivery of the applicable invoice.

# 8. INTELLECTUAL PROPERTY

- 8.1 <u>Pre-Existing Intellectual Property</u>. Each party [\* \* \*].
- 8.2 <u>CHEF1 Technology</u>. Notwithstanding anything to the contrary in this Agreement, [\* \* \*].
- 8.3 <u>Customer's Grant of License for the Services</u>. Customer hereby grants to CMC and its Affiliates for the Term a non-exclusive, royalty-free, sublicensable (but only to Affiliates and third party contractors), license [\* \* \*].
- 8.4 Intellectual Property Created in the Course of the Services. Without affecting Section 8.2, all data, information and Intellectual Property first generated by CMC in its performance of the Services and that is [\* \* \*] owned by Customer (**"Customer IPR"**). CMC hereby assigns and agrees to assign to Customer all right, title and interest of CMC in any Customer IPR. CMC shall (a) disclose promptly to Customer all Customer IPR, and (b) whether during or after the period of the Services with Customer, execute such written instruments and do such other acts as may be necessary in the opinion of Customer to obtain a patent, register a copyright or otherwise evidence or enforce Customer's rights in and to such Customer IPR.
- 8.5 <u>CMC IPR</u>. All Intellectual Property developed by CMC in the performance of the Services other than Customer IPR will be owned by CMC ("**CMC IPR**"). Customer hereby assigns to CMC all right, title and interest of Customer in any CMC IPR.
- 8.6 <u>License to CMC IPR</u>. Provided that Customer has satisfied its payment obligations under this Agreement, CMC hereby grants to Customer a perpetual, irrevocable (subject to the termination of this Agreement by CMC pursuant to Section 12.2), non-exclusive, royalty free, sublicensable, worldwide license to use CMC Intellectual Property Rights (including,





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for clarity, CMC's Pre-Existing IPR) and CMC IPR [\* \* \*] owned or controlled by CMC to the extent reasonably necessary to make, use, sell, offer to sell and import the Product and use (or have used) the Cell Line or Process to manufacture Product. [\* \* \*].

- 8.7 <u>Right to File for Protection</u>. Each party may file patent protection on any Intellectual Property it owns in accordance with Section 8.1, 8.2, 8.4 or 8.5, and the other party will [\* \* \*].
- 8.8 <u>Party's Name</u>. Except as otherwise provided in this Agreement or required by any applicable law, regulation or order of an administrative agency or court of competent jurisdiction, neither party shall use the name of the other party or of the other party's Affiliates, directors, officers or employees in any advertising, news release or other publication except that CMC may identify Customer by name as a customer of CMC.
- 8.9 <u>Third Party IPR and Confidential Information</u>. CMC will not use or incorporate any intellectual property of a third party ("Third Party Technology") or any other confidential or proprietary information of any third party in the performance of the Services, the development of the Process or into any Deliverable.
- 8.10 <u>No Implied Licenses</u>. Except for the licenses expressly granted in this Agreement, no rights or licenses are granted by implication, estoppel or otherwise.

#### 9. CONFIDENTIAL INFORMATION

- 9.1 The Recipient Party must
  - 9.1.1 Except as is authorized in Section 8.6, use the Confidential Information of the Disclosing Party only [\* \* \*] to carry out this Agreement;
  - 9.1.2 protect the Confidential Information of the Disclosing Party against unauthorized use or disclosure applying standards of care reasonably expected and no less stringent than the standards applied to protection of Recipient Party's own confidential information of a similar nature; and
  - 9.1.3 not disclose any Confidential Information of the Disclosing Party to any person or entity except to its Permitted Recipients but then only on a need-to-know basis to those Permitted Recipients who are bound by confidentiality restrictions as restrictive as this Section 9.
- 9.2 The obligations in Section 9.1 do not apply to information that:
  - 9.2.1. at the time of its disclosure by the Disclosing Party, was available to the public and could be obtained without reference to the Confidential Information by any person with no more than reasonable diligence;



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- 9.2.2 becomes generally available to the public other than by reason of a breach of this Agreement or any breaches of confidence by the Recipient Party or it's Permitted Recipients;
- 9.2.3 at the time of disclosure and as evidenced by the Recipient Party's written records, was lawfully already within its possession; or
- 9.2.4 is independently developed by the Recipient Party without reference to the Confidential Information of the Disclosing Party as evidenced by the Recipient Party's written records.
- 9.3 The Recipient Party may disclose certain Confidential Information of the Disclosing Party, without violating the obligations of this Agreement, to the extent that disclosure is required by and in compliance with a valid order of a court or other governmental body having jurisdiction, provided that the Recipient Party provides the Disclosing Party with reasonable prior written notice of the disclosure and makes a reasonable effort to obtain, or to assist the Disclosing Party in obtaining, a protective order preventing or limiting the disclosure.
- 9.4 If the Recipient Party or any of its Permitted Recipients becomes aware of any actual or potential unauthorized use or disclosure of the Confidential Information of the Disclosing Party, the Recipient Party must inform the Disclosing Party as soon as reasonably possible after it becomes aware of that actual or potential unauthorized use or disclosure. The Recipient Party must cooperate in any action that the Disclosing Party may decide to take.
- 9.5 Except as otherwise provided in this Agreement or otherwise required by law, neither Customer nor CMC will disclose any terms of this Agreement to any third party without the prior written consent of the other party except to its Permitted Recipients, investors, potential investors, potential acquirers of the Product or other professional advisers but then only on a need-to-know basis to those Permitted Recipients investors, potential investors, potential acquirers of the Product or other professional advisers who are bound by confidentiality restrictions as restrictive as this Section 9.
- 9.6 On the termination of this Agreement or at the request of the Disclosing Party, the Recipient Party must promptly return to the Disclosing Party any Confidential Information of the Disclosing Party then in its possession or control except where that Confidential Information is covered under surviving license rights between the parties. However, each party may retain in its legal files a single copy of any document that contains the Disclosing Party's Confidential Information solely for the purpose of determining the scope of the obligations under this Agreement. Neither party is obligated to destroy electronic files securely archived in accordance with its customary data retention policies.





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#### 10. LIMITED WARRANTIES

- 10.1 <u>Customer Warranties</u>. Customer warrants and represents to CMC that:
  - 10.1.1 Customer has [\* \* \*];
  - 10.1.2 [\* \* \*];
  - 10.1.3 to its knowledge, [\* \* \*]
  - 10.1.4 (a) to its knowledge, [\* \* \*].
- 10.2. <u>CMC Warranties</u>. CMC warrants, represents and covenants to Customer that:
  - 10.2.1 it has the necessary permits, facilities, third party contractors and skilled personnel that may be reasonably anticipated to be necessary of a biologics contract manufacturer for the regular provision of manufacturing and development services of biologic material;
  - 10.2.2 [\* \* \*];
  - 10.2.3. [\* \* \*];
  - 10.2.4 [\* \* \*];
  - 10.2.5 [\* \* \*]; and
  - 10.2.6 all Services will be conducted in a professional and workmanlike manner by personnel qualified to perform the Services.
- 10.3 <u>Disclaimer of All Other Warranties</u>. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, EXCEPT FOR THOSE EXPRESS WARRANTIES IN THIS SECTION 10, NEITHER PARTY MAKES OR GIVES ANY OTHER WARRANTIES, EXPRESS OR IMPLIED (WHETHER BY STATUTE, CUSTOM, COURSE OF DEALING OR OTHERWISE) AND EACH PARTY HEREBY DISCLAIMS ALL OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE OR USE, NON-INFRINGEMENT AND TITLE.

#### 11. INDEMNIFICATION

11.1 <u>CMC's Indemnity</u>. Customer must indemnify and defend and hold harmless CMC and its Affiliates and each of their respective directors and officers and Testing Laboratories ("**CMC Parties**") against any and all losses, demands, claims, liabilities, damages, costs and expenses (including court costs and reasonable attorneys' fees and expenses)



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("Claims") arising from a third-party (except with respect to claims described under Section 11.1.3) that the CMC Parties incur as a result of any:

- 11.1.1 alleged or actual infringement or misappropriation of any Intellectual Property rights of any third party to the extent arising from CMC's use of the Cell Line, Process, Customer Intellectual Property Rights or Customer Materials in the performance of the Services and/or manufacture of the Product;
- 11.1.2 claims resulting from the administration, use, handling, storage or other disposition of the Product or Drug Substance in any form, except to the extent (i) any such Claim arises from, is based on or results from any activity set forth in Section 11.2.1, 11.2.2, or 11.2.3, for which CMC is obligated to indemnify the Customer Parties under Section 11.2 or (ii) any such Claim arises from, is based on, or results from CMC's negligence, intentional misconduct or breach of this Agreement;
- 11.1.3 contamination or damage to CMC's operations or any facility caused by the Cell Line or Customer Materials except to the extent the Cell Line and Customer Materials were not handled in accordance with the Materials and Safety Data Sheet;
- 11.1.4 use of any Product that was the subject of a Release for Further Processing in accordance with Section 6.3 and such use was prior to receiving the Certificate of Analysis from CMC; and
- 11.1.5 any acts or omissions of any third party auditor of Customer.

The foregoing indemnity obligation shall not apply to the extent that the CMC Parties fail to comply with the indemnification procedures set forth in Section 11.3 and Customer's defense of the relevant Claims is prejudiced by such failure.

- 11.2 <u>Customer's Indemnity</u>. CMC must indemnify, defend and hold harmless Customer and its Affiliates and each of their respective directors and officers ("**Customer Parties**") against any and all Claims arising from a third-party (except with respect to claims described under Section 11.2.1 and 11.2.2) that the Customer Parties incur as a result of any:
  - 11.2.1 material inaccuracy in a Certificate of Analysis such that the certified Product at the time of Delivery does not meet the Specification when certified to meet it;
  - 11.2.2 failure of CMC to manufacture the Product according to cGMP when the Product is released by CMC at the time of Delivery as a cGMP Product; and
  - 11.2.3 actual or alleged infringement or misappropriation of any Intellectual Property rights of any third party to the extent that infringement or misappropriation is due to the Process developed as part of the Services but excluding claims to the extent the infringement or misappropriation is caused by the use of the Process



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developed as part of the Services in combination with the Cell Line, Customer Materials, Process supplied by the Customer, or Customer Intellectual Property Rights.

The foregoing indemnity obligation shall not apply to the extent that the Customer Parties fail to comply with the indemnification procedures set forth in Section 11.3 and CMC's Customer's defense of the relevant Claims is prejudiced by such failure.

- 11.3 Indemnification Procedure. The party ("Indemnitee") that claims indemnification under this Section 11 must:
  - 11.3.1 promptly, and in any event within [\* \* \*] of it receiving notice of the Claim, notify the other party (**"Indemnitor"**) in writing of the Claim; provided, that failure to give that notice will not relieve the Indemnitor of its indemnification and defense obligations except to the extent the failure materially prejudices the ability of the Indemnitor to defend against the Claim;
  - 11.3.2 permit the Indemnitor to control the defense of the Claim; and
  - 11.3.3 have the right (at the Indemnitee's expense) to participate in the defense of the Claim.
- 11.4 <u>Settlement</u>. The Indemnitor must not settle or consent to an adverse judgment in any Claim indemnified by the Indemnitor that adversely affects the interests of the Indemnitee or imposes additional obligations on the Indemnitee, without the prior written consent of the Indemnitee.
- 11.5 <u>IP Claims</u>. Each party must [\* \* \*] (and within [\* \* \*] if permissible under applicable law or stock exchange rules) notify the other party of any third party allegation of infringement or misappropriation of any third party Intellectual Property rights due to the handling, storage or use of the Cell Line, Customer Materials, Customer Intellectual Property Rights or CMC Intellectual Property Rights or the manufacture of the Product.

#### 12. TERM AND TERMINATION

- 12.1 <u>Term</u>. The term of this Agreement commences on the Effective Date and terminates on the later of [\* \* \*] unless sooner terminated in accordance with Section 4.4, 12.2, 12.3, 12.4, 12.5 or 15.1 or extended by mutual written agreement of the parties (**"Term"**).
- 12.2 <u>Termination for Default</u>. Either party (**"Non-Defaulting Party"**) may terminate this Agreement on notice to the other party (**"Defaulting Party"**) if
  - 12.2.1 the Defaulting Party fails to pay any amount payable under this Agreement within [\* \* \*] after the due date;



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- 12.2.2 the Defaulting Party commits a material breach of its obligations under this Agreement and fails to remedy it during a period of [\* \* \*] starting on the date of receipt of notice from the Non-Defaulting Party identifying the breach and requiring it to be remedied;
- 12.2.3 a petition is filed against the Defaulting Party for an involuntary proceeding under any applicable bankruptcy or other similar law and that petition has not been dismissed within [\* \* \*] after filing or a court having jurisdiction has appointed a receiver, liquidator, trustee or similar official of the Defaulting Party for any substantial portion of its property, or ordered the winding up or liquidation of its affairs; or
- 12.2.4 the Defaulting Party commences a voluntary proceeding under applicable bankruptcy or other similar law, has made any general assignment for the benefit of creditors, or has failed generally to pay its debts as they become due.

#### 12.3 <u>Termination for Convenience</u>.

- 12.3.1 Customer may terminate this Agreement or any Stage of the Services at any time before completion of the Services or Stage by giving no less than [\* \* \*] notice in writing to CMC detailing the Stages of the Services that are to be terminated.
- 12.3.1 CMC may terminate this Agreement at any time after the completion of all Stages under all Work Statements by giving [\* \* \*] to Customer.

#### 12.4 <u>Termination for Scientific or Technical Difficulties</u>.

CMC may terminate this Agreement or any Stage on [\* \* \*] notice if CMC reasonably concludes that it cannot technically or scientifically deliver the Services contemplated by this Agreement or any Stage despite applying its[\* \* \*] efforts. During the [\* \* \*] notice period or when CMC notifies Customer that it has become aware that a technical or scientific problem has or may arise, the parties must in good faith discuss the difficulties and scientific and technical hurdles in an attempt to resolve those problems. If the parties agree during those discussions that the Services can be delivered then the notice to terminate will expire and this Agreement (or the Stage as the case may be) will continue in effect. If agreement cannot be reached this Agreement or Stage, at CMC's election, will terminate on expiration of the [\* \*\*] notice period. During the notice period, CMC will not undertake any new activities under the Services and will use [\* \*\*] efforts to promptly wind down the affected Services and to mitigate or otherwise minimize costs relating to such affected Services (including cancelling all revocable fees and expenses).

Customer may terminate this Agreement or any Stage on [\* \* \*] notice if Customer reasonably concludes that CMC cannot technically or scientifically deliver the Services contemplated by this Agreement or any Stage despite applying its [\* \* \*] efforts after a delay of greater than [\* \* \*] in the Timeline or upon the agreement of the parties, but only after the parties have discussed the difficulties and scientific and technical hurdles in an attempt to resolve those problems. If agreement cannot be reached as to a technical or





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scientific path forward this Agreement or Stage, at Customer's election, will terminate on expiration of the [\* \* \*] notice period. During the notice period, CMC will not undertake any new activities under the services and will use [\* \* \*] efforts to promptly wind down the affected Services and to mitigate or otherwise minimize costs relating to such affected Services (including cancelling all revocable fees and expenses).

12.5 <u>Termination for Certain Unresolved Indemnity Claims</u>. If a Claim for indemnification is made under Section 11.1.1, 11.1.3 or 11.2.3 and the parties do not reach an agreement to settle or overcome the Claim within [\* \* \*]after notification under Section 11.3.1, the party to whom the indemnity Claim has been made, may, on [\* \* \*]notice in writing terminate this Agreement.

#### 12.6 Effect of Termination.

- 12.6.1 Upon termination of this Agreement for any reason Customer shall pay to CMC:
  - (a) payments due by Customer to CMC for Services performed up to and including the day of termination for all completed Stages and for partially completed Stages an amount calculated on a pro-rata basis taking into account the Price for the cancelled Stages (fairly determined by the Project Team taking into account FTE hours, materials, profit element and irreversible commitments incurred by CMC). Notwithstanding anything to the contrary, unless otherwise agreed upon by the parties (e.g., in the context of finalizing certain Stages of Services or otherwise preparing for a technology transfer), CMC shall use [\* \* \*] efforts to minimize all costs and expenses and to cease conducting the Services upon the receipt or delivery (as applicable) of notice of termination;
  - (b) To the extent applicable under Section 5.2, payments due pursuant to Section 5.2, to the extent not already included in the payments contemplated in this Section 12.6.1; and
  - (c) payments due at the time of termination pursuant to Section 7 and also in accordance with the payment terms in the Work Statement, to the extent not already included in the payments contemplated in this Section 12.6.1.
- 12.6.2 Upon termination of this Agreement for any reason, provided that Customer has paid all amounts outstanding, CMC will, within [\* \* \*]of (a) those payments having been made or (b) the date of termination of this Agreement, (whichever is the later) provide the Customer with all Deliverables then manufactured or generated and all transferable work in progress and all Product then manufactured and released, subject to Regulatory Obligations. Work in progress is transferred to Customer [\* \* \*].
- 12.7 <u>Survival</u>. Termination will not affect the accrued rights of CMC or Customer arising under this Agreement. The provisions of this Agreement, which by their terms or reasonable





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implication would continue beyond any termination or expiration of this Agreement, including without limitation Sections 1, 3.4, 7, 8, 9, 10, 11, 12.6, 13, 14 and 15 shall survive any termination or expiration of this Agreement to the degree necessary to permit their complete fulfillment or discharge.

#### 13. TECHNOLOGY TRANSFER

- 13.1 <u>Scope</u>. Upon termination or expiration or during the notice period for termination of this Agreement other than where Customer is the "Defaulting Party," Customer may seek assistance from CMC for the transfer to a single skilled and qualified manufacturer of the then-current Process solely for the purpose of manufacturing Product for Customer (**"Technology Transfer"**); [\* \* \*].
- 13.2 <u>Limits</u>. The obligations of CMC under Section 13.1 will only be exercisable by Customer within a period of [\* \* ] after the date of termination or expiration and CMC is not obliged to commit any human resources greater than [\* \* ]. [\* \* ].

#### 14. LIMITATIONS OF LIABILITY

- 14.1 Limitation of Liability. Except as provided in Section 14.3, CMC's aggregate liability to Customer for any loss or damage suffered by Customer as a result of breach of this Agreement or any other liability (including negligence, misrepresentation or claims under the indemnities) under this Agreement or in connection with the Services is limited, in the aggregate, to the lesser of [\* \*\*].
- 14.2 <u>Disclaimer of Certain Damages</u>. EXCEPT AS PROVIDED IN SECTION 14.3, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INCIDENTAL, INDIRECT, PUNITIVE, CONSEQUENTIAL (INCLUDING LOST PROFITS) OR SPECIAL DAMAGES ARISING OUT OF ITS BREACH OF THIS AGREEMENT OR ANY OTHER LIABILITY (INCLUDING NEGLIGENCE, MISREPRESENTATION OR CLAIMS UNDER THE INDEMNITIES) ARISING IN CONNECTION WITH THIS AGREEMENT, EVEN IF THOSE DAMAGES WERE FORESEEABLE AND WHETHER THOSE DAMAGES ARISE IN TORT, IN CONTRACT OR OTHERWISE.
- 14.3 <u>Exclusions</u>. The limitations in Sections 14.1 and 14.2 do not apply to (a) claims arising from either party's gross negligence;
   (b) liability for any fraud or fraudulent misrepresentation; (c) amounts owing by a party under Section 7; or (d) [\* \* \*] or (e) [\* \* \*].

# 15. MISCELLANEOUS

15.1 <u>Excused Performance</u>. CMC will not be liable to Customer nor be considered to have breached this Agreement for failure or delay in performing to the extent, and for so long as, the failure or delay is caused by or results from a force majeure, Such excuse shall be continued so long as the condition constituting force majeure continues and CMC takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the reasonable control of the Parties, including without limitation an act of God, war, civil commotion, terrorist act, labor strike or lock-out,





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epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe. CMC must notify Customer of any force majeure event that prevents CMC from performing the Services. If a force majeure event continues for more than [\* \* \*] after CMC's notice, and is adversely affecting the performance of this Agreement, each party will have the right terminate this Agreement on [\* \* \*]. In that event, Customer will not have any claim for damages as a result of the termination or non-performance of the Services; provided CMC will reimburse Customer for all fees paid by Customer less costs incurred by CMC (if any) with respect to such affected Services and for clarity, Customer will have no obligation to pay CMC for Services which cannot be performed as a result of a force majeure.

- 15.2 Insurance. During the Term and [\* \* \*] thereafter, CMC must maintain a comprehensive general liability insurance against claims for bodily injury or property damage arising from CMC's activities in performing the Services as well as claims for which CMC is obligated to indemnify, defend and hold harmless the Customer Parties pursuant to Section 11.2, with insurance companies and in amounts as CMC customarily maintains for similar activities, but in all events, no less than CMC's coverage limits on the Effective Date. Customer must during the Term and for the longer of [\* \* \*].
- 15.3 <u>Press Release</u>. CMC will not issue any press release to announce the collaboration under this Agreement without Customer's prior approval; provided if Customer issues a press release announcing the collaboration between the parties, CMC may issue such a press release but shall not disclose the Product or financial information.
- 15.4 <u>Amendment</u>. Other than as provided for elsewhere in this Agreement, any amendment of this Agreement (or any document entered into pursuant to this Agreement) will be valid only if it is in writing and signed by each party.
- 15.5 <u>Assignment</u>. Neither party may assign this Agreement without the prior written consent of the other party, such consent not to be unreasonably withheld, except that either party may assign this Agreement without the prior consent of the other party: (a) to a third party successor to all or substantially all of the business or assets relating to the Product (an "**Acquiror**"), whether in connection with a merger, consolidation or sale of assets or other transaction; or (b) to its Affiliate provided that the acquired party notifies the other of that transaction within [\* \* \*] after the earlier of the public announcement or closing of that transaction. Any permitted assignment shall be binding on the successors of the assigning Party. Any successor or assignee of rights and/or obligations permitted hereunder shall, in writing to the other Party, expressly assume performance of such rights and/or obligations. Any attempted or purported assignment in violation of this Section 15.5 shall be null and void.
- 15.6 <u>Subcontracting</u>. CMC may subcontract to (a) its Affiliates, any of the Services provided that the Affiliate may not further subcontract those Services; (b) Testing Laboratories, only those parts of the Services identified in the Work Statement; and (c) any other third party, any of the Services with the prior written consent of Customer (that consent not to be unreasonably withheld, delayed or conditioned). CMC will remain responsible for the





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activities of its subcontractors except to the extent that Customer requires CMC to use a subcontractor that Customer selects over CMC's objection.

- 15.7 <u>Waiver</u>. In no event will any delay, failure or omission (in whole or in part) in enforcing, exercising or pursuing any right, power, privilege, claim or remedy conferred by or arising under this Agreement or by law, be deemed to be or construed as a waiver of that or any other right, power, privilege, claim or remedy in respect of the circumstances in question, or operate so as to bar the enforcement of that, or any other right, power, privilege, claim or remedy, in any other instance at any time or times subsequently.
- 15.8 <u>Severability</u>. If any provision of this Agreement is found by any court or administrative body of competent jurisdiction to be invalid or unenforceable, that invalidity or unenforceability will not affect the other provisions of this Agreement which shall remain in full force and effect. The parties must, in the circumstances referred to in this Section 15.8, attempt to substitute for any invalid or unenforceable provision a valid or enforceable provision that achieves to the greatest extent possible the same effect as would have been achieved by the invalid or unenforceable provision.
- 15.9 <u>Notices</u>. Any notice or other communication given under this Agreement (including under Section 3.4 or 6.6) must be in writing and in English and signed by or on behalf of the party giving it and must be given by hand or by delivering it or sending it by prepaid post or overnight delivery service, to the address and for the attention of the relevant party set out in this Section 15.9 (or as otherwise notified by that party under this Section 15.9). Any notice will be deemed to have been received:
  - 15.9.1 if hand delivered or sent by prepaid overnight delivery service, at the time of delivery; or
  - 15.9.2 if sent by post, five Business Days from the date of posting.



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The addresses of the parties for the purposes of this Section 15.9 are:

# CMC ICOS Biologics, Inc.

22021 20th Ave. S.E. Bothell, Washington U.S.A. 98021

For the attention of: Legal Department

# **Catalyst Biosciences, Inc.** 260 Littlefield Avenue

South San Francisco, CA 94080

For the attention of: Vice President of Manufacturing Operations

Neither party has any obligation to notify any person or entity other than as provided in Section 15.9.

- 15.10 <u>Applicable Law</u>. This agreement will be interpreted and governed, and all rights and obligations of the parties determined, in accordance with the laws of the state of New York (regardless of choice of law provisions to the contrary). The parties waive application of the provisions of the 1980 U.N. Convention on Contracts for the International Sale of Goods, as amended.
- 15.11 <u>Dispute Resolution</u>. Before resorting to litigation, unless emergency relief is required by either party when either party will be free to resort to litigation, the parties must use their reasonable efforts to negotiate in good faith and settle amicably any dispute that may arise out of or relate to this Agreement (or its construction, validity or termination) (a "**Dispute**"). If a Dispute cannot be settled through negotiations by appropriate representatives of each of the parties, either party may give to the other a notice in writing (a "**Dispute Notice**"). Within [\* \* \*] of the Dispute Notice being given the parties must each refer the Dispute to their respective Chief Executive Officers who shall meet in order to attempt to resolve the dispute. If within [\* \*\*] of the Dispute Notice (a) the Dispute is not settled by agreement in writing between the parties or (b) the parties have failed to discuss the Dispute or use good faith negotiations, the Dispute may be submitted to and finally be settled by the state or federal courts located in the state of [\* \*\*].
- 15.12 <u>Relationship of the Parties</u>. Nothing in this Agreement operates to create a partnership or joint venture between the parties or authorizes either party to act as agent for the other. Neither party has authority to act in the name of or otherwise to bind the other in any way.
- 15.13 <u>Entire Agreement</u>. This agreement together with the Quality Agreement, and the documents referred to in it, constitutes the entire agreement and understanding of the parties and supersedes any previous agreement (including the Letter of Agreement between the parties dated November 20, 2015) between the parties relating to the subject matter of this Agreement. If any term of this Agreement conflicts with any term of



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the Quality Agreement, the conflicting term of this Agreement will prevail. This Agreement is written in English, and the English version of this Agreement will control.

- 15.14 <u>Counterparts</u>. This agreement may be executed in any number of counterparts.
- 15.15 [\* \* \*].





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THIS DEVELOPMENT AND MANUFACTURING SERVICES AGREEMENT has been executed by the parties on the date first written above.

# CMC ICOS Biologics, Inc.

Signature:	/s/Gustavo Mahler			
Print Name:	Gustavo Mahler			
Position :	President & CEO			
CATALYST BIOSCIENCES, INC.				
Signature:	/s/Nassim Usman, Ph.D.			
Name :	Nassim Usman, Ph.D.			
Position :	President & CEO			



# **APPENDIX I**

#### Definitions

"Affiliate" means, with respect to any entity, any other entity that directly or indirectly controls, is controlled by or is under common control with that entity. For this definition, "control" means that more than 50% of the controlled entity's shares or ownership interests representing the right to make decisions for that entity are owned or controlled, directly or indirectly, by the controlling entity.

"Batch" means [\* \* \*].

"Business Day" means any day that is not a Saturday, Sunday or U.S. public holiday.

"Cell Line" [\* \* \*].

"Certificate of Analysis" means CMC's standard form certificate of analysis confirming that Product to which the certificate relates meets the Specification and any other criteria identified on the certificate.

"cGMP" means Current Good Manufacturing Practices as promulgated under each of the following as in effect on the Effective Date and as amended or revised after the Effective Date: (a) the U.S. Food, Drug & Cosmetics Act (21 U.S.C. § 301 *et seq.*) and related U.S. regulations, including 21 Code of Federal Regulations (Chapters 210 and 211) and other FDA regulations, policies, or guidelines in effect at a particular time for the manufacture, testing and quality control of investigational drugs; and (b) the ICH guide Q7a "ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients" as applied to investigational drugs (Section 19).

"cGMP Batch" means a Batch that is stipulated in the Work Statement to be manufactured according to cGMP.

"cGMP Product" means Product manufactured under a cGMP Batch.

"CHEF1® Technology" means [\* \* \*].

"CMC Facility" means [\* \* \*].

"CMC Intellectual Property Rights" means [\* \* \*].

"CMC Know-How" means [\* \* \*].

"CMC's Fault" means [\* \* \*].

"Commencement Date" means, with respect [\* \* \*].

"**Confidential Information**" means information of a confidential nature and in any form (oral, written or otherwise) the use of which is governed according to the provisions of Section 9. For clarity, the Confidential Information of each party will include all information and materials disclosed by the parties and their representatives under the Confidentiality Agreement by and between the parties dated as of June 12, 2015.

"Customer Intellectual Property Rights" means Intellectual Property rights and Customer Know-How owned by Customer or licensed to Customer by a third party covering any aspect of the Services or materials, techniques or processes used in the Services.

"Customer Know-How" means all information, techniques and technical information known to Customer in connection with the Cell Line, Customer Materials or Process which is not known to CMC or of general public knowledge.

"Customer Materials" means the [\* \* \*].

"Deliverables" means the data, results and materials generated from the performance of the Services [\* \* \*].

"Development Services" means any or all parts of the development and manufacturing services to be conducted by CMC as fully described in the relevant Work Statement which are not subject to cGMP standards, for clarity the Development Services will include the full scale engineering batch.

"Manufacturing Services" means any or all parts of the development and manufacturing services to be conducted by CMC as fully described in the relevant Work Statement which are subject to cGMP standards.

"**Drug History Record**" means all lot disposition documentation relevant to a cGMP Batch to be provided to Customer with the Product from that cGMP Batch as described in the Work Statement, including a Certificate of Analysis.

"Drug Substance" means the biological or chemical entities described or classified in the Work Statement [\* \* \*].

"Intellectual Property" means all intellectual property rights, including patents, supplementary protection certificates, utility models, trademarks, database rights, rights in designs, copyrights (whether or not any of these are registered or capable of being registered) and including all applications and the right to apply for registered protection of the foregoing and all inventions, trade secrets, know-how, techniques and confidential information, and all rights and forms of protection of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the world, in each case for their full term and together with any renewals or extensions.

"Non-Fault Delay" means a delay in the Services to the extent caused by [\* \* \*].

"Objective" means the desired outcome of the Services as described in the Work Statement.

"Permitted Recipients" means the directors, officers, employees, Testing Laboratories or professional advisers who are required, on a need-to-know basis, in the course of their duties to receive and consider the Confidential Information for the purpose of enabling the relevant party to perform its obligations under this Agreement; provided, that those persons are under obligations of confidence no less onerous than those set out in Section 9 imposed on the Recipient Party.

"Price" means [\* \* \*].

"Process" means [\* \* \*].

"Product" means [\* \* \*].

"Quality Agreement" means the agreement between the parties defining the quality responsibilities, including cGMP standards, regarding the performance of the Services.

"Regulatory Obligations" means those mandatory regulatory requirements applicable in Europe and the U.S. to the manufacture of cGMP Product for human use.

"Scientific Delay" means a delay in the Services to the extent caused by [\* \* \*].

"Services" means any or all parts of the Development Services and Manufacturing Services to be conducted by CMC as fully described in the relevant Work Statement.

"Shipping Guidelines" means the storage and transport guidelines for the Product that are determined by mutual written agreement of the parties.

"Slot" means, with respect to CMC's cGMP manufacturing suite, the period of time the suite is reserved in preparation for and the performance of a Batch.

"Specification" means the specification of the Product either as defined in the Work Statement or as otherwise agreed between the parties or modified in accordance with Section 4.2.2.

"Stage" means a particular activity or series of conjoined activities that constitute a main step in the Services and that is more specifically identified in the Work Statement by the breakdown of the Services into numbered stages.

"Standard Operating Procedures" or "SOPs" means the standard operating procedures of CMC in place from time to time that define CMC's methods of performing activities applicable to the Services.

"Testing Laboratories" means any [\* \* \*].

"Timeline" means the non-binding estimated timeline for the performance of the Services as set out in the Work Statement.

"Work Statement" means the work statement attached as Appendix II and any other work statements that may be agreed on by the parties during the Term, as may be revised by [\* \* \*]. To be valid, a Work Statement must be signed by both parties.

# **APPENDIX II**

#### **Incidental Fees**

Storage Fees for Deliverables:

Handling Fee for Shipments:

Storage Fee:

#### Appendix III

#### WORK STATEMENT NO. 01

THIS WORK STATEMENT NO. 01 ("[\* \* \*] DMSA WS01") is dated as of May 20 2016 ("**Effective Date**") by and between CMC ICOS BIOLOGICS, INC. ("**CMC**"), CMC BIOLOGICS A/S ("**CMC**") and Catalyst Bioscience, Inc. ("**Customer**"), and upon execution will be incorporated into and governed by the terms and conditions of the Development and Manufacturing Services Agreement between Customer and CMC dated May 2016 (the "**Agreement**"). Capitalized terms used in this Work Statement but not otherwise defined will have the same meanings as set forth in the Agreement.

Customer engages CMC to provide the Services, as follows.

#### 1. <u>API/Drug Substance and Product</u>.

A recombinant human Factor VIIa (CB 813d). CB 813d is an improved version of this molecule with enhanced activity and longer halflife, thus requiring lower and fewer doses than the commercially available NovoSeven<sup>®</sup>.

2. <u>Services</u>. CMC will provide the following Services to Customer:

As described on the APPENDIX 1

3. <u>Facility(ies)</u>. The Services described above will be rendered at the following facilities of CMC:

[\* \* \*]

4. <u>Customer Materials</u>. Customer will provide to CMC the following materials to be used by CMC to perform the Services:

As described in the APPENDIX 1

5. <u>Customer Equipment</u>.

NA

- 6. <u>CMC Representative</u>. [\* \* \*], Sr. Director, Business Development, [\* \* \*], Tel: [\* \* \*]
- 7. <u>Customer Representative</u>. [\* \* \*], VP Manufacturing Operations, [\* \* \*], Tel: [\* \* \*]
- 8. <u>Compensation</u>. The total compensation due CMC for Services under this Work Statement is **Three Million, Seven Hundred Ninety**four Thousand, Five Hundred U.S. Dollars (\$3,794,500). If Customer elects to amend this Work Statement to add cGMP manufacture of one or more additional Batches of Product for use in Customer's clinical trials within [\* \* \*] of the Effective Date of this Work Statement, [\* \* \*].

CMC will invoice Customer for all amounts due under this Work Statement. Such amounts will be invoiced in [\*\*\*] to the attention of [\*\*\*] and per Payment Terms in 7.2 the Agreement:

Stage	Description	Estimated Price (USD)
[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]
	Total	\$3,794,500

[\* \* \*].

#### 9. <u>Incidental Fees</u>.

[\* \* \*]

#### 10. <u>Assumptions</u>.

The activities outlined in this proposal are based on the following assumptions.

[\* \* \*]

[Signatures on next page]

IN WITNESS WHEREOF the parties have caused this Work Statement No. 01 to be executed by their respective representatives duly authorized as of the day and year first above written.

# WORK STATEMENT AGREED TO AND ACCEPTED BY:

Catalyst Biosciences, Inc.		CMC ICOS BIOLOGICS, INC.	
Ву	/s/Nassim Usman, Ph.D.	Ву	/s/Gustavo Mahler
Print Name	Nassim Usman, Ph.D.	Print Name	Gustavo Mahler
Title	President & CEO	Title	President & CEO
Date	May 20, 2016	Date	May 23, 2016

# **APPENDIX 1**

#### SCOPE OF WORK

Stage 1 – [\* \* \*]

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Stage 4 - [* * *]
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Stage 6 - [* * *]
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Stage 7 – [* * *]
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Stage 8 – [* * *]
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Stage 9 - [* * *]
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Stage 10 - [* * *]
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Stage 11 - [\* \* \*]



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Stage 12 -[\* \* \*]

[\* \* \*]

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Stage 13 – [\* \* \*]

[\* \* \*]

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CONFIDENTIAL

Stage 14 - [\* \* \*]

[\* \* \*]

[\* \* \*]

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[\* \* \*]

CONFIDENTIAL

[\* \* \*]

CONFIDENTIAL

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# CONFIDENTIAL

All terms and conditions of the Agreement will apply to this Work Statement. In the event of any conflict between this Work Statement and the terms of the Agreement, the terms of the Agreement will control.

[Remainder of page left blank intentionally]

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APPENDIX IV

**Commercial Supply Terms** 

[\* \* \*].

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

I, Nassim Usman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Catalyst Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: August 4, 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: August 4, 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 June 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: August 4, 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 June 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: August 4, 2016

/s/ Fletcher Payne

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