UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2021

OR

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

For the transition period from _____ to _____

Commission file number: 000-51173

Catalyst Biosciences, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**56-2020050**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
611 Gateway Blvd., Suite 710 South San Francisco, California	**94080**
(Address of Principal Executive Offices)	**(Zip Code)**

(650) 871-0761
(Registrant's Telephone Number, Including Area Code)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock	CBIO	NASDAQ

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 8, 2021, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 31,409,707.

CATALYST BIOSCIENCES, INC.
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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 59,157	$ 30,360
Short-term investments	5,371	48,994
Accounts receivable	1,114	3,313
Prepaid and other current assets	8,322	6,843
Total current assets	73,964	89,510
Long-term investments	—	2,543
Other assets, noncurrent	869	528
Right-of-use assets	2,613	1,832
Property and equipment, net	1,091	433
Total assets	$ 78,537	$ 94,846
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,862	$ 5,931
Accrued compensation	2,548	2,476
Deferred revenue	853	1,983
Other accrued liabilities	8,144	6,743
Operating lease liability	1,844	663
Total current liabilities	17,251	17,796
Operating lease liability, noncurrent	550	981
Total liabilities	17,801	18,777
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized; zero shares issued and outstanding	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized; 31,392,618 and 22,097,820 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	31	22
Additional paid-in capital	443,069	390,803
Accumulated other comprehensive income	1	5
Accumulated deficit	(382,365)	(314,761)
Total stockholders' equity	60,736	76,069
Total liabilities and stockholders' equity	$ 78,537	$ 94,846

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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
License	$ —	$ 32	$ —	$ 15,100
Collaboration	2,299	861	4,898	3,817
License and collaboration revenue	2,299	893	4,898	18,917
Operating expenses:				
Cost of license	—	32	—	3,102
Cost of collaboration	2,307	879	4,926	4,030
Research and development	20,352	12,249	52,754	38,419
General and administrative	4,869	3,833	14,799	11,895
Total operating expenses	27,528	16,993	72,479	57,446
Loss from operations	(25,229)	(16,100)	(67,581)	(38,529)
Interest and other income (expense), net	(9)	67	(23)	1,195
Net loss	$ (25,238)	$ (16,033)	$ (67,604)	$ (37,334)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.80)	$ (0.73)	$ (2.23)	$ (2.05)
Shares used to compute net loss per share attributable to common stockholders, basic and diluted	31,379,755	22,072,243	30,382,231	18,199,575

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss	$ (25,238)	$ (16,033)	$ (67,604)	$ (37,334)
Other comprehensive loss:				
Unrealized loss on available-for-sale debt securities	(1)	(33)	(4)	(26)
Total comprehensive loss	$ (25,239)	$ (16,066)	$ (67,608)	$ (37,360)

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balance at December 31, 2020	—	$ —	22,097,820	$ 22	$ 390,803	$ 5	$ (314,761)	$ 76,069
Stock-based compensation expense	—	—	10,149	—	1,026	—	—	1,026
Issuance of common stock from stock grants and option exercises	—	—	38,058	—	182	—	—	182
Issuance of common stock for public offering, net of issuance costs of $3,563	—	—	9,185,000	9	49,241	—	—	49,250
Net loss	—	—	—	—	—	—	(22,438)	(22,438)
Balance at March 31, 2021	—	—	31,331,027	31	441,252	5	(337,199)	104,089
Stock-based compensation expense	—	—	13,713	—	983	—	—	983
Issuance of common stock from stock grants and option exercises	—	—	5,000	—	23	—	—	23
Unrealized loss on available-for-sale debt securities	—	—	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	—	—	(19,928)	(19,928)
Balance at June 30, 2021	—	—	31,349,740	31	442,258	2	(357,127)	85,164
Stock-based compensation expense	—	—	15,961	—	713	—	—	713
Issuance of common stock from stock grants and option exercises	—	—	26,917	—	98	—	—	98
Unrealized loss on available-for-sale debt securities	—	—	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	—	—	(25,238)	(25,238)
Balance at September 30, 2021	—	$ —	31,392,618	$ 31	$ 443,069	$ 1	$ (382,365)	$ 60,736

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balance at December 31, 2019	—	$ —	12,040,835	$ 12	$ 326,810	$ 34	$ (258,520)	$ 68,336
Stock-based compensation expense	—	—	7,817	—	805	—	—	805
Issuance of common stock from stock grants and option exercises	—	—	62,969	—	339	—	—	339
Issuance of common stock for public offering, net of issuance costs of $2,514	—	—	5,307,692	5	31,981	—	—	31,986
Unrealized gain on available-for-sale debt securities	—	—	—	—	—	106		106
Net loss	—	—	—	—	—	—	(4,053)	(4,053)
Balance at March 31, 2020	—	—	17,419,313	17	359,935	140	(262,573)	97,519
Stock-based compensation expense	—	—	16,048	—	834	—	—	834
Issuance of common stock for public offering, net of issuance costs of $2,045	—	—	4,615,384	5	27,950	—	—	27,955
Unrealized loss on available-for-sale debt securities	—	—	—	—	—	(99)	—	(99)
Net loss	—	—	—	—	—	—	(17,248)	(17,248)
Balance at June 30, 2020	—	—	22,050,745	22	388,719	41	(279,821)	108,961
Stock-based compensation expense	—	—	12,295	—	1,068	—	—	1,068
Issuance of common stock from stock grants	—	—	19,884	—	96	—	—	96
Unrealized loss on available-for-sale debt securities	—	—	—	—	—	(33)	—	(33)
Net loss	—	—	—	—	—	—	(16,033)	(16,033)
Balance at September 30, 2020	—	$ —	22,082,924	$ 22	$ 389,883	$ 8	$ (295,854)	$ 94,059

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

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

	Nine Months Ended September 30,	
	2021	2020
Operating Activities		
Net loss	$ (67,604)	$ (37,334)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,722	2,707
Depreciation and amortization	175	93
Changes in operating assets and liabilities:		
Accounts receivable	2,199	13,445
Prepaid and other assets	(2,028)	225
Accounts payable	(2,063)	(35)
Accrued compensation and other accrued liabilities	1,473	2,156
Operating lease liability and right-of-use asset	177	45
Deferred revenue	(1,130)	(14,236)
Net cash flows used in operating activities	(66,079)	(32,934)
Investing Activities		
Proceeds from maturities of short-term investments	46,162	74,082
Purchase of short-term investments	—	(91,742)
Purchases of property and equipment	(839)	(228)
Net cash flows provided by (used in) investing activities	45,323	(17,888)
Financing Activities		
Issuance of common stock for public offering, net of issuance costs	49,250	59,941
Issuance of common stock from stock grants and option exercises	303	435
Net cash flow provided by financing activities	49,553	60,376
Net increase in cash and cash equivalents	28,797	9,554
Cash and cash equivalents at beginning of the period	30,360	15,369
Cash and cash equivalents at end of the period	$ 59,157	$ 24,923
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Right-of-use assets obtained in exchange for operating lease liabilities	$ 1,850	$ —

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

1. Nature of Operations and Liquidity

Catalyst Biosciences, Inc. and its subsidiary (the "Company" or "Catalyst") is a fully integrated research and clinical development biopharmaceutical company with expertise in protease engineering, discovery, translational research, clinical development, and manufacturing. The Company is focused on advancing its protease product candidates in the fields of hemostasis and complement regulation. The Company is located in South San Francisco, California and operates in one segment.

The Company had a net loss of $67.6 million for the nine months ended September 30, 2021 and an accumulated deficit of $382.4 million as of September 30, 2021. The Company expects to continue to incur losses for the next several years. As of September 30, 2021, the Company had $64.5 million of cash, cash equivalents and short-term investments. Its primary uses of cash are to fund operating expenses, including research and development expenditures and general and administrative expenditures. Based on the current status of its research and development plans, the Company believes that its existing cash, cash equivalents and short-term investments as of September 30, 2021 will be sufficient to fund its cash requirements for at least the next 12 months from the date of the filing of this quarterly report. If, at any time, the Company's prospects for financing its research and development programs decline, the Company may decide to reduce research and development expenses by delaying, discontinuing or reducing its funding of one or more of its research or development programs. Alternatively, the Company might raise funds through strategic collaborations, public or private financings or other arrangements. Such funding, if needed, may not be available on favorable terms, or at all.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") and following the requirements of the Securities and Exchange Commission (the "SEC") for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP can be condensed or omitted. These financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair presentation of the Company's financial information. These interim results and cash flows for any interim period are not necessarily indicative of the results to be expected for the year ending December 31, 2021, or for any other future annual or interim period.

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, 2020 ("Annual Report").

Accounting Pronouncements Recently Adopted

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes.* The amendments in ASU 2019-12 are intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. The Company adopted ASU 2019-12 as of January 1, 2021, on a prospective transition basis. The adoption of ASU 2019-12 did not have a material impact on the Company's condensed consolidated financial statements.

New Accounting Pronouncements Recently Issued But Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, *Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). The main objective of ASU 2016-13 is to provide financial statement users with more decision-useful information about an entity's expected credit losses on financial instruments and other commitments to extend credit at each reporting date. To achieve this objective, the amendments in this update replace the incurred loss impairment methodology currently used today with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to develop credit loss estimates. ASU 2016-13 will be effective for the Company for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, using a modified retrospective approach. Early adoption

is permitted. The Company plans to adopt ASU 2016-13 and related updates as of January 1, 2023. The Company will assess the impact of adoption of this standard on its condensed consolidated financial statements.

In May 2021, the FASB issued ASU 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*. The amendments in ASU No. 2021-04 provide guidance to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. The amendments in this ASU No. 2021-04 are effective for all entities for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years, with early adoption permitted, including interim periods within those fiscal years. The Company plans to adopt ASU 2021-04 and related updates on January 1, 2022. The Company is currently evaluating the impact of adopting this ASU on its condensed consolidated financial statements.

Research and Development Expenses

Research and development costs are expensed as incurred. Nonrefundable advance payments for goods or services used in research and development are initially deferred and capitalized in prepaid and other current assets. The capitalized amounts are then expensed as the related goods are delivered or services are performed, or until it is no longer expected that the goods or services will be delivered. Research and development costs consist of payroll and other personnel-related expenses, laboratory supplies and reagents, contract research and development services, materials, and consulting costs, as well as allocations of facilities and other overhead costs. Under the Company's collaboration agreement with Biogen, certain specific expenditures are reimbursed by third parties. The Company recorded $1.9 million and $0.8 million during the three months ended September 30, 2021 and 2020, respectively, and $4.3 million and $3.8 million during the nine months ended September 30, 2021 and 2020, respectively, of research and development expense as cost of collaboration revenue related to the collaboration agreement with Biogen signed in December 2019.

Stock-Based Compensation

The Company measures the cost of employee, non-employee and director services received in exchange for an award of equity instruments based on the fair value of the award on the date of grant and recognizes the related expense over the period during which the employee, non-employee or director is required to provide service in exchange for the award on a straight-line basis. The estimated fair value of equity awards that contain performance conditions is expensed over the term of the award once the Company has determined that it is probable that performance conditions will be satisfied.

The Company uses the Black-Scholes option-pricing valuation model to estimate the grant-date fair value of stock-based awards. The determination of fair value for stock-based awards on the date of grant using an option-pricing model requires management to make certain assumptions regarding a number of variables. The Company elected to account for forfeitures when they occur. As such, the Company recognizes stock-based compensation expense, over their requisite service period, based on the vesting provisions of the individual grants.

3. Fair Value Measurements

For a description of the fair value hierarchy and the Company's fair value methodology, see "*Part II - Item 8 - Financial Statements and Supplementary Data - Note 3 – Summary of Significant Accounting Policies*" in the Company's Annual Report. There were no significant changes in these methodologies during the nine months ended September 30, 2021.

The following tables present the fair value hierarchy for assets and liabilities measured at fair value on a recurring basis as of September 30, 2021 and December 31, 2020 (*in thousands*):

	September 30, 2021			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds(1)	$ 59,157	$ —	$ —	$ 59,157
U.S. government agency securities(2)	2,514	—	—	2,514
Federal agency securities(2)	—	2,857	—	2,857
Total financial assets	$ 61,671	$ 2,857	$ —	$ 64,528

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds[1]	$ 30,360	$ —	$ —	$ 30,360
U.S. government agency securities[2]	37,837	—	—	37,837
Federal agency securities[2]	—	13,700	—	13,700
Total financial assets	$ 68,197	$ 13,700	$ —	$ 81,897

(1) Included in cash and cash equivalents on the accompanying condensed consolidated balance sheets.
(2) Included in short-term investments on the accompanying condensed consolidated balance sheets and classified as available-for-sale debt securities. $2.5 million of U.S. government agency securities as of December 31, 2020 are included in long-term investments on the accompanying condensed consolidated balance sheets due to the maturity being more than 12 months.

4. Financial Instruments

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

September 30, 2021	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds (cash equivalents)	$ 59,157	$ —	$ —	$ 59,157
U.S. government agency securities	2,513	1	—	2,514
Federal agency securities	2,857	—	—	2,857
Total financial assets	$ 64,527	$ 1	$ —	$ 64,528
Classified as:				
Cash and cash equivalents				$ 59,157
Short-term investments				5,371
Total financial assets				$ 64,528

December 31, 2020	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds (cash equivalents)	$ 30,360	$ —	$ —	$ 30,360
U.S. government agency securities	37,835	2	—	37,837
Federal agency securities	13,697	3	—	13,700
Total financial assets	$ 81,892	$ 5	$ —	$ 81,897
Classified as:				
Cash and cash equivalents				$ 30,360
Short-term investments				48,994
Long-term investments				2,543
Total financial assets				$ 81,897

There have been no material realized gains or losses on available-for-sale debt securities for the periods presented. As of September 30, 2021, the remaining contractual maturities of $5.4 million of available-for-sale debt securities were less than one year.

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, and other accrued liabilities approximate their fair values due to the short-term maturity of these instruments.

5. Lease

The Company leases office space for its corporate headquarters, located in South San Francisco, CA. The lease term is through April 30, 2023 and there are no stated renewal options. Operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term. In calculating the present value of the lease payments, the Company has elected to utilize its incremental borrowing rate based on the original lease term and not the remaining lease term. The lease

includes non-lease components (*e.g.*, common area maintenance) that are paid separately from rent based on actual costs incurred and therefore were not included in the right-of-use asset and lease liability but are reflected as an expense in the period incurred.

In April 2021, the Company entered into a license agreement (the "License Agreement") for the use of laboratory facilities in South San Francisco, CA, for an aggregated undiscounted future payment of $1.9 million. This License Agreement has an original lease term of one year and a renewal period of six months. This License Agreement commenced during the second quarter of 2021.

For the three and nine months ended September 30, 2021, the Company's operating lease expense was $0.5 million and $1.1 million, respectively. For the three and nine months ended September 30, 2020, the Company's operating lease expense was $0.2 million and $0.6 million, respectively. The present value assumptions used in calculating the present value of the lease payments were as follows:

	September 30, 2021	December 31, 2020
Weighted-average remaining lease term	1.3 years	2.3 years
Weighted-average discount rate	4.9%	5.7%

The maturity of the Company's operating lease liabilities as of September 30, 2021 were as follows *(in thousands)*:

Year Ending December 31,	Amount
Remaining in 2021	$ 498
2022	1,719
2023	259
Total undiscounted lease payments	2,476
Less imputed interest	(82)
Total operating lease liability	$ 2,394

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

	Nine Months Ended September 30,	
	2021	2020
Cash paid for amounts included in the measurement of lease liabilities	$ 977	$ 433
Prepaid cash payment for lease liabilities	208	—
Cash paid for operating leases that were included in operating cash outflows	$ 1,185	$ 433

6. Stock-Based Compensation

2018 Omnibus Incentive Plan

In June 2018, stockholders of the Company approved the Company's 2018 Omnibus Incentive Plan (the "2018 Plan"). The 2018 Plan had previously been approved by the Company's Board of Directors (the "Board") and the Compensation Committee (the "Committee") of the Board, subject to stockholder approval. The 2018 Plan became effective on June 13, 2018. On June 9, 2021, the stockholders of the Company approved an amendment to the 2018 Plan to increase the number of shares of common stock reserved for issuance by 2,500,000 shares to a total of 5,300,000 shares. The amendment became effective immediately upon stockholder approval.

Performance-Based Stock Option Grants

In February 2021, the Committee approved the issuance of option grants to purchase 647,000 shares of common stock for executive officers pursuant to the 2018 Plan, which will vest upon (a) the achievement of specified performance goals and (b) the grantees' continued employment during the service period specified in each grant.

The following table summarizes stock option activity under the Company's 2018 Plan and related information:

	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)
Outstanding — December 31, 2020	2,355,615	$ 8.59	8.0
Options granted	1,301,238	$ 5.73	
Options exercised	(5,000)	$ 4.63	
Options forfeited	(631,827)	$ 6.73	
Options expired	(569)	$ 582.27	
Outstanding — September 30, 2021	3,019,457	$ 7.65	7.9
Exercisable — September 30, 2021	1,468,499	$ 9.39	

Valuation Assumptions

The Company estimated the fair value of stock options granted using the Black-Scholes option-pricing model and a single option award approach. Due to its limited history as a public company and limited number of sales of its common stock, the Company estimated its volatility considering a number of factors including the use of the volatility of comparable public companies. The expected term of options granted under the Plan, all of which qualify as "plain vanilla" per SEC Staff Accounting Bulletin 107, is determined based on the simplified method due to the Company's limited operating history. The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the option. This fair value is being amortized ratably over the requisite service periods of the awards, which is generally the vesting period.

The fair value of employee stock options was estimated using the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Employee Stock Options:				
Risk-free rate	0.91%	0.39%	0.76%	0.96%
Expected term (in years)	6.0	6.1	6.0	5.8
Dividend yield	0.00%	0.00%	0.00%	0.00%
Volatility	90.95%	115.62%	93.34%	112.87%
Weighted-average fair value of stock options granted	$ 3.23	$ 4.61	$ 4.31	$ 5.17

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ 158	$ 493	$ 921	$ 1,151
General and administrative(1)	555	575	1,801	1,556
Total stock-based compensation expense	$ 713	$ 1,068	$ 2,722	$ 2,707

(1) Included in general and administrative for the three and nine months ended September 30, 2021 is stock-based compensation expense related to 15,961 shares and 39,823 shares, respectively, of common stock issued to certain board members in lieu of their cash compensation.

As of September 30, 2021, 3,037,815 shares of common stock were available for future grant and 3,019,457 options to purchase shares of common stock were outstanding. As of September 30, 2021, the Company had unrecognized employee stock-based compensation expense of $5.3 million, related to unvested stock awards, which is expected to be recognized over an estimated weighted-average period of 2.6 years.

7. Collaborations

Mosaic

In October 2017, the Company entered into a strategic research collaboration with Mosaic to develop intravitreal anti-complement factor 3 (C3) products for the treatment of dry Age-related Macular Degeneration (AMD) and other retinal diseases. The Company entered into two amendments to the Mosaic research collaboration agreements in December 2019 and May 2020. See Note 11, *Related Parties*.

ISU Abxis

In December 2018, the Company entered into an amended and restated license agreement with ISU Abxis (the "A&R ISU Abxis Agreement"), which amended and restated its previous license and collaboration agreement with ISU Abxis previously entered into in September 2013, as subsequently amended in October 2014 and December 2016 (the "Original ISU Abxis Agreement"). Under the A&R ISU Abxis Agreement, ISU Abxis will receive commercialization rights in South Korea to the Company's engineered Factor IX dalcinonacog alfa - DalcA and the Company will receive clinical development and commercialization rights in the rest of world (excluding South Korea) and manufacturing development and manufacturing rights worldwide (including South Korea). The A&R ISU Abxis Agreement eliminates the profit-sharing arrangement in the Original ISU Abxis Agreement and provides for a low single-digit royalty payment to ISU Abxis, on a country-by-country basis, for net product sales of DalcA by the Company or its affiliates in each country other than South Korea. Pursuant to the A&R ISU Abxis Agreement, the Company will also pay up to an aggregate of $19.5 million in milestone payments to ISU Abxis, including $2.5 million in regulatory and development milestone payments and up to $17.0 million in commercial milestone payments, if the applicable milestones are met. As of September 30, 2021, no milestones have been met.

Biogen

On December 18, 2019, the Company and Biogen International GmbH ("Biogen") entered into a License and Collaboration Agreement (the "Biogen Agreement"), under which the Company granted Biogen a worldwide, royalty-bearing, exclusive, with the right to sublicense, license ("Exclusive License") to develop and commercialize CB 2782-PEG and other anti-C3 proteases for potential treatment of dry age-related macular degeneration ("AMD") and other disorders. Pursuant to the Biogen Agreement, the Company will perform certain pre-clinical and manufacturing activities ("Research Services"), and Biogen will be solely responsible for funding the pre-clinical and manufacturing activities and performing IND-enabling activities, worldwide clinical development, and commercialization. The Company will provide the Research Services over a term of thirty months with Biogen having the option to extend the term for two additional twelve-month periods.

Under the terms of the Biogen Agreement, the Company received an up-front payment for the transfer of the Exclusive License (inclusive of certain know-how) of $15.0 million in January 2020. The Company is eligible to receive development milestones and sales milestones of up to $340.0 million. In addition, the Company is eligible to receive royalties in the range of single-digit to low double-digit percentage rates of annual net sales on a product-by-product and country-by-country basis. The Company will also receive reimbursements for costs associated with the performance of the Research Services.

The Company determined that the performance obligations under the Biogen Agreement were the Exclusive License and the Research Services. For the Exclusive License, the Company used the residual approach in determining the standalone selling price, or SSP, which includes the upfront payments, milestones and royalties. For the Research Services, the Company used the historical pricing approach for determining the SSP, which includes the reimbursement of personnel and out-of-pocket costs.

The Biogen Agreement will continue on a product-by-product and country-by-country basis until the tenth anniversary of the first commercial sale of the first product in a country, unless terminated earlier by either party as specified under the agreement.

For the nine months ended September 30, 2021, the Company recognized no license revenue from the Biogen Agreement. For the nine months ended September 30, 2020, the Company recognized $15.0 million in license revenue upon the transfer of the Exclusive License and the related know-how, and $0.1 million in license revenue for reimbursable out-of-pocket costs incurred.

The Company recognized $2.3 million and $0.9 million for the three months ended September 30, 2021 and 2020, respectively, and $4.9 million and $3.8 million for the nine months ended September 30, 2021 and 2020, respectively, in collaboration revenue for reimbursable third-party vendor, out-of-pocket and personnel costs incurred related to Research Services.

For the nine months ended September 30, 2021, the Company recognized $1.6 million in collaboration revenue from the beginning of period deferred revenue balance.

8. Net Loss per Share Attributable to Common Stockholders

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:

	September 30,	
	2021	2020
Options to purchase common stock	3,019,457	2,264,141
Common stock warrants	85	722
Total	3,019,542	2,264,863

9. Stockholders' Equity

In the first quarter of 2021, the Company issued and sold an aggregate of 9,185,000 registered shares of its common stock (including 485,000 shares sold pursuant to the exercise of the underwriters' overallotment option) at a price of $5.75 per share. The net proceeds to the Company, after deducting $3.6 million in underwriting discounts and commissions, and offering expenses, were approximately $49.3 million.

10. Commitments and Contingencies

Manufacturing Agreements

On May 20, 2016, the Company signed a development and manufacturing services agreement with AGC Biologics, Inc. ("AGC"), pursuant to which AGC will conduct manufacturing development of agreed upon product candidates. The Company currently has firm work orders with AGC to manufacture MarzAA and DalcA to support its clinical trials totaling $16.5 million and the payment obligations remaining as of September 30, 2021 were $3.6 million.

In July 2021, the Company entered into two separate agreements, one for additional clinical trial services for MarzAA, and another for the Company's screening and natural history of disease clinical studies related to CFI deficiency, with total payments of up to $3.2 million and $6.5 million, respectively. The Company can terminate these agreements at its discretion and upon termination will be responsible to pay for those services incurred prior to termination plus reasonable wind-down expenses.

On September 16, 2021, the Company signed a Manufacturing and Research and Development Studies Agreement to support the lyophilized drug product, CB4332. The agreement will cover analytical method qualification to support GMP manufacturing. The Company currently has firm work orders related to this agreement totaling $0.3 million and the payment obligations remaining as of September 30, 2021 were $0.3 million.

COVID-19

The current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting the Company's employees, potential trial participants and business operations. The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national, and international markets. The COVID-19 pandemic may disrupt the operations of the Company's manufacturers or disrupt supply logistics, which could impact the timing of deliveries and potentially increase expenses under the Company's agreements. The Company is actively monitoring the impact of COVID-19 and the possible effects on its financial condition, liquidity, operations, clinical trials, suppliers, industry and workforce. All required MarzAA supplies for the MAA-304 and MAA-202 studies have been manufactured.

11. Related Parties

On October 24, 2017, the Company announced a strategic research collaboration with Mosaic to develop intravitreal anti-complement factor C3 products for the treatment of dry AMD and other retinal diseases. Dr. Usman, the Company's Chief Executive Officer and a member of the Company's board of directors, and Mr. Lawlor, a member of the Company's board of directors, were also members of the board of directors of Mosaic. On December 21, 2018, the Company amended its collaboration agreement with Mosaic to, among other things, include certain additional products. According to the Mosaic collaboration agreement, as amended, the Company and Mosaic co-funded certain research.

On December 18, 2019, the Company entered into the second amendment to the Mosaic collaboration agreement following completion of the co-funded research. Pursuant to the second amendment, any future services provided by Mosaic will be performed on a fee-for-service basis.

In connection with the Biogen Agreement, the Company received a $15.0 million upfront license fee on January 10, 2020, see Note 7, *Collaborations*. As a result, the Company paid Mosaic a $3.0 million sublicense fee and recorded such payment as cost of license revenue for the nine months ended September 30, 2020.

On May 8, 2020, the Company entered into a subsequent amendment to the Mosaic collaboration agreement. As part of this amendment, the Company paid a one-time $0.8 million cash payment to Mosaic, and Mosaic is eligible to receive up to $4.0 million in potential future milestone payments related to regulatory and clinical development events for CB 2782-PEG and an additional anti-complement product candidate in lieu of the Company's obligations to pay Mosaic a double-digit percentage of funds the Company receives from Biogen or any other amounts the Company receives related to sublicense fees, research and development payments, or any other research, regulatory, clinical or commercial milestones and royalties on any other development candidates. The Company now owns one hundred percent of all future payment streams related to these product candidates.

As of June 30, 2020, Mosaic was no longer a related party.

12. Interest and Other Income (Expense), Net

The following table shows the detail of interest and other income (expense), net as follows (*in thousands*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Interest income	$ 7	$ 74	$ 35	$ 536
Miscellaneous income (expense)	(3)	—	8	679
Other	(13)	(7)	(66)	(20)
Total interest and other income (expense), net	$ (9)	$ 67	$ (23)	$ 1,195

13. Subsequent Events

Lease Amendment

In October 2021, the Company amended the License Agreement entered into in April 2021 to extend the lease term for a period of 12 months. The monthly lease payment during the extension period is approximately $0.1 million. The amended lease term will commence on May 1, 2022 and expire at the end of April 2023.

At-the-Market Equity Offering

On October 15, 2021, the Company entered into an Equity Distribution Agreement (the "ATM Agreement") with Piper Sandler & Co. ("Piper Sandler"), as sales agent, pursuant to which the Company may offer and sell, from time to time, through Piper Sandler, shares of the Company's common stock, par value of $0.001 per share, with aggregate gross sales proceeds of up to $50.0 million through an "at the market" equity offering program. The Company will pay Piper Sandler a commission of 3.0% of the gross proceeds of any shares sold. The Company also agreed to reimburse Piper Sandler for certain expenses incurred in connection with its services under the ATM Agreement, including up to $50,000 for legal expenses in connection with the establishment of the ATM Program.

Sales of shares of common stock under the ATM Agreement will be made pursuant to the registration statement on Form S-3 (File No. 333-253874), which was declared effective by the SEC on May 3, 2021, and a related prospectus supplement file with the SEC on October 15, 2021.

Other Event

On November 11, 2021, the Company made a strategic decision to stop the clinical development of MarzAA and focus solely on its complement programs and protease medicines platform. The strategic shift from late-stage hemophilia to earlier-stage complement development offers the Company a path forward for long-term success.

The Company implemented a restructuring plan under which it provided or will provide employees one-time severance payments upon termination, continued benefits for a specific period, and outplacement services. The Company expects to incur total expenses of approximately $0.6 million. The Company expects that the cash payments due under this restructuring will be approximately $0.4 million and $0.2 million in the fourth quarter of 2021 and first quarter of 2022, respectively. In the first quarter of 2022, the Company may also occur other charges or cash expenditures not currently contemplated due to events that occur as a result of, or associated with, the decision to stop clinical development of MarzAA.

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

Unless otherwise indicated, in this Quarterly Report on Form 10-Q, references to "Catalyst," "we," "us," "our" or the "Company" mean Catalyst Biosciences, Inc. and our subsidiary. The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited condensed consolidated financial statements and related notes that appear in this Quarterly Report on Form 10-Q (this "Report") and with the audited consolidated financial statements and related notes that are included as part of our Annual Report on Form 10-K for the year ended December 31, 2020 ("Annual Report").

In addition to historical information, this Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended ("the Exchange Act"). Forward-looking statements are identified by words such as "believe," "will," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "could," "potentially" or the negative of these terms or similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. For example, forward-looking statements include any statements regarding the strategies, prospects, plans, expectations or objectives of management for future operations, the progress, scope or duration of the development of product candidates or programs, clinical trial plans, timelines and potential results, the benefits that may be derived from product candidates or the commercial or market opportunity in any target indication, our ability to protect intellectual property rights, our anticipated operations, financial position, revenues, costs or expenses, statements regarding future economic conditions or performance, statements of belief and any statement of assumptions underlying any of the foregoing. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this report in Part II, Item 1A — "Risk Factors," elsewhere in this Report and in Part I - Item 1A – "Risk Factors" in the 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

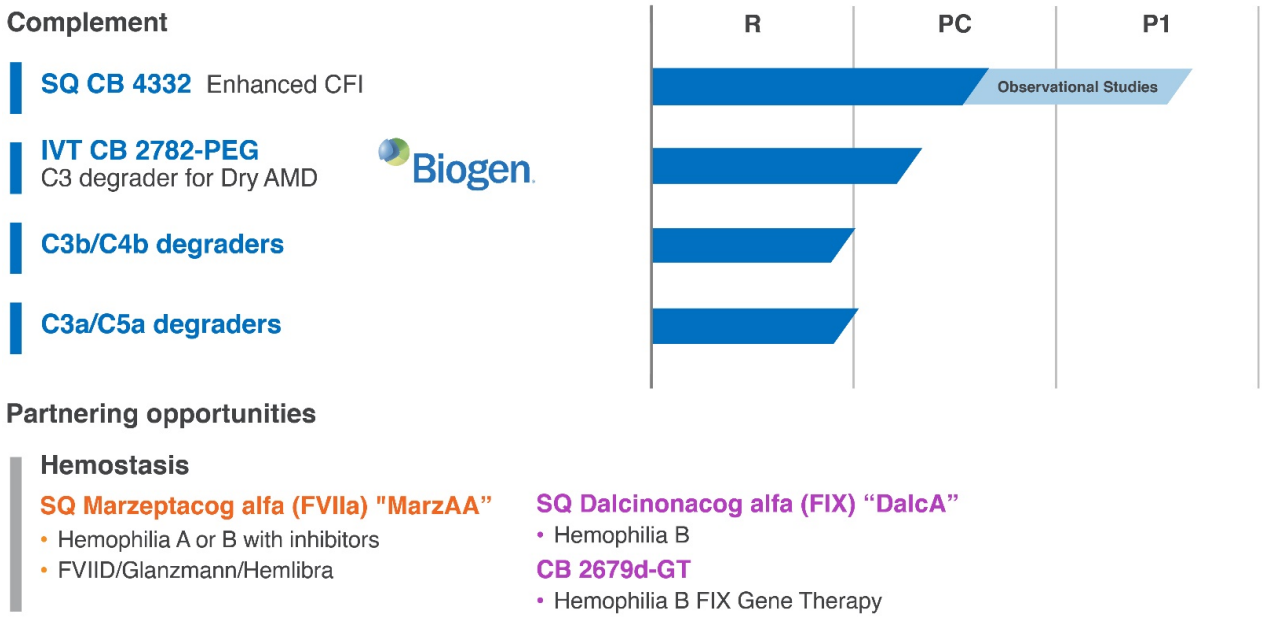
We are a research and clinical development biopharmaceutical company focused on developing protease therapeutics to address unmet medical needs in disorders of the complement system or where complement components are associated with progression of the disease state. Proteases are an important class of enzymes, which are the natural regulators of this biological system. We engineer proteases to create improved or novel molecules for treatment of diseases that result from dysregulation of the complement cascade. Our complement pipeline consists of a preclinical complement component 3 ("C3") degrader program licensed to Biogen International GmbH ("Biogen") for geographic atrophy ("GA") in dry age-related macular degeneration ("dAMD"), an improved Complement Factor I ("CFI") protease CB 4332 for subcutaneous ("SQ") replacement therapy in patients with CFI deficiency, and proteases from our ProTUNE™ C3b/C4b degrader and ImmunoTUNE™ C3a/C5a degrader platforms designed to target specific disorders of the complement or inflammatory pathways. Our pipeline also includes other complement programs in discovery, such as a complement Factor B degrader program using proteases engineered by our proprietary protease engineering platform. Historically, we also used our protein engineering platform to develop potential therapies for coagulation disorders, including marzeptacog alfa (activated) ("MarzAA"), a SQ administered next-generation engineered coagulation Factor VIIa ("FVIIa") for the treatment of episodic bleeding and prophylaxis in subjects with rate bleeding disorders, and dalcinonacog alfa ("DalcA"), a next-generation SQ FIX, which has shown sustained efficacy and safety in a Phase 2b clinical trial for prophylaxis in individuals with Hemophilia B.

The product candidates generated by our protease engineering platform are designed to have improved functional properties such as longer half-life, improved specificity and targeting, higher potency, and increased bioavailability. These characteristics potentially allow for improved safety and efficacy for SQ administration of recombinant complement regulators, or less frequently dosed intravitreal therapeutics than current therapeutics in development.

Our current complement portfolio consists of the development candidates CB 4332 and CB 2782-PEG. CB 4332 is a wholly owned, first-in-class improved CFI molecule intended for prophylactic SQ administration in individuals with CFI deficiency. CB 2782-PEG is a potential best-in-class C3 degrader product candidate in preclinical development for the treatment of dry AMD that we have licensed to Biogen. We have several engineered protease programs in discovery or early non-clinical development. These programs all target diseases caused by deficient regulation of the complement system and inflammation.

In July 2021 we commenced patient enrollment in the screening ("CFI-001") and natural history of disease ("CFI-002") studies to assess CFI blood levels in patients who have diseases related to CFI deficiency and identify those who would benefit from CB 4332 treatment ("ConFIrm" and "ConFIdence", respectively).

The following table summarizes our current development programs.



We continue to experience operational and other challenges as a result of the COVID-19 global pandemic, which could delay or impact our development programs. See Note 10, *Commitments and Contingencies* and Other Recent Developments and Item 1A - Risk Factors for further discussion of the current and expected impact on our business and development programs.

Recent Development Program Updates

Complement

We have several protease programs currently in preclinical discovery or early non-clinical development. These programs target diseases caused by aberrant regulation of the complement system. An ocular program for dry AMD is licensed to Biogen; the remaining complement programs are focused on systemic complement disorders and are wholly owned by Catalyst.

The complement system is an enzyme-based defense system and part of the innate immune system with a primary role of protecting the body from pathogens. Deficient or excessive activation of the complement system may lead to severe disorders, including microthrombotic, autoimmune and/or immune-complex diseases, and severe infectious diseases in a variety of tissues. The absence of regulation can cause the complement system to become self-destructive or not provide the necessary protection when needed. The protease therapeutic candidates generated by our platforms are designed to restore the missing balance in the complement system for individuals who may potentially benefit from these therapies.

Proteases are uniquely poised to regulate key biological functions such as the complement system, either by promoting or limiting the cascade of events that leads to eventual clearing of foreign and damaged proteins, inflammation and formation of the membrane attack complex, which is deposited on the surface of cells and drives their destruction. Compared with antibodies and small molecule inhibitors that generally require a sustained excess of therapeutic compound over that of the target, Catalyst's protease therapeutic candidates are capable of rapidly engaging and regulating large quantities of target molecules as each protease molecule can cleave many target molecules over their effective lifetime. This means that our proteases are ideal for regulating high abundancy targets such as complement proteins in a way antibodies and small molecule inhibitors cannot.

CB 2782-PEG is an engineered pegylated C3 degrader that we designed with a best-in-class anti-C3 profile for geographic atrophy ("GA") in dry AMD, which we have licensed to Biogen. Dry AMD is an ocular disease leading to vision loss and blindness for which there is currently no approved therapy. Complement system hyperreactivity plays an important role in dry AMD pathogenesis. Using the protease CB 2782-PEG to degrade C3 allows for the neutralization of C3 activity. It is expected that maintaining low C3 levels in the eye can significantly slow disease progression and vision loss in dry AMD in patients. In September 2021, Apellis released the

results of the DERBY and OAKS phase 3 trials for GA secondary to dAMD showing that once-monthly pegcetacoplan, a pegylated C3 targeted inhibitor, was safe and efficacious, meeting its primary endpoint in one trial and narrowly missing the primary endpoint in the second trial for reducing GA lesion growth over a 12 month period. Further subpopulation analyses demonstrated a greater effect of reducing GA lesion growth in those subjects with extrafoveal lesions at baseline. CB 2782-PEG provides a differentiated mechanism of action by degrading C3 directly and potentially offering a less frequent dosing than pegcetacoplan or other complement inhibitors in development for GA.

CB 4332 is an engineered version of the CFI protease with an extended half-life that is designed as a subcutaneously dosed replacement therapy for patients who are deficient in CFI or have deficient CFI activity. We commenced patient enrollment in the screening ("CFI-001" or "ConFIrm") study in July 2021. Once CFI deficiency is identified, subjects may enroll in natural history of disease ("CFI-002" or "ConFIdence") study, for which we have enrolled our first subjects in November 2021. These studies are designed to assess CFI blood levels in patients who have diseases related to CFI deficiency to identify those who might benefit from CB 4332 treatment. This will prepare us for the planned initiation of a Phase 1 clinical study of CB 4332 in 2022 in subjects with a significant deficiency or absence of endogenous CFI and identify opportunities to potentially develop CB 4332 for treatment in other indications. We have received pre-IND guidance from the FDA on the design of the CB 4332 phase 1 clinical study as well as the overall development program.

Individuals with complete or significant absence of endogenous CFI may present with a variety of disease manifestations, such as recurrent invasive infections with encapsulated bacteria, but these patients are also at risk of developing autoimmune and/or immune-complex diseases such as chronic inflammation of the blood vessels of the brain, spinal cord, heart or the kidneys. Clinical presentations of bacterial infections include but are not limited to peritonitis, meningitis, pneumonia and sepsis, which may be fatal or leave serious long-term consequences. No primary prophylaxis CFI replacement therapeutic has been approved, and patients often receive lifelong antibiotic treatment, which may cause a range of additional problems.

The non-infectious CFI deficiency manifestations include a sizeable proportion of kidney disease, also called glomerulonephritis, such as: Atypical Hemolytic Uremic Syndrome ("aHUS"), C3 Glomerulonephritis ("C3G") or Immune Complex Membranoproliferative Glomerulonephritis ("IC-MPGN"). These are severe, chronic, life-threatening diseases that result in renal impairment and may require renal transplant.

Low circulating serum CFI levels have been shown to be associated with rare CFI genetic variants and advanced AMD. Studies have estimated that the prevalence of rare CFI variants in the overall AMD population to be approximately 6%, of which approximately 40% are expected to display low serum CFI levels and could potentially benefit from targeted CFI therapy.

We believe that the heterogenous clinical presentation of CFI deficiency likely makes the disease significantly underdiagnosed, and some patients may experience life threatening emergencies that may have severe long-term impact on their quality of life. Currently, there are no therapeutic options approved to specifically replace the deficient CFI protein with a well-functioning CFI to treat these disorders. While not specifically targeting CFI deficiency, eculizumab and ravulizumab are indicated for the treatment of aHUS. Neither eculizumab nor ravulizumab address the root cause of the CFI deficiency; instead, they are designed to prevent the downstream effects of uncontrolled complement activity. Patients with aberrant CFI may therefore still have uncontrolled complement activation downstream of CFI. This may cause deposition of complement proteins, for example, on red blood cells, and some CFI deficient patients may have a worse prognosis than others even when on non-replacement therapy. CB 4332 is designed to address this unmet need by providing a therapeutic option that corrects the root problem of these diseases using simple, fast and easy SQ administration. As a key complement regulator, CFI has also the potential to be used in non-CFI-deficient complement dysregulated diseases (e.g., hyperactive alternative pathway) in which additional upstream regulation may prove more effective than inhibiting specific downstream targets.

We have additional early stage complement discovery programs that target different proteins of the complement system including proteases from our ProTUNE™ C3b/C4b degrader and ImmunoTUNE™ C3a/C5a degrader platforms. These proteases are designed to target specific disorders of the complement or inflammatory pathways. We are also developing other discovery-stage complement programs, including a complement Factor B degrader program using proteases engineered by the Company's proprietary protease engineering platform.

The initial disease indication for which we are prioritizing our ProTUNE™ C3b/C4b degrader platform is IgA nephropathy ("IgAN"). IgAN is the most common cause of primary glomerulonephritis, is associated with glomerular IgA deposits and with limited treatment options. The disease progresses slowly and presents as gross hematuria and persistent asymptomatic microscope hematuria eventually leading to end-stage renal disease ("ESRD") in up to 50% of patients within 20 years of diagnosis. Current care is limited to the use of non-disease modifying agents in an effort to improve renal function, slow the progression and treat the inflammation such as angiotensin-converting enzyme inhibitors, gluticocorticoids and immunosupressants, which may cause a range of additional problems

following long term use. The prevalence of IgAN in the US is estimated to be greater than 100,000 and represents a significant economic burdon due to significant morbidity, chronic treatment and kidney transplant costs.

The ImmunoTUNE™ C3a/C5a degrader platform targets diseases in which the accumulation of C5a and/or C3a is believed to drive disease progression. Molecules from this platform are being directed towards the inflammatory disease, anti-neutrophil cytoplasmic antibody vasculitis ("ANCA"), which is a form of small vessel vasculitis predominantly affecting intraparenchymal arteries, arterioles, capillaries, and venules, with little or no immune deposits. ANCA occurs when the autoantibodies specifically bind to neutrophil proteinase 3 ("PR3") or myeloperoxidase ("MPO") which causes the release of substances that damage the vessel wall and promote neutrophil-driven pathological inflammation. Current standard of care is the use of gluticocorticoids and immunosuppressives, which carry a range of potential problems following long term use. Avacopan, an orally-available C5a receptor ("C5aR") inhibitor was recently approved in October 2021 for combination therapy in ANCA. The addressable ANCA patient population in the US is estimated to be around 50,000.

Coagulation Programs

MarzAA

MarzAA is a potent, subcutaneously administered, next-generation Factor VIIa variant. We commenced enrollment of a Phase 3 registrational trial of MarzAA for episodic treatment of spontaneous or traumatic bleeding episodes in adolescents and adults with congenital hemophlia A or hemophilia B with inhibitors in May 2021. We have discontinued this trial based on a number of factors, including challenges in enrollment resulting from the limited number of potential patients eligible to enroll in this trial, competition from competing approved therapies, delays in enrollment resulting from COVID-19, the capital requirements to complete the trial and other factors. Patients enrolled in the study will return to their standard of care and will complete all required safety assessments. In the patients enrolled to date, we have successfully treated bleeds with SQ MarzAA and have not observed any treatment-related adverse or thrombotic events. We plan to disclose these data at an appropriate medical conference in the future. We had also begun enrollment of a Phase 1/2 trial of MarzAA for treatment of bleeding in Factor VII Deficiency, Glanzmann Thrombasthenia, and in individuals with HA with inhibitors treated with Hemlibra. We have discontinued this trial as well in light of the difficulties in identifying and enrolling eligible patients, the capital requirements to complete the trial and other factors. We believe that a SQ rFVIIa therapy, like MarzAA, should become an important treatment option for patients with bleeding disorder and are exploring opportunities to license or sell MarzAA to another party for further development.

DalcA

DalcA is a next-generation SQ Factor IX product candidate for the prophylactic treatment of individuals with HB that completed an open-label Phase 2b study in 2020, demonstrating that FIX plasma activity levels were raised from the severe to mild phenotype and maintained throughout the course of the study. We have received guidance from the FDA on the design of the registrational Phase 3 clinical trial and the necessary data to support its initiation and are actively seeking a partner for this program. We are exploring opportunities to license or sell DalcA to another party for further development.

Recent Manufacturing Updates

CB 4332

CB 4332 is an engineered version of the CFI protease with an extended half-life that is designed as a subcutaneously dosed replacement therapy for patients who are deficient in CFI or have deficient CFI activity. A clinical lot of CB-4332 to enable Phase 1 trials was manufactured in September 2021. Additional GMP lots to support the clinical trials are in progress.

Other Recent Developments

COVID-19 Business Impact

The global coronavirus pandemic has resulted in widespread requirements for individuals to work from their homes, strained medical facilities worldwide and is causing disruptions to certain pharmaceutical manufacturing and product supply chains. While our offices in California have been reopened to all employees, we may experience future disruptions in applicable guidelines for workplace safety require returning to a remote working environment. We are also still experiencing operational and other challenges as a result of the COVID-19 global pandemic, which delayed our enrollment in MAA-304 and MAA-202, contributing to the decision to discontinue these trials, and which may delay or halt our other development programs.

Recent Financing

In the first quarter of 2021, we issued and sold an aggregate of 9,185,000 shares of our common stock (including 485,000 shares sold pursuant to the exercise of the underwriters' overallotment option) at a price of $5.75 per share. The net proceeds to us, after deducting $3.6 million in underwriting discounts and commissions and offering expenses, were approximately $49.3 million.

We have no drug products approved for commercial sale and have not generated any revenue from drug product sales. From inception to September 30, 2021, we have raised net proceeds of approximately $508.2 million, primarily from private placements of convertible preferred stock since converted to common stock, proceeds from our merger with Targacept, issuances of shares of common stock and warrants, including $82.4 million in total cash receipts from our license and collaboration agreements.

We have never been profitable and have incurred significant operating losses in each year since inception. Our net losses were $25.2 million and $16.0 million for the three months ended September 30, 2021 and 2020, respectively, and $67.6 million and $37.3 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of $382.4 million. As of September 30, 2021, our cash, cash equivalents and investments balance were $64.5 million. Substantially all our operating losses were incurred in our research and development programs and in our general and administrative operations.

We expect to incur significant expenses and increasing operating losses for at least the next several years as we continue preclinical, manufacturing and clinical development, and seek regulatory approval for our drug candidates. Our operating losses may fluctuate significantly from quarter to quarter and year to year due to timing of preclinical, manufacturing, clinical development programs and regulatory guidance spending.

Leadership Changes

On August 5, 2021, we promoted Grant Blouse, Ph.D., to chief scientific officer and Tom Knudsen, DVM, Ph.D., to senior vice president, corporate development. Howard Levy, M.B.B.Ch, Ph.D., M.M.M., chief medical officer, announced his plan to retire and transition to a senior clinical advisor role to Catalyst.

On September 9, 2021 (the "Effective Date"), we appointed Ms. Jeanne Y. Jew as a Class III director of Catalyst with a term to expire at the 2024 Annual Meeting of Stockholders. In connection with the appointment, the Board approved an increase in the size of the Board, from seven to eight members, effective as of the Effective Date.

On October 13, 2021, Clinton Musil, the chief financial officer, resigned for personal reasons effective October 29, 2021. We promoted Seline Miller, the Company's controller, to senior vice president, finance. She will serve as the interim chief financial and principal accounting officer while the Company initiates a search for a successor.

Financial Operations Overview

License and Collaboration Revenue

License and collaboration revenue consist of revenue earned for performance obligations satisfied pursuant to our license and collaboration agreement with Biogen which was entered into in December 2019. In consideration for the grant of an exclusive license and related know-how, we received an up-front license payment of $15.0 million in January 2020, which was recorded in license revenue during the year ended December 31, 2020. We recognized collaboration revenue for reimbursable third-party vendor, out-of-pocket and personnel costs pertaining to the Biogen Agreement of $5.8 million during the year ended December 31, 2020, and $2.3 million and $4.9 million for the three and nine months ended September 30, 2021, respectively. There can be no assurance when any future milestone or royalty payments under the Biogen agreement may occur, if at all.

We have not generated any revenue from the sale of any drug products and we do not expect to generate any revenue from the sale of drug products until we obtain regulatory approval of and commercialize our product candidates.

Cost of License and Collaboration

Cost of license and collaboration revenue consists of fees for research and development services payable to third-party vendors, and personnel costs, corresponding to the recognition of license and collaboration revenue from Biogen. Cost of license and collaboration revenue does not include any allocated overhead costs. In connection with the license revenue recognized from Biogen as discussed above in 2020, we paid Mosaic a $3.0 million sublicense fee and recorded such payment as cost of license. We recognized third-party vendor, out-of-pocket and personnel costs, most of which were reimbursable, pertaining to the Biogen Agreement of $6.1 million during the year ended December 31, 2020, and $2.3 million and $4.9 million for the three and nine months ended September 30, 2021, respectively, and recorded such costs as cost of collaboration revenue.

Research and Development Expenses

Research and development expenses represent costs incurred to conduct research, such as the discovery and development of our product candidates. We recognize all research and development costs as they are incurred. Nonrefundable advance payments for goods or services used in research and development are deferred and capitalized. The capitalized amounts are then expensed as the related goods are delivered or services are performed, or until it is no longer expected that the goods or services will be delivered.

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 and third parties, related to the execution of preclinical, non-clinical, and clinical studies;
- the cost of acquiring and manufacturing preclinical and clinical materials and developing manufacturing processes;
- clinical trial expenses, including costs of third-party clinical research organizations;
- performing toxicity and other preclinical 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 table below details our internal and external costs for research and development for the period presented (*in thousands)*. See Overview and Recent Development Program Updates for further discussion of the current research and development programs.

	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2021
Hemophilia	$ 6,024	$ 17,838
Complement	9,924	20,449
Personnel and other	4,246	13,546
Stock-based compensation	158	921
Total research and development expenses	$ 20,352	$ 52,754

The largest component of our total operating expenses has historically been our investment in research and development activities, including the clinical and manufacturing development of our product candidates. We are focusing substantially all our resources and development efforts on MarzAA and our complement programs. Costs listed for our hemophilia and complement programs above consist of clinical trial, manufacturing and research costs. Our internal resources, employees and infrastructure, identified above as personnel and other, are generally not directly tied to individual product candidates or development programs. As such, we do not maintain information regarding these costs incurred for these research and development programs on a project-specific basis.

We expect our aggregate research and development expenses will increase during the next year as we advance the clinical and manufacturing development of our programs. The global coronavirus pandemic may also delay and increase costs of our current development plans.

On May 20, 2016, we signed a development and manufacturing services agreement with AGC, formerly known as CMC ICOS Biologics, Inc., pursuant to which AGC will conduct manufacturing development of agreed upon product candidates. We will own all intellectual property developed in such manufacturing development activities that are specifically related to our product candidates and will have a royalty-free and perpetual license to use AGC's intellectual property to the extent reasonably necessary to make these product candidates, including commercial manufacturing. As of September 30, 2021, six GMP batches have been manufactured at AGC in addition to an engineering batch to support the planned clinical trials.

The initial term of the agreement is ten years or, if later, until all stages under outstanding statements of work have been completed. Either party may terminate the agreement in its entirety upon written notice of a material uncured breach or upon the other party's bankruptcy, and we may terminate the agreement upon prior notice for any reason. In addition, each party may terminate the agreement in the event that the manufacturing development activities cannot be completed for technical or scientific reasons. We have firm work orders with AGC to manufacture MarzAA and DalcA to support clinical trials totaling $16.5 million. The payment obligations remaining as of September 30, 2021 were $3.6 million.

In July 2021, the Company entered into two separate agreements, one for additional clinical trial services for MarzAA, and another for the Company's screening and natural history of disease clinical studies related to CFI deficiency, with total payments of up to $3.2 million and $6.5 million, respectively. The Company can terminate these agreements at its discretion and upon termination will be responsible to pay for those services incurred prior to termination plus reasonable wind-down expenses.

On September 16, 2021, we signed a Manufacturing and Research and Development Studies Agreement to support the lyophilized drug product, CB4332. The agreement will cover analytical method qualification to support GMP manufacturing. We have firm work orders related to this agreement totaling $0.3 million and the payment obligations remaining as of September 30, 2021 were $0.3 million.

We also have a long-term clinical supply services agreement with Catalent Indiana, LLC ("Catalent"). Catalent has facilities in the U.S. and Europe and conducts drug product development and manufacturing for MarzAA and DalcA. We successfully completed development work for a variety of vial sizes which supports flexible dosing.

The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in achieving marketing approval for our product candidates. The probability of success of each product candidate may be affected by numerous factors, including clinical data, competition, manufacturing capability and commercial viability. As a result, we are unable to determine the duration of and costs to complete our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

Successful development of current and future product candidates is highly uncertain. Completion dates and costs for our research programs can vary significantly for each current and future product candidate and are difficult to predict. Thus, we cannot estimate with any degree of certainty the costs we will incur in the development of our product candidates. We anticipate we will determine which programs and product candidates to pursue and how much funding to direct to each program and product candidate on an ongoing basis in response to the scientific success of early research programs, results of ongoing and future clinical trials, our ability to enter into collaborative agreements with respect to programs or potential product candidates, as well as ongoing assessments as to each current or future product candidate's commercial potential.

General and Administrative Expenses

General and administrative expenses consist of personnel costs, allocated expenses and other expenses for outside professional services, including legal, human resources, audit and accounting services. Personnel costs consist of salaries, bonus, benefits and stock-based compensation. We incur expenses associated with operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and Nasdaq Stock Market LLC ("Nasdaq"), insurance expenses, audit expenses, investor relations activities, Sarbanes-Oxley compliance expenses and other administrative expenses and professional services. We expect such expenses to increase as we advance our programs.

Results of Operations

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

	Three Months Ended September 30,			
	2021	2020	Change ($)	Change (%)
Revenue:				
License	$ —	$ 32	$ (32)	(100)%
Collaboration	2,299	861	1,438	167%
License and collaboration revenue	2,299	893	1,406	157%
Operating expenses:				
Cost of license	—	32	(32)	(100)%
Cost of collaboration	2,307	879	1,428	162%
Research and development	20,352	12,249	8,103	66%
General and administrative	4,869	3,833	1,036	27%
Total operating expenses	27,528	16,993	10,535	62%
Loss from operations	(25,229)	(16,100)	(9,129)	57%
Interest and other income (expense), net	(9)	67	(76)	(113)%
Net loss	$ (25,238)	$ (16,033)	$ (9,205)	57%

	Nine Months Ended September 30,			
	2021	2020	Change ($)	Change (%)
Revenue:				
License	$ —	$ 15,100	$ (15,100)	(100)%
Collaboration	4,898	3,817	1,081	28%
License and collaboration revenue	4,898	18,917	(14,019)	(74)%
Operating expenses:				
Cost of license	—	3,102	(3,102)	(100)%
Cost of collaboration	4,926	4,030	896	22%
Research and development	52,754	38,419	14,335	37%
General and administrative	14,799	11,895	2,904	24%
Total operating expenses	72,479	57,446	15,033	26%
Loss from operations	(67,581)	(38,529)	(29,052)	75%
Interest and other income (expense), net	(23)	1,195	(1,218)	(102)%
Net loss	$ (67,604)	$ (37,334)	$ (30,270)	81%

License and Collaboration Revenue

License and collaboration revenues were $2.3 million and $0.9 million in the three months ended September 30, 2021 and 2020, respectively, and $4.9 million and $18.9 million in the nine months ended September 30, 2021 and 2020, respectively. In the three and nine months ended September 30, 2021, these consisted primarily of reimbursable collaboration expenses from our Biogen Agreement, which was entered into on December 18, 2019. In the nine months ended September 30, 2020, we recorded $15.1 million in license revenue from the Biogen Agreement upon receipt of an up-front license payment and $3.8 million in reimbursable collaboration expenses from the Biogen Agreement.

Cost of License and Collaboration

Cost of license and collaboration were $2.3 million and $0.9 million for the three months ended September 30, 2021 and 2020, respectively, and $4.9 million and $7.1 million during the nine months ended September 30, 2021 and 2020, respectively. Cost of collaboration for the three and nine months ended September 30, 2021 was primarily reimbursable third-party vendor and personnel costs we incurred pertaining to the Biogen Agreement. Cost of license and collaboration in the nine months ended September 30, 2020 was primarily the $3.0 million sublicense fee we paid to Mosaic and $4.0 million in reimbursable third-party vendor and personnel costs related to the Biogen Agreement.

Research and Development Expenses

Research and development expenses were $20.4 million and $12.2 million during the three months ended September 30, 2021 and 2020, respectively, an increase of approximately $8.1 million, or 66%. The increase was due primarily to an increase of $5.1 million in clinical manufacturing costs and an increase of $3.5 million in preclinical research costs, partially offset by a decrease of $0.5 million in personnel and facilities costs.

Research and development expenses were $52.8 million and $38.4 million during the nine months ended September 30, 2021 and 2020, respectively, an increase of approximately $14.3 million, or 37%. The increase was due primarily to an increase of $6.1 million in clinical manufacturing costs, an increase of $5.4 million in preclinical research costs, and an increase of $2.8 million in personnel and facilities costs.

General and Administrative Expenses

General and administrative expenses were $4.9 million and $3.8 million during the three months ended September 30, 2021 and 2020, respectively, an increase of approximately $1.0 million, or 27%. This increase was due primarily to an increase of $0.6 million in professional services and $0.4 million in personnel-related costs.

General and administrative expenses were $14.8 million and $11.9 million during the nine months ended September 30, 2021 and 2020, respectively, an increase of $2.9 million, or 24%. The increase was due primarily to an increase of $1.6 million in personnel-related costs, and an increase of $1.4 million in professional services, partially offset by a $0.1 million decrease in facilities, overhead and administration costs.

Interest and Other Income (Expense), Net

The $0.1 million decrease in interest and other income (expense), net for the three months ended September 30, 2021 compared to the three months ended September 30, 2020 was primarily due to a decrease in interest income on investments.

The $1.2 million decrease in interest and other income (expense), net for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020 was primarily due to a decrease in interest income and due to the payment received in the first quarter of 2020 under an agreement associated with neuronal nicotinic receptor asset sold in 2016.

Recent Accounting Pronouncements

Refer to "Accounting Pronouncements Recently Adopted" and "New Accounting Pronouncements Recently Issued But Not Yet Adopted" included in Note 2, *Summary of Significant Accounting Policies*, in the "Notes to the Condensed Consolidated Financial Statements" in this Form 10-Q.

Liquidity and Capital Resources

As of September 30, 2021, we had $64.5 million of cash, cash equivalents and short-term investments. For the nine months ended September 30, 2021, we had a $67.6 million net loss and $66.1 million cash used in operating activities. We have an accumulated deficit of $382.4 million as of September 30, 2021. Our primary uses of cash are to fund operating expenses, including research and development expenditures and general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

We believe that our existing capital resources, including cash, cash equivalents and investments will be sufficient to meet our projected operating requirements for at least the next 12 months from the date of this filing. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We plan to continue to fund losses from operations and capital funding needs through future equity and/or debt financings, as well as potential additional asset sales, licensing transactions, collaborations or strategic partnerships with other companies. As of the date of this quarterly report, we had effective registration statements on Form S-3 that enable us to sell up to $232.0 million in securities. The sale of additional equity or convertible debt could result in additional dilution to our stockholders. The incurrence of indebtedness would result in debt service obligations and could result in operating and financing covenants that would restrict our operations. Licensing transactions, collaborations or strategic partnerships may result in us relinquishing valuable rights. We can provide no assurance that financing will be available in the amounts we need or on terms acceptable to us, if at all. If we are not able to secure adequate additional funding we may be forced to delay, make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially harm our business.

During the first quarter 2021, we received approximately $49.3 million in cash proceeds from the sale of equity securities. See Note 9, *Stockholders' Equity*, in the "Notes to the Condensed Consolidated Financial Statements" in this Form 10-Q.

In October 2021, we entered into the ATM Agreement with Piper Sandler, which provides that, upon the terms and subject to the conditions and limitations set forth in the ATM Agreement, we may elect to issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to $50.0 million through Piper Sandler acting as our sales agent. Under the ATM Agreement, Piper Sandler may sell the shares of common stock by methods deemed to be an "at the market" offering as defined in Rule 415 under the Securities Act of 1933, as amended, including sales made directly on the Nasdaq Capital Market or any other trading market for the common stock. Piper Sandler will use commercially reasonable efforts to sell the shares of common stock subject to the ATM Agreement from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions that we may impose). We will pay Piper Sandler a commission of 3.0% of the gross proceeds of any shares sold through Piper Sandler under the ATM Agreement; however, we are not obligated to make any sales of common stock.

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

	Nine Months Ended September 30,	
	2021	2020
Cash used in operating activities	$ (66,079)	$ (32,934)
Cash provided by (used in) investing activities	45,323	(17,888)
Cash provided by financing activities	49,553	60,376
Net increase in cash and cash equivalents	$ 28,797	$ 9,554

Cash Flows from Operating Activities

Cash used in operating activities for the nine months ended September 30, 2021 was $66.1 million. The most significant component of our cash used was a net loss of $67.6 million. This included non-cash expense related to stock-based compensation of $2.7 million and depreciation and amortization of $0.2 million. In addition, cash outflow of $1.4 million was attributable to the change in our net operating assets and liabilities primarily as a result of a $2.0 million increase in prepaid and other assets, a $2.1 million decrease in accounts payable, and a $1.1 million decrease in deferred revenue related to the Biogen Agreement, offset by a $2.2 million decrease in accounts receivable and a $1.5 million increase in accrued compensation and other accrued liabilities.

Cash used in operating activities for the nine months ended September 30, 2020 was $32.9 million, due primarily to a net loss of $37.3 million, and the change in our net operating assets and liabilities of $1.6 million, due primarily to a $13.4 million decrease in accounts receivable, a $2.2 million increase in accrued compensation and other accrued liabilities and a $0.2 million decrease in prepaid and other assets, partially offset by a $14.2 million decrease in deferred revenue related to the Biogen Agreement.

Cash Flows from Investing Activities

Cash provided by investing activities for the nine months ended September 30, 2021 was $45.3 million, due to $46.2 million in proceeds from maturities of investments, offset by $0.9 million used in purchases of property and equipment.

Cash used in investing activities for the nine months ended September 30, 2020 was $17.9 million, due primarily to $91.7 million in purchases of investments, partially offset by $74.1 million in proceeds from maturities of investments.

Cash Flows from Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2021 was $49.6 million, due to $49.3 million in net proceeds from the issuance of common stock related to our public offering in the first quarter of 2021 and $0.3 million in stock grants and option exercises.

Cash provided by financing activities for the nine months ended September 30, 2020 was $60.4 million, due to $32.0 million in net proceeds from the issuance of common stock related to our public offering in February 2020, $28.0 million in net proceeds from the issuance of common stock related to our public offering in June 2020, and $0.4 million in stock grants and option exercises.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Critical Accounting Polices and Estimates

Except for the new equity awards with performance conditions mentioned below, there have been no significant changes to our critical accounting policies since December 31, 2020. For a description of critical accounting policies that affect our significant judgments and estimates used in the preparation of our unaudited condensed consolidated financial statements, refer to Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” contained in our Annual Report on Form 10-K.

Stock-based Compensation

We measure the cost of employee and director services received in exchange for an award of equity instruments based on the fair value-based measurement of the award on the date of grant and recognize the related expense over the period during which an employee or director is required to provide service in exchange for the award on a straight-line basis. The estimated fair value of equity awards that contain performance conditions is expensed over the term of the award once we have determined that it is probable that performance conditions will be satisfied.

Determining the fair value of stock-based awards at the grant date requires judgment. We use the Black-Scholes option-pricing model to determine the fair value of stock options. The determination of the grant date fair value of options using an option-pricing model is affected by our assumptions regarding a number of variables including the fair value of our common stock, our expected common stock price volatility over the expected life of the options, expected term of the stock option, risk-free interest rates and expected dividends. We record stock-based compensation as a compensation expense, net of the forfeited awards. We elected to account for forfeitures when they occur. As such, we recognize stock-based compensation expense only for those stock-based awards that are expected to vest, over their requisite service period, based on the vesting provisions of the individual grants. See Note 6, *Stock-Based Compensation* to our unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for more information.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Management, with the participation of our Chief Executive Officer and Interim Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2021. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2021, our Chief Executive Officer and Interim Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

As of September 30, 2021, we have not experienced any significant impact to our internal controls over financial reporting despite the fact that most of our employees who are involved in our financial reporting processes and controls are working remotely due to the COVID-19 pandemic. The design of our processes and controls allows for remote execution with accessibility to secure data. We are continually monitoring and assessing the COVID-19 situation on our internal controls to minimize the impact on their design and operating effectiveness.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) identified during the three months ended September 30, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings.

ITEM 1A. RISK FACTORS

The risk factors disclosed in *"Part I - Item 1A - Risk Factors"* of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, filed with the Securities and Exchange Commission on March 4, 2021, disclose risk and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our common stock.

You should carefully consider the risks and uncertainties disclosed as "Risk Factors" in our Annual Report, together with all of the other information in this Report, including the section titled *"Part I - Financial Information - Item 2 - Management's Discussion and Analysis of Financial Condition and Results of Operations"* and the condensed consolidated financial statements and related notes.

The risk factors below modify the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2020:

Risks related to the discovery, development and commercialization of our product candidates

Our complement product candidates, including CB 4332, are in the early stages of development. Commercial viability of CB 4332 remains subject to current and future preclinical studies, clinical trials, regulatory approvals and the risk that we are unable to identify a sufficient number of patients who could benefit from CB 4332.

Our complement product candidates, including CB 4332, are in early stages of clinical development. CFI deficiency, which CB 4332 is designed to treat, is very rare and presents in patients with a variety of symptoms. We have not yet identified the target patient population for initial human trials of CB 4332, and there may be delays clinical trials due to limited number of potential patients, insufficient capital or competition from competing therapies in development. We cannot assure you that we will identify sufficient patients with CFI deficiency through the screening ("ConFIrm", CFI-001) and natural history of disease ("ConFIdence", CFI-002) studies of CFI deficiency, or that these trials will provide information that informs the clinical development of CB 4332. There can also be no assurance that these or future clinical trials will support or justify the continued development of CB 4332, or that we will receive approval from the FDA, or similar regulatory authorities in other countries, to advance the development of CB 4332. Engineered protease biopharmaceuticals are a relatively new class of therapeutics. While we have received guidance from FDA regarding a Phase 1 clinical trial of CB 4332, there is no assurance that FDA will agree to our proposed clinical trials or approve the IND that we plan to file, and delays or refusal by FDA to approve our IND trial could delay the start of clinical trials for CB 4332. There can also be no assurance as to the length of the trial period, the number of individuals the FDA or EMA will require to be enrolled in the trials to establish the safety, efficacy, purity and potency of the engineered protease products, or that the data generated in these trials will be acceptable to the FDA, EMA or other foreign regulatory agencies to support marketing approval.

All of our product candidates will require additional pre-clinical and clinical testing before they can be sold. If we are unable to successfully advance or develop our complement product candidates, our business will be materially harmed.

To date, we have not successfully developed, commercially marketed, distributed or sold any product candidate. The success of our business depends primarily upon our ability to successfully advance the development of our product candidates through preclinical studies and clinical trials, have the product candidates approved for sale by the FDA or regulatory authorities in other countries, and ultimately have the product candidates successfully commercialized by us or a strategic partner. Failure can occur at any stage, including during clinical trials where we could encounter problems that cause us to abandon or repeat clinical trials. Our product candidates, including CB 4332, must satisfy rigorous regulatory standards of safety and efficacy before we can advance or complete their clinical development or they can be approved for sale. To satisfy these standards, we must engage in expensive and lengthy preclinical studies and clinical trials, develop acceptable manufacturing processes, and obtain regulatory approval of our complement product candidates. Despite these efforts, our product candidates, including CB 4332, may not:

- offer therapeutic or other medical benefits over existing drugs or other product candidates in development to treat the same patient population;
- be proven to be safe and effective in current and future preclinical studies or clinical trials;
- have the desired effects;
- be free from undesirable or unexpected effects;

- meet applicable regulatory standards;
- be capable of being formulated and manufactured in commercially suitable quantities and at an acceptable cost; or
- be successfully commercialized by us or by collaborators.

Even if we demonstrate favorable results in preclinical studies and early-stage clinical trials, we cannot assure you that the results of late-stage clinical trials will be favorable enough to support the continued development of our product candidates. A number of companies in the pharmaceutical and biopharmaceutical industries have experienced significant delays, setbacks and failures in all stages of development, including late-stage clinical trials, even after achieving promising results in preclinical testing or early-stage clinical trials. Accordingly, results from completed preclinical studies of our product candidates, including CB 4332, may not be predictive of the results we may obtain in later-stage trials. Furthermore, even if the data collected from preclinical studies and clinical trials involving our product candidates demonstrate a favorable safety and efficacy profile, such results may not be sufficient to support the submission of a new drug application or biologics license application ("BLA") to obtain regulatory approval from the FDA in the United States or other similar regulatory agencies in other jurisdictions, which is required to market and sell the products.

CB 4332 and our other complement product candidates will require significant additional research and development efforts, the commitment of substantial financial resources, and regulatory approvals prior to advancing into clinical development or being commercialized by us or collaborators. We cannot assure you that CB 4332 or our other complement product candidates will progress into clinical development or result in a commercially viable product. We do not expect CB 4332 or any of our other complement product candidates to be commercialized by us or collaborators for at least several years.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our regulatory approvals could be delayed or prevented, and we could elect to cease clinical trial enrollment and development of some or all of our product candidates.

We or our collaborators may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate, enroll and maintain enrollment of a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. For example, there is a small number of individuals with CFI deficiency for which CB 4332 is a potential therapy. Some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates and thus compete with us to enroll patients in their clinical trials. The availability of other approved products and other products in clinical trials may limit the number of patients willing to participate in our clinical trials.

Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the availability of competitive products;
- the efforts to facilitate timely enrollment in clinical trials;
- laboratory testing and turnaround time for samples needed for eligibility assessments;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

As was the case for MarzAA, our inability to enroll a sufficient number of patients for any of our clinical trials could result in significant delays and may require us to abandon one or more clinical trials altogether. Enrollment delays in clinical trials conducted by us may also result in increased development costs for our product candidates, which would cause the value of the Company to decline and limit our ability to obtain additional financing or lead us to cease developing particular product candidates.

The coronavirus disease, COVID-19, may impact our third-party supply of the raw materials and components needed for our product candidates, which increases the risk that we will not have sufficient quantities of such product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development efforts.

If supplies of the raw materials for our product candidates are significantly delayed, or if the third parties that we engage to supply any materials or to manufacture any products for our preclinical tests and clinical trials should cease to continue to do so for any reason, including due to the effects of the COVID-19 pandemic and the actions undertaken by governments and private enterprises to contain COVID-19 or requisition facilities for COVID-19 vaccine supplies, we likely would experience delays in advancing these tests and trials while we identify and qualify replacement suppliers or manufacturers and we may be unable to obtain replacement supplies on terms that are favorable to us. In addition, if we are not able to obtain adequate supplies of our product candidates or the substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

Our current and anticipated dependence upon third-party suppliers may adversely affect our ability to develop product candidates and could delay our clinical trials and development programs, and otherwise harm our operations and financial condition and increase our costs and expenses.

All of our product candidates are in preclinical development. If we are unable to obtain regulatory clearance and commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

All our other product candidates are still in preclinical development. 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 our product candidates. The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical studies;
- successful initiation and completion of 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 are focused on the discovery and clinical development of our complement product candidates. Any adverse events, trial failures or material delays in these programs could materially harm our business.

The failure of CB 4332 to start clinical trials, achieve successful clinical trial endpoints, delays in clinical development, unanticipated adverse side effects, the cessation of clinical development or any other adverse developments or information related to CB 4332 or our other product candidates would significantly harm our business, its prospects and the value of the Company’s common stock. There is no guarantee that we will be able to initiate clinical trials of CB 4332 as planned or that the results of clinical trials of CB 4332 will be positive or will not generate unanticipated safety concerns. If neutralizing antibodies or other adverse events in patients receiving CB 4332 lead to concerns about patient safety, the long-term efficacy, or commercial viability of CB 4332, its development could be

halted. Depending on the availability of additional capital, we may also delay or terminate clinical development of one or more of our product candidates.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we may face similar setbacks. The design of a clinical trial can determine whether our results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. Any Phase 2, Phase 3 or other clinical trials that we may conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates.

If our product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon development or limit development of the product candidate to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Any such limitations could adversely affect the value of our product candidates or common stock.

Even if the FDA or other regulatory agency approves our product candidates, 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 our product candidates 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 or our product candidates would be limited.

We may not succeed at generating additional complement product candidates.

The complement cascade is a complex biological system, and engineering protease molecules is also a complex process. While our ProTUNE™ C3b/C4b degrader and ImmunoTUNE™ C3a/C5a degrader platforms are designed to target specific disorders of the complement or inflammatory pathways, there can be no assurance that the platforms will generate molecules that meet criteria necessary to become potential product candidates, including without limitation safety, efficacy, manufacturability, stability and the ability to be formulated into a deliverable therapy. If we are unable to generate additional product candidates, our business and prospects will be materially harmed.

Risks related to our reliance on third parties

Our collaboration with Biogen may not result in successful product development or payments to us.

We have entered into a collaboration and license agreement with Biogen to develop and commercialize CB 2782-PEG and our other anti-C3 proteases for potential treatment of dry AMD and other disorders. We will perform preclinical and manufacturing activities, and Biogen will be solely responsible for funding the preclinical and manufacturing activities and performing IND-enabling activities, worldwide clinical development, and commercialization. Future revenues from this collaboration depend upon the achievement of milestones and payment of royalties based on product sales after successful product development and regulatory approval. Biogen can terminate this agreement on 60 days' prior written notice. If Biogen terminates the agreement, our reputation in the business and scientific community may suffer and we will not receive payments from them after termination. If milestones are not achieved or Biogen is unable to successfully develop and commercialize products from which milestones and royalties are payable, we will not earn the revenues contemplated by the collaboration.

We have limited or no control over the resources that Biogen may devote to the development and commercialization of products under our agreement. Biogen may not perform its obligations as expected or may breach or terminate the agreement with us or otherwise fail to conduct research, development or commercialization activities successfully or in a timely manner. Further, Biogen may elect not to

develop pharmaceutical products arising out of our collaborative arrangement or may not devote sufficient resources to the development, regulatory approval, manufacture, marketing or sale of these products. If any of these events occurs, we may not receive collaboration revenue or otherwise realize anticipated benefits from such collaborations, our product development efforts may be delayed and our business, operating results and financial condition could be adversely affected.

We expect to seek to establish additional collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We have previously relied on collaborators, such as Pfizer and ISU, to contribute to the development of our product candidates, and we are currently working with Biogen to support the development of our dry AMD product candidates. We intend to seek one or more additional collaborators for the development and commercialization of one or more of our complement product candidates.

We face significant competition in seeking appropriate collaborators. Whether we can reach a definitive agreement with a collaborator will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of preclinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us. There can also be no assurance that any collaboration agreements will be on favorable terms.

Collaborations are complex and time consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, and increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

We contract with third parties for the manufacture of our product candidates for preclinical testing and expect to continue to do so for clinical testing and commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We currently have no internal capabilities to manufacture our product candidates for clinical use or for preclinical trials following good manufacturing practices ("GMP"), or good laboratory practices ("GLP"). We expect to rely on one or more third-party contractors to manufacture, package, label and distribute clinical supplies and commercial quantities of any product candidate that we commercialize following approval for marketing by applicable regulatory authorities. We also expect to rely on one or more third-party contractors to manufacture our product candidates for use in our clinical trials. Reliance on such third-party contractors entails risks, including:

- our inability to identify and negotiate manufacturing and supply agreements with suitable manufacturers;
- manufacturing delays if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the possible termination or nonrenewal of agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the possible breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;

- the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;

- the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and

- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

We may incur delays in product development resulting from the need to identify or qualify manufacturers for our product candidates. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We are subject to many manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates and any future products.

To date, our product candidates have been manufactured by third-party manufacturers solely for preclinical studies and relatively small clinical trials. The process of manufacturing CB 4332 and our other complement product candidates is complex, highly regulated and subject to several risks, including:

- the process of manufacturing biologics is susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error and improper storage conditions. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, the manufacturing facilities may need to be closed for an extended period of time to investigate and eliminate the contamination;

- the manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor and raw material shortages, financial difficulties of our contract manufacturers, including as a result of the evolving effects of the COVID-19 pandemic, natural disasters, power failures, local political unrest and numerous other factors; and

- any adverse developments affecting manufacturing operations or the scale up of manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of our product candidates. We may also have to record inventory write-offs and incur other charges and expenses for product candidates or drug substances that fail to meet specifications, undertake costly remediation efforts or seek costlier manufacturing alternatives.

Specifically, we have entered into various development, manufacturing and clinical supply services agreements with third-party manufacturers for drug substance and drug product manufacturing of CB 4332. If any of our third-party manufacturers is not able to provide us with sufficient quantities of CB 4332 for our preclinical trials on a timely basis, or at all, whether due to production shortages or other supply delays or interruptions resulting from the ongoing COVID-19 pandemic or otherwise, our preclinical trials, clinical trials or regulatory approval, as applicable, may be delayed. Significant portions of our research and development resources are focused on manufacturing. If any of our third-party manufacturers experiences difficulties in scaling production or experiences product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error or improper storage conditions, the potential trials of the affected product candidate would be delayed, perhaps substantially, which could materially and adversely affect our business.

We have minimal process development capabilities and have access only to external manufacturing capabilities. We do not have, and we do not currently plan to acquire or develop, the facilities or capabilities to manufacture bulk drug substance or filled drug product for use in clinical trials or commercialization. Any delay or interruption in the supply of clinical trial material or preclinical trial material could delay the completion of clinical trials or preclinical trials, increase the costs associated with maintaining such trial programs and, depending upon the period of delay, require us to commence new clinical trials or preclinical trials at additional expense or terminate the trials completely.

We and our contract manufacturers will be subject to significant regulation with respect to manufacturing our products. The manufacturing facilities on which we will rely may not continue to meet regulatory requirements and have limited capacity.

All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including any contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial

sale or used in late-stage clinical studies must be manufactured in accordance with GMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a BLA on a timely basis and must adhere to the FDA's GLP and GMP regulations enforced by the FDA through its facilities inspection program. Our facilities and quality systems and the facilities and quality systems of some or all our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection or do not have a GMP compliance status acceptable for the FDA, FDA approval of the products will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third-party to implement and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. An alternative manufacturer would need to be qualified through a BLA supplement which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause the delay of clinical studies, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed, or we could lose potential revenue.

We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We rely on third parties such as contract research organizations ("CROs"), medical institutions and clinical investigators to enroll qualified patients and conduct, supervise and monitor clinical trials. Our reliance on these third parties for clinical development activities will reduce our control over these activities. Our reliance on these third parties, however, will not relieve us of our regulatory responsibilities, including ensuring that our clinical studies are conducted in accordance with good clinical practices, and the investigational plan and protocols contained in the relevant regulatory application, such as an investigational new drug application, or IND. In addition, the CROs with whom we contract may not complete activities on schedule or may not conduct our preclinical studies or clinical studies in accordance with regulatory requirements or our clinical study design. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, our efforts to obtain regulatory approvals for, and to commercialize, our product candidates may be delayed or prevented.

Risks related to employee matters, managing growth and our business operations

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our executive management and scientific personnel. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. In addition, we will need to add personnel to achieve our business objectives. The loss of the services of any of our executive officers, other key employees, and our inability to find suitable replacements, or our inability to hire new clinical development and manufacturing personnel, could result in delays in product development and harm our business.

In November 2021, we announced our decision to discontinue the development of MarzAA. In connection with the discontinuation, we eliminated employee positions representing approximately 35% of our prior headcount (the "restructuring"). The restructuring could harm our ability to attract and retain qualified personnel. The restructuring could also result in reduced morale and productivity among our remaining personnel. In addition, the restructuring may negatively impact our clinical, regulatory and technical operations, which would have a negative impact on our ability to successfully develop, and ultimately, commercialize our complement product candidates and other product candidates.

We conduct operations at our facility in the San Francisco Bay Area. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at Catalyst, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in the Company's stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of management and scientific and development teams may terminate their employment with the Company on short notice. Our employees are under at-will employment arrangements, which means that any of our employees can leave employment with Catalyst at any time, with or without notice. Failure to retain, replace or recruit personnel could harm our business.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and collaborators. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-US regulators, to provide accurate information to the FDA and non-US regulators, to comply with healthcare fraud and abuse laws and regulations in the United States and abroad, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained during clinical studies that could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We will continue to incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives.

As a public company, we have and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting and corporate governance requirements, in order to comply with the rules and regulations imposed by the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection (the "Dodd-Frank Act"), as well as rules implemented by the SEC and Nasdaq. Stockholder activism, the political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways that are not currently anticipated. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. In addition, these rules and regulations make it difficult and expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain our current levels of such coverage. We expect that we will annually incur significant expenses to comply with the requirements imposed on us as a public company.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our offices are located in the San Francisco Bay Area, which is prone to earthquakes. Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove

adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans that, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Risks related to our financial condition and capital requirements

The outbreak of the novel coronavirus disease, COVID-19, has and may continue to adversely impact our business, including our drug product supply to support preclinical studies and clinical trials.

The global coronavirus pandemic has resulted in widespread requirements for individuals to work from their homes, strained medical facilities worldwide and is causing disruptions to certain pharmaceutical manufacturing and product supply chains. While our offices in California have been reopened to all employees, we may experience future disruptions if applicable guidelines for workplace safety require returning to a remote working environment. We are also still experiencing operational and other challenges as a result of the COVID-19 global pandemic, which may delay or halt development in our complement drug development programs. In addition, as a result of the COVID-19 pandemic, we may experience disruptions that could severely impact our business, preclinical studies, drug manufacturing and clinical trials including:

- additional delays or difficulties in enrolling potential trial participants in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- delays in manufacturing of our product candidates as third-party manufacturing capacity is shifted towards the production of COVID-19 vaccines;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal, state or country governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA, European Medicines Agency (the “EMA”) or other regulatory authorities, which may impact review and approval time lines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems shortage of critical raw material supplies, study laboratory specimen kits and key equipment components;
- interruptions in preclinical studies due to restricted or limited operations at laboratory facilities and disruptions in delivery systems, shortage of critical raw material supplies, study laboratory supplies and key equipment components;
- suspension or termination of our clinical trials for various reasons, such as a finding that the participants are being exposed to infectious diseases like COVID-19 or the participants and/or principal investigators involved in our clinical trials have become infected with COVID-19;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- material delays and complications with respect to our research and development programs.

In addition, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. Furthermore, a recession or market correction resulting from the spread of COVID-19 could materially affect our operations and the value of our common stock.

We have incurred significant losses since our inception and are expected to continue to incur significant losses for the foreseeable future.

We are a clinical-stage biotechnology company, and we have not yet generated significant revenues. We have incurred net losses in each year since our inception in August 2002, including net losses of $56.2 million, $55.2 million and $67.6 million for the years ended December 31, 2020 and 2019 and the nine months ended September 30, 2021, respectively. As of September 30, 2021, we had an accumulated deficit of $382.4 million. Our losses have resulted principally from expenses incurred in research and development, including clinical trial expenses, and from management and administrative costs and other expenses that we have incurred while building our business.

We are still in the early stages of development of our product candidates, and have no products approved for commercial sale. To date, we have financed our operations primarily through issuances of shares of common stock, from private placements of convertible preferred stock, and from payments under collaboration agreements.

We have devoted most of our financial resources to research and development, including our preclinical and clinical development activities. We expect to continue to incur significant expenses and operating losses over the next several years as we continue preclinical and begin clinical development of our complement product candidates. Our operating losses may fluctuate significantly from quarter to quarter and year to year. We are expected to continue to incur significant expenses and increasing operating losses for at least the next several years, and our expenses will increase substantially if and as we:

- continue preclinical development and begin clinical development of CB 4332 and our other complement product candidates;
- further develop the manufacturing process for our product candidates;
- attract and retain skilled personnel;
- seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical studies;
- acquire or in-license other product candidates and technologies;
- make milestone or other payments under collaboration agreements, or any in-license agreements we may enter;
- maintain, protect and expand our intellectual property portfolio;
- create additional infrastructure to support operations as a public company and our product development and planned future commercialization efforts; and
- experience any delays or other issues with any of the above.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which regulatory approval is obtained. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, we may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Failure to become and remain profitable would depress the value of our common stock and could impair our ability to raise capital, expand our business, maintain research and development efforts, diversify product offerings or even continue operations. A decline in the value of our common stock could also cause you to lose all or part of your investment.

We implemented a strategic restructuring to prioritize our complement product candidates and explore strategic alternatives for our hemophilia product candidates, and we cannot assure you that we will be able to successfully execute on a strategic alternative for our hemophilia product candidates.

We recently implemented a strategic restructuring to focus our efforts on our complement product candidates, which included a reduction in our workforce. We are seeking strategic alternatives for our hemophilia product candidates, including MarzAA and

DalcA. Our prior efforts to license MarzAA or DalcA to a third party for development and commercialization were not successful, and our ability to successfully execute on a strategic alternative for our hemophilia product candidates depends on a number of factors, including the commercial potential for these products, competition and the costs of additional clinical trials and manufacturing. We may not be able to complete a transaction or other strategic alternative for our hemophilia product candidates with favorable terms, within an advantageous timeframe, or at all. Additionally, the negotiation and consummation of a transaction or other strategic alternative involving our hemophilia product candidates may be costly and time-consuming.

Our strategic restructuring to prioritize our complement product candidates may not result in savings as great as expected and could adversely impact our operations.

Our strategic restructuring to focus on our complement product candidates may not result in anticipated savings or other economic benefits, could make it more difficult to attract and retain qualified personnel and may disrupt our operations, each of which could have a material adverse effect on our business. Workforce changes can also temporarily reduce workforce productivity, which could be disruptive to our business and could adversely affect our results of operations. In addition, we may be required to take potentially material, restructuring charges related to, among other things, employee terminations or exit costs, which may result in an adverse market reaction and decline in our stock price.

We will need additional capital. If we are unable to raise sufficient capital, we will be forced to delay, reduce or eliminate product development programs.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our research and development expenses to increase with our ongoing activities, particularly activities related to the preclinical and clinical development of our complement product candidates. We believe that our available cash, cash equivalents and investments will be sufficient to fund our operations for at least the next 12 months. However, we may need to raise substantial additional capital to complete the development and commercialization of our complement product candidates, and depending on the availability of capital, may need to delay or cease development of some of our product candidates. Even if we raise additional capital, we may elect to focus our efforts on one or more development programs and delay or cease other development programs.

Until we can generate sufficient revenue from our product candidates, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings, corporate collaborations and/or licensing arrangements. Additional funds may not be available when we need them on terms that are acceptable, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs.

Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds required to complete research and development and commercialize our products under development. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the costs and results of preclinical studies or clinical trials of CB 4332 or our other complement product candidates, and expenses related to potential clinical development of such candidates;
- the number and characteristics of product candidates that we pursue;
- the terms and timing of any future collaboration, licensing or other arrangements that we may establish;
- the outcome, timing and cost of regulatory approvals;
- the cost of obtaining, maintaining, defending and enforcing intellectual property rights, including patent rights;
- the effect of competing technological and market developments;
- the cost and timing of completing outsourced manufacturing activities;
- market acceptance of any product candidates for which we may receive regulatory approval;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval; and
- the extent to which we acquire, license or invest in businesses, products or technologies.

Raising additional funds by issuing securities 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 will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of common stockholders.

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. 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. 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.

As of the date of this filing, we have effective registration statements on Form S-3 that allow us to offer up to $232.0 million of securities in one or more offerings. Any additional sales in the public market of our common stock or other securities under these shelf registration statements could adversely affect prevailing market prices for our common stock. On October 15, 2021, we entered into an Equity Distribution Agreement (the “ATM Agreement”) with Piper Sandler & Co. (“Piper Sandler”) pursuant to which we may offer and sell, from time to time in our sole discretion, shares of our common stock with aggregate gross sales proceeds of up to $50.0 million through an “at the market” equity offering program under which Piper Sandler will act as sales agent. Depending upon market liquidity at the time, sales of shares of our common stock under the ATM Agreement may cause the trading price of our common stock to decline and may result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock under the ATM Agreement, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

We have no history of commercialization of pharmaceutical products, which may make it difficult to evaluate the Company’s prospects.

We began operations in August 2002. Our operations to date have been limited to financing and staffing the Company, developing our technology and product candidates, establishing collaborations and conducting clinical trials on small numbers of patients. We have not yet demonstrated an ability to successfully conduct a Phase 3 clinical trial, obtain marketing approvals, manufacture a product at commercial scale repeatedly, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about the Company’s future product development timelines, clinical trial plans, expenses, success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

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, although there are no currently approved treatments for dry AMD, several companies are developing cyclic peptide, aptamer, antibody or gene therapy based anti-complement product candidates in clinical studies. For example, Apellis has completed two Phase 3 studies to compare the efficacy and safety of intravitreal APL-2, (pegcetacoplan), a pegylated cyclic peptide based C3 inhibitor therapy with sham injections in patients aged 60 years and older with GA secondary to AMD; Iveric Bio (formerly Ophthotech) is developing two therapies to treat GA secondary to dry AMD, iveric Bio completed its Phase 2b clinical of Zimura® (avacincaptad pegol) with positive data in patients with dry AMD; Gemini Therapeutics is developing “GEM103” a recombinant human complement factor H (“CFH”) for patients with genetically well-defined dry AMD as well as additional molecules in preclinical development for other genetically defined subpopulations of patients with dry AMD and Gyroscope Therapeutics is developing “GT005” a gene therapeutic approach to expressing additional CFI in the patient’s eye after subretinal delivery. In addition, while there are currently no approved agents specifically targeting systemic factor I deficiency, there are less specific treatment options on the market or in clinical development which may be applicable to some disease manifestations of systemic CFI deficiency, for instance aHUS and C3G. These treatment options include: eculizumab and ravulizumab marketed by Alexion

Pharmaceuticals (acquired by AstraZeneca) for use in aHUS irrespective of the patients' CFI status; APL-2, which is in clinical development by Apellis, in IgA Nephropathy ("IgAN"), LN, Membranous Nephropathy ("MN"), C3G, and Dense Deposit Disease; CCX168 (avacopan), a twice daily oral small molecule inhibitor of the complement 5a receptor ("C5aR") in C3G—currently in phase 2 being developed by ChemoCentryx; iptacopan ("LNP023"), a small peptide complement factor B inhibitor which is currently in development by Novartis for PNH, C3G and several other rare renal diseases including IgAN, aHUS, and membranous nephropathy; and Omeros has initiated clinical activities in igAN, LN, MN, & C3G and a phase 3 clinical program in aHUS with OMS721 ("narsoplimab"), a human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 ("MASP-2"), the effector enzyme of the lectin pathway of the complement system. Biocryst Pharmaceuticals, Inc. is also developing BCX9930, a small molecule inhibitor of Factor D, for the treatment of complement-mediated diseases, including PNH and renal complement mediated disease.

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 earlier 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 our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition, and the availability of reimbursement from government and other third-party payors.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do.

Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and individual registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our business could be negatively affected as a result of actions of activist stockholders, and such activism could impact the trading value of our securities.

One of our stockholders has requested that we add one or more individuals to our board of directors, and this stockholder or other stockholders could engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on our board of directors and management. Such an activist campaign could conflict with our strategic direction or seek changes in the composition of our board of directors and could have an adverse effect on our operating results and financial condition. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs, and require significant time and attention by our board of directors and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our board of directors or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business or instability which may result in the loss of potential business opportunities, make it more difficult to pursue our strategy, or limit our ability to attract and retain qualified personnel, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our business strategy and create additional value for our stockholders. We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our board of directors and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

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

Unregistered Sales of Equity Securities

None.

Issuer Repurchase of Equity Securities

None.

Use of Proceeds

In the first quarter of 2021, we issued and sold 9,185,000 shares of our common stock, which included the partial exercise by the underwriters of their option to purchase additional shares, at the public offering price of $5.75 per share and received net proceeds of approximately $49.3 million, after deducting underwriting discounts and commissions of approximately $3.2 million and offering-related transaction costs of approximately $0.4 million. None of the expenses associated with the offering were paid to directors, officers, persons owning ten percent or more of any class of equity securities, or to their associates, or to our affiliates. Piper, Sandler & Co., acted as sole lead active bookrunner and Raymond James & Associates, Inc. acted as a bookrunner for the offering.

There has been no material change in the planned use of proceeds from our public offering from that described in the prospectus filed by us with the SEC on May 3, 2021.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

See Index to Exhibits at the end of this Report, which is incorporated by reference here. The Exhibits listed in the accompanying Index to Exhibits are filed as part of this Report.

EXHIBIT INDEX

Exhibit Number	Description
10.1	License Agreement, dated as of April 15, 2021, by and between SL 2T, LLC and Catalyst Biosciences, Inc.
31.1	Certification of the Chief 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 Interim Chief 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 Chief Executive Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Interim Chief Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets as of September 30, 2021 (unaudited) and December 31, 2020; (ii) the Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2021 and 2020 (unaudited); (iii) the Condensed Consolidated Statements of Comprehensive Income for the three and nine months ended September 30, 2021 and 2020 (unaudited); (iv) the Condensed Consolidated Statement of Stockholders' Equity as of September 30, 2021 and September 30, 2020 (unaudited); (v) the Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2021 and 2020 (unaudited); and (vi) the Notes to Unaudited Interim Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CATALYST BIOSCIENCES, INC.

Date: November 12, 2021

/s/ Nassim Usman, Ph.D.

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

Date: November 12, 2021

/s/ Seline Miller

Seline Miller
Interim Chief Financial Officer
(*Interim Financial and Principal Accounting Officer*)

License Agreement

This License Agreement, made and entered into as of April 15, 2021 ("**Agreement**"), is by and between Catalyst Biosciences, Inc., a Delaware corporation, having a place of business located at 611 Gateway Blvd, Suite 710, South San Francisco, CA 94080 ("**Licensee**") and SL 2T, LLC a Delaware limited liability company having a place of business located at Two Tower Place, South San Francisco, CA 94080 ("**SmartLabs**" or "**Licensor**").

RECITALS

WHEREAS, SmartLabs has leased certain space located at Two Tower Place, South San Francisco, California 94080 (the "**Building**") through a lease agreement (the "**Lease**") between SmartLabs and AP3-SF3 CT NORTH, LLC, which was subsequently assigned to GNS NORTH TOWER, LP ("**Landlord**"); and

WHEREAS, Licensee desires to engage SmartLabs for certain services, as set forth below, for laboratory, research and development.

For good and valuable consideration, the receipt and legal sufficiency of which are hereby acknowledged, accepted and agreed to, the parties agree as follows:

1. License.

(a) **License Description**. SmartLabs grants to Licensee a non-transferable, non-assignable, revocable nonexclusive license (the "**License**") to use Lab Suite 17A and Office Suite 17B located in the Building and more specifically detailed in the shaded portion of the floor plan attached to this Agreement as **Exhibit 1** (the "**Licensed Premises**") solely to: (i) use as office and laboratory space consistent with all applicable laws; (ii) conduct Licensee's business; and (iii) collaborate with SmartLabs' staff and other licensees in accordance with this Agreement. The License shall also include access to use certain common areas of the Building as designated by SmartLabs (the "**Shared Premises**"), subject to SmartLabs' reasonable rules and restrictions. Licensee shall accept the Licensed Premises and Shared Premises in their "as-is" conditions and SmartLabs shall have no obligation to alter, repair or otherwise prepare the Licensed Premises for Licensee's use or to pay for, or provide any, improvements to the Licensed Premises. Licensee shall not use the Licensed Premises or Shared Premises for any use other than the foregoing, including but not limited to medical care or human clinical trials, without first obtaining written permission from SmartLabs, which SmartLabs may withhold in its sole discretion.

(b) **Scope of License**. The License shall not grant access to any space not specifically set forth in this Agreement. Licensee understands and agrees that other licensee(s) may jointly occupy portions of the Building, including but not limited to the Shared Premises. Licensee agrees to cooperate and coordinate with any other licensee(s) that occupies portions of the Building and that, other than the Licensed Premises, use of any other portion of the Building shall not be exclusive to Licensee. Sections 10, 11 and 13 below shall apply to any and all Claims (as defined below) arising out of, or in connection with, any other licensee(s), persons or entities using or occupying the Building.

(c) **Occupants**. The License shall only grant Licensee, and no more than twenty-two (22) of Licensee's members, employees or agents (collectively, "**Occupants**"), access to the Licensed Premises and Shared Premises; provided, however, that SmartLabs may grant access to additional Occupants ("**Additional Occupants**") as set forth in Section 3 below.

2. Term and Termination.

(a) **Term.** Unless terminated earlier in accordance with this Section 2, the term ("**Term**") of this Agreement shall commence on May 1, 2021("**Term Commencement Date"**) and expire on April 30, 2022 ("**Expiration Date**"). Under no circumstance shall SmartLabs be liable to Licensee for failure to provide access to the Licensed Premises or Shared Premises on or before May 1, 2021, including but not limited to, failure due to an event of force majeure including, but not limited to, strikes, work stoppages, accidents, acts of war or terrorism, civil or military disturbances, government actions or prohibitions or emergencies, disruptions arising from health or safety (including, but not limited to pandemic or epidemic), nuclear or natural catastrophes or acts of God, and interruptions, loss or malfunctions of utilities, communications or computer (software and hardware) services (collectively, a "**Force Majeure**"); provided, however, that if SmartLabs is unable to provide Licensee access to the Licensed Premises on or before May 1, 2021, the Term Commencement Date and Expiration Date shall be extended by the number of days SmartLabs is unable to provide access to the Licensed Premises.

(b) **Extension Option.** Provided Licensee is not in breach of the Agreement, Licensee shall have an option to extend the Term for an additional six (6) month period commencing immediately upon the Expiration Date ("**Extended Term**") upon the same terms as set forth herein, including the License Fee increase as set forth in Section 3(a). Licensee shall exercise the foregoing option by providing written notice to Licensor given no less than six (6) months prior to the Expiration Date. This option shall terminate if written notice is not timely given, time being of the essence.

(c) **Termination for Licensee Default.** SmartLabs may terminate this Agreement for "cause" if SmartLabs has provided written notice of a breach by Licensee of the terms of this Agreement and such breach is not cured within ten (10) days of such notice being sent to Licensee; provided, however, in the event any "cause" that endangers the health and/or safety of any other Building occupant and/or the Building itself, such failure shall be deemed "cause" if Licensee receives notice of the same (which may be oral) and fails to cure within 24 hours, whereas for the avoidance of doubt in such instances Licensor shall have the immediate right to terminate this License following such failure to cure within 24 hours. Such breaches shall include, but are not limited to: (i) Licensee's violation of this Agreement or any applicable provisions of the Lease; (ii) Licensee's failure to materially comply with any covenants contained herein; or (iii) Licensee's use of the Licensed Premises or Shared Premises in violation of any rules and procedures promulgated by SmartLabs or Landlord. If any such breach is not timely cured, and at any time thereafter, with or without notice or demand and without limiting SmartLabs in the exercise of any right or remedy that SmartLabs may have, SmartLabs may do any or all of the following

by written notice to Licensee to the fullest extent permitted by applicable law: (A) terminate Licensee's access to the Licensed Premises, or (B) terminate the License. In either instance, Licensee shall promptly remove all persons and property from the Licensed Premises. In such event, SmartLabs shall have the immediate right to enter and remove all persons and property from the Licensed Premises and Shared Premises, and such property may be removed and stored in a public warehouse or elsewhere at the cost and for the account of Licensee, without SmartLabs being deemed guilty of trespass or becoming liable for any loss or damage that may be occasioned thereby. In the event that SmartLabs shall elect to so terminate this License, then SmartLabs shall be entitled to recover from Licensee all direct and indirect damages incurred by SmartLabs by reason of Licensee's default, including, but not limited to, recovery of any broker's fee paid by SmartLabs in relation to this Agreement and all reasonable attorneys' fees. Upon termination of this Agreement, the License shall expire and Licensee shall immediately remove all persons and property from the Licensed Premises and Shared Premises. Under no circumstances shall SmartLabs or Landlord be liable for any alleged, purported, consequential, direct or indirect damages resulting from SmartLabs or Landlord terminating this Agreement.

3. License Fee.

(a) **Base Fee**. Licensee shall pay a monthly license fee equal to $104,000.00 ("**License Fee**"), which Licensee shall pay in advance on or before the first day of each and every month during the Term by electronic payment to SmartLabs. The License Fee shall be subject to a three and one half percent (3.5%) increase upon each anniversary of the Term Commencement Date.

(b) **Late Fee**. If any payment of the License Fee, or any other payment due under this Agreement, is not received by SmartLabs on or before the first day of each month, or when otherwise due, Licensee shall pay to SmartLabs a late payment charge equal to ten percent (10%) of the amount of such delinquent payment, in addition to any outstanding License Fee or any other payment due under this Agreement then owing. Thereafter, Licensee shall pay eighteen percent (18%) interest on any outstanding sums due under this Agreement that remain unpaid. The foregoing interest shall accrue from the date such payment is due until the date such payment is actually paid.

(c) **Additional Fees**. Licensee may request that SmartLabs grant access to Additional Occupants, provided that Licensee first (i) submits a written request to SmartLabs requesting Additional Occupants; (ii) Licensee receives written confirmation from SmartLabs granting access to Additional Occupants (which SmartLabs may withhold in its sole discretion); and (iii) Licensee pays, in addition to the License Fee, an amount equal to $1,500 per month for each Additional Occupant.

(d) **Security Deposit.** Licensee shall to pay a Security Deposit equal to $104,000.00 ("**Security Deposit**"). The purpose of the Security Deposit is to guarantee the full, prompt and faithful performance by Licensee of all of the terms, conditions, covenants, agreements, warranties and provisions of this Agreement to be performed, fulfilled or observed by Licensee hereunder, including but not limited to the payment of the License

Fee and other charges. If Licensee breaches any term or condition of this Agreement, said Security Deposit or any part thereof may be used to pay any such payment or perform any obligations of the Licensee, and the Licensee shall immediately replace the amount of the Security Deposit so used. Said Security Deposit may be co-mingled with the SmartLabs' other funds, need not be kept in a separate account, and SmartLabs shall not be required to pay interest on same. SmartLabs shall return the balance of the Security Deposit to Licensee, less any amounts duly owed from Licensee to SmartLabs, within sixty (60) days after the end of Term, as extended from time to time. SmartLabs, from time to time, may transfer the Security Deposit to any mortgagee or any grantee or grantees to be held by such mortgagee, grantee or grantees as the Security Deposit hereunder on the above terms, and upon such transfer to such mortgagee, grantee or grantees, SmartLabs thereupon shall be relieved from all further liability to the Licensee with respect to the Security Deposit, and Licensee thereafter shall look only to such mortgagee, grantee or grantees for the return of the Security Deposit.

(e) **Initial Payment**. Licensee shall pay, immediately upon executing this Agreement, an amount equal to the License Fee for the first month of the Term of this Agreement ($104,000.00), the License Fee for the last month of the Term of this Agreement ($104,000.00) and the Security Deposit. As such, Licensee shall pay a total of $312,000.00 on or before the execution of this Agreement.

4. **Service Agreement.** SmartLabs agrees to provide to Licensee, during the entire Term of this Agreement, the services set forth in the Service Agreement attached hereto as **Exhibit 2**, except when prevented from providing same because of a Force Majeure. The License Fee shall cover and include the cost of the services set forth in the Service Agreement and, unless the scope of services requested by Licensee exceed those set forth in the Service Agreement, Licensee shall not be assessed any additional fees for services contained in the Service Agreement. The Service Agreement shall be governed by the terms of this Agreement and if there is any conflict between the covenants and representations contained in this Agreement and the Service Agreement, the terms of this Agreement shall prevail and be binding upon the parties. SmartLabs shall not be liable for any failure to provide the services set forth in the Service Agreement to the extent such failure is beyond SmartLabs' reasonable control.

5. **Common Areas.** Licensee hereby acknowledges that other licensees and/or occupants are occupying or may in the future occupy portions of the Building. Licensee's use of the Licensed Premises and Shared Premises, and access to and use of the common areas and any other services in connection with the Licensed Premises or this Agreement, shall be subject to any and all rules and procedures reasonably promulgated by SmartLabs and/or Landlord and delivered to Licensee from time to time. Licensee's compliance with such rules and procedures constitutes a material inducement to SmartLabs' willingness to enter into this Agreement; any violation thereof shall constitute a material breach of this Agreement. Licensee shall not in any way obstruct or interfere with the rights of other licensees, occupants or users of the Building, nor shall it permit its employees, representatives, or contractors to do so. SmartLabs shall use reasonable efforts to ensure that other licensees, occupants or users of the Building, do not and do not permit their employees, representatives, or contractors to unreasonably obstruct or interfere with the rights of Licensee under this Agreement.

6. **Parking.** During the Term, Licensee shall have a non-exclusive license to use fifteen (15) unreserved parking spaces on a "first-come, first-serve" basis, in common with other occupants of the Building and free of parking charges. The parking spaces are located within or adjacent to the Building (the "**Parking Facility**"). Licensee's right to use the parking spaces is conditioned upon Licensee (a) abiding by any reasonable rules and regulations promulgated by SmartLabs or the Landlord ("**Parking Rules and Regulations**") and (b) ensuring that Licensee's employees, Occupants and visitors also comply with the Parking Rules and Regulations. Licensee's rights hereunder are subject to SmartLabs' rights under the Lease, including but not limited to the Landlord's right to change the size, configuration, design, layout, location and all other aspects of the Parking Facility (including without limitation, implementing paid visitor parking).

7. **Modifications to Licensed Premises.** Licensee shall not make any modification to the Licensed Premises without SmartLabs' prior written approval, which approval may be withheld or conditioned in SmartLabs' sole discretion. Licensee shall bear the cost of any approved modifications to the Licensed Premises. All articles of personal property, and all business and trade fixtures, machinery and equipment, cabinet work, furniture and movable partitions, if any, paid for or installed by Licensee in the Licensed Premises will be and remain the property of Licensee and may be removed by Licensee at any time, provided that Licensee, at its expense, shall repair any damage to the Licensed Premises caused by such removal or by the original installation. Licensee shall remove all of Licensee's personal property at the expiration of the Term of this Agreement or sooner termination of this Agreement, in which event the removal shall be done at Licensee's expense and Licensee, prior to the end of the Term of this Agreement or upon sooner termination of this Agreement, shall repair any damage to the Licensed Premises caused by its removal.

   Notwithstanding the foregoing, SmartLabs has agreed to install a wall separating the tissue culture room, and to install an additional sink and safety shower as set forth in Exhibit 1-A ("**Approved Initial Modifications**"). Licensee understands that the Approved Initial Modifications will not be completed on or before the Term Commencement Date, provided, however, that SmartLabs shall use commercially reasonable efforts to complete the Approved Initial Modifications as soon as is reasonably practicable. Licensee shall bear the cost of the Approved Initial Modifications, which is currently estimated at Eight Thousand Dollars ($8,000.00), and shall pay the same to SmartLabs upon substantial completion of the Approved Initial Modifications.

8. **Hazardous Materials.** Licensee shall strictly comply with all Environmental Laws to the extent such provisions relate to the Licensed Premises during the Term of this Agreement and are the obligation of Licensee under this Agreement (and not the obligation of SmartLabs with respect to provision of services described on **Exhibit 2**). For purposes hereof, "**Environmental Laws**" shall mean all laws, statutes, ordinances, rules and regulations of any local, state or federal governmental authority having jurisdiction concerning environmental, health and safety matters, including but not limited to any discharge by Licensee or Licensee's Occupants into the air, surface water, sewers, soil or groundwater of any Hazardous Material (defined below) whether within or outside the Licensed Premises, including, without limitation

(i) the Federal Water Pollution Control Act, 33 U.S.C. Section 1251 et seq., (ii) the Federal Resource Conservation and Recovery Act, 42 U.S.C. Section 6901 et seq., (iii) the Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. Section 9601 et seq., and (iv) the Toxic Substances Control Act of 1976, 15 U.S.C. Section 2601 et seq.. Licensee, at its sole cost and expense, shall comply with (a) Environmental Laws, and (b) any rules, requirements and safety procedures of the California Environmental Protection Agency ("CalEPA"), the city in which the Building is located, and any insurer of the Building or the Licensed Premises with respect to Licensee's use, storage and disposal of any Hazardous Materials. Notwithstanding anything in this Agreement to the contrary, Licensee shall have no liability to SmartLabs or responsibility under this Agreement for any Hazardous Materials in, on, under or about the Licensed Premises that were not released, discharged, stored or introduced by Licensee or its agents. Licensee understands and agrees that SmartLabs must decontaminate the Licensed Premise prior to Licensee vacating same and therefore Licensee shall fully cooperate with SmartLabs in the aforementioned decontamination, which may include Licensee ceasing its operations and/or removing personal property prior to the expiration of the Term. The term "**Hazardous Material**" means asbestos, oil or any hazardous, radioactive or toxic substance, material, waste or petroleum derivative which is or becomes regulated by any Environmental Law or which is designated as a "hazardous substance," "hazardous material," "oil," "hazardous waste" or toxic substance under any Environmental Law. Licensee shall follow all of SmartLabs' Environmental Health and Safety ("**EH&S**") guidelines and requirements, which may be modified from time to time.

9. Fire, Other Casualty; Eminent Domain. In the event of a fire or other casualty affecting the Building or the Licensed Premises, or a taking of all or a part of the Building or Licensed Premises under the power of eminent domain, (i) SmartLabs shall not have any obligation to repair or restore the Licensed Premises, alterations or personal property; (ii) Licensee shall be entitled only to a proportionate abatement of the License Fee during the time and to the extent the Licensed Premises are unfit for the purposes permitted under this Agreement and not used by Licensee as a result thereof; (iii) Licensee shall not, by reason thereof, have a right to terminate this Agreement unless the Lease shall be terminated; and (iv) SmartLabs and Landlord reserve the right to terminate this Agreement in connection with any right granted to either SmartLabs or Landlord under the Lease whether or not the Licensed Premises is damaged or the subject of a taking. In the event SmartLabs or Landlord exercises the right to terminate the Lease as the result of any such fire, casualty or taking, (a) SmartLabs shall provide Licensee with a copy of the relevant termination notice and this Agreement shall terminate on the date upon which the Lease terminates and (b) Licensee shall immediately pay to SmartLabs all of Licensee's insurance proceeds relating to all alterations.

10. Limit of Liability. Notwithstanding anything to the contrary contained in this Agreement, Landlord, SmartLabs, their respective, members, officers, directors, employees, agents, servants, lenders, mortgagees, ground lessors beneficiaries and contractors (collectively, the "**SmartLabs Parties**"), shall not be liable for any damages or injury to person or property or resulting from the loss of use thereof sustained by Licensee or anyone having claims through or on behalf of Licensee, based on, arising out of, or resulting from, any cause whatsoever, including any due to the Building becoming out of repair, or due to the occurrence of any accident or event in or about the Building, or due to any act or neglect of any tenant or occupant

of the Building or any other person. Notwithstanding the foregoing provision of this Section, SmartLabs Parties shall not be released from liability to Licensee for any physical injury to any natural person caused by SmartLabs Parties' gross negligence or willful misconduct to the extent such injury is not covered by insurance either carried by Licensee (or such person) or required by this Agreement to be carried by Licensee; provided that SmartLabs Parties shall not, under any circumstances, be liable for any exemplary, punitive, consequential or indirect damages (or for any interruption of or loss to business). Notwithstanding anything to the contrary set forth in this Agreement, if Licensee or anyone having claims through or on behalf of Licensee is awarded a judgment or other remedy against SmartLabs Parties, the recourse for satisfaction of the same shall be limited to execution against SmartLabs' interest in the Building. No other asset of SmartLabs Parties' shall be available to satisfy, or be subject to, such judgment or other remedy, nor shall any such person be held to have any personal liability for satisfaction or any claim or judgment.

11. Waiver of Claims. Licensee hereby releases and waives any and all claims against the SmartLabs Parties for injury or damage to person, property or business of every kind, nature and description, sustained in or about the Building or the Licensed Premises by Licensee or anyone claiming under Licensee, other than by reason of gross negligence or willful misconduct of the SmartLabs Parties and except as provided herein or in any case which would render this release and waiver void under applicable law.

12. Insurance. Licensee shall procure insurance as set forth in the Insurance Requirements attached hereto as **Exhibit 3**.

(a) **Subrogation.** Licensee and its insurers hereby waive any and all rights of recovery or subrogation against the SmartLabs Parties with respect to any Claims (as defined below) howsoever caused, that are covered or should have been covered, by valid and collectible insurance, including any deductibles or self-insurance maintained thereunder. If necessary, Licensee shall endorse the required insurance policies to permit waivers of subrogation as required hereunder and hold harmless and indemnify the SmartLabs Parties for any loss or expense incurred as a result of a failure to obtain such waivers of subrogation from insurers. Such waivers shall continue so long as Licensee's insurers so permit. Any termination of such a waiver shall be by written notice to SmartLabs. Licensee, upon obtaining the policies of insurance required or permitted hereunder, shall give notice to its insurance carriers that the foregoing waiver of subrogation is contained in herein. If such policies shall not be obtainable with such waiver or shall be so obtainable only at a premium over that chargeable without such waiver, then Licensee shall notify SmartLabs of such conditions. SmartLabs and its insurers hereby waive any and all rights of recovery or subrogation against the Licensee with respect to any Claims (as defined below) howsoever caused, that are covered or should have been covered, by valid and collectible insurance, including any deductibles or self-insurance maintained thereunder.

(b) **Assumption of Risk**. Licensee assumes the risk of damage, and subject to the waiver of subrogation contained in Section 12(a) above, shall be liable for any damage caused to, any fixtures, goods, inventory, merchandise, equipment and leasehold improvements, and the SmartLabs Parties shall not be liable for injury to Licensee's business or any loss of

income therefrom, relative to such damage. Licensee shall, at Licensee's sole cost and expense, carry such commercially reasonable insurance as Licensee desires for Licensee's protection with respect to personal property of Licensee or business interruption.

13. Indemnification. Licensee shall indemnify, defend (by counsel acceptable to SmartLabs), release, protect and hold the SmartLabs Parties harmless from and against any and all demands, claims, liabilities, losses, costs, expenses, actions, causes of action, damages, suits or judgments, and all reasonable expenses (including reasonable attorneys' fees, charges and disbursements, regardless of whether the applicable demand, claim, action, cause of action or suit is voluntarily withdrawn or dismissed) incurred in investigating or resisting the same (collectively, "**Claims**") of any kind or nature that arise before, during or after the Term, arising out of or related to: (i) the use or occupancy of the Licensed Premises or Shared Premises by Licensee or its Occupants or anyone claiming by, through or under Licensee; (ii) the failure by Licensee or anyone claiming by, through or under Licensee to comply with any term, condition, or covenant of this Agreement or the Lease, including, without limitation, Licensee's obligation to surrender the Licensed Premises in the condition herein required; (iii) the negligence or willful misconduct of Licensee, its agents or anyone claiming by, through or under Licensee; (iv) the existence of Hazardous Materials on, under or about the Licensed Premises to the extent caused, stored, released, discharged or introduced by Licensee or its agents; (v) the death of or injury to any person or damage to any property in the Licensed Premises; or (vi) the death of or injury to any person or damage to any property on or about the Building to the extent caused by the negligence, recklessness or willful misconduct of Licensee or its agents.

14. Assignment.

(a) No Assignment. Licensee cannot and shall not assign, encumber or transfer this Agreement, or any part of it, or its right or interest in it, without SmartLabs' prior written approval. SmartLabs may assign this Agreement.

(b) Prohibited Transfers. Notwithstanding any other provision contained in this Agreement to the contrary, Licensee shall not knowingly, after reasonable inquiry, transfer or permit the transfer of any legal or beneficial interest in Licensee to, or assign, sublicense or otherwise transfer all or any portion of its interest under this Agreement or in all or any portion of the Licensed Premises to, or enter into any sublicense or other use or occupancy agreement to, any:

i. Person (or any Person whose operations are directed or controlled by a Person) that has been convicted of or has pleaded guilty in a criminal proceeding to a felony or that is an ongoing target of a grand jury investigation convened pursuant to applicable statutes concerning organized crime;

ii. Person organized in or controlled from a country, the activities with respect to which are regulated or controlled pursuant to the following laws and the regulations or executive orders promulgated thereunder: (A) the Trading with the Enemy Act of 1917, 50 U.S.C. App. §1, *et seq.*, as amended; (B) the International Emergency Economic

Powers Act of 1976, 50 U.S.C. §1701, *et seq.*, as amended; or (C) the Anti-Terrorism and Arms Export Amendments Act of 1989, codified at Section 6(j) of the Export Administration Act of 1979, 50 U.S.C. App. §2405W, as amended; or

iii. Person with whom Landlord or SmartLabs is restricted from doing business under either (A) Executive Order No. 13224 on Terrorist Financing (effective September 24, 2001 (as amended or supplemented from time to time, the "**Executive Order**"), or (B) the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (Public Law 10756; as amended, from time to time, the "**Patriot Act**"), or (C) the regulations of the United Stated Department of the Treasury Office of Foreign Assets Control (including, without limitation, those Persons named on the list of "Specially Designated Nationals and Blocked Persons" as modified from time to time), or other governmental action; or

iv. Affiliate of any of the Persons described in the preceding paragraphs (i), (ii) or (iii).

As used herein, "Person" shall mean any individual or entity, and the heirs, executors, administrators, legal representatives, successors and assigns of such Person where the context so admits; "Affiliate" shall mean, with respect to any Person, (i) in the case of any such Person which is an Entity, any partner, shareholder, member or other owner of such Entity, provided that such partner, shareholder, member or other owner owns more than fifty percent (50%) of the Equity Interests of such Entity, and (ii) any other Person which is a Parent, a Subsidiary, or a Subsidiary of a Parent with respect to such Person or with respect to one or more of the Persons referred to in the preceding clause (i); "Equity Interest" shall mean with respect to any Entity, (i) the legal (other than as a nominee) or beneficial ownership of outstanding voting or non-voting stock of such Entity if such Entity is a business corporation, a real estate investment trust or a similar entity, (ii) the legal (other than as a nominee) or beneficial ownership of any partnership, membership or other voting or non-voting ownership interest in a partnership, joint venture, limited liability company or similar entity, (iii) a legal (other than as a nominee) or beneficial voting or non-voting interest in a trust if such Entity is a trust and (iv) any other voting or nonvoting interest that is the functional equivalent of any of the foregoing; "Parent" shall mean, with respect to any Subsidiary, any Person which owns directly or indirectly through one or more Subsidiaries the entire Equity Interest in such Subsidiary; and "Subsidiary" shall mean, with respect to any Parent, any Entity in which a Person owns, directly or indirectly through one or more Subsidiaries, the entire Equity Interest in such Subsidiary.

15. Miscellaneous.

(a) **Attorneys' Fees**. In the event of any litigation or arbitration between Licensee and SmartLabs, whether based on contract, tort or other cause of action or involving bankruptcy or similar proceedings, in any way related to this Agreement, the non-prevailing party shall pay to the prevailing party all reasonable attorneys' fees and costs and expenses of any type, without restriction by statute, court rule or otherwise, incurred by the prevailing party in connection with any action or proceeding (including arbitration proceedings, any appeals and the enforcement of any judgment or award), whether or not the dispute is litigated or prosecuted to final judgment. The "prevailing party" shall be determined based upon an

assessment of which party's major arguments or positions taken in the action or proceeding could fairly be said to have prevailed (whether by compromise, settlement, abandonment by other party of its claim or defense, final decision after any appeals, or otherwise) over the other party's major arguments or positions on major disputed issues. Any fees and cost incurred in enforcing a judgment shall be recoverable separately from any other amount included in the judgment and shall survive and not be merged in the judgment.

(b) **Brokerage**. Licensee warrants and represents that Licensee has dealt with no broker in connection with the consummation of this Agreement other than Newmark ("**Broker**"), and, in the event of any brokerage claims asserted against SmartLabs predicated upon prior dealings with Licensee, Licensee agrees to defend the same and indemnify SmartLabs against any such claim (except any claim by Broker).

(c) **Authority.** Each person executing this Agreement on behalf of a party hereto represents and warrants that he or she is authorized and empowered to do so and to thereby bind the party on whose behalf he or she is signing.

(d) **Captions.** All captions and headings in this Agreement are for the purposes of reference and convenience and shall not limit or expand the provisions of this Agreement.

(e) **Counterparts.** This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original and all of which taken together shall comprise but a single instrument.

(f) **Entire Agreement.** This Agreement contains all of the covenants, conditions and agreements between the parties concerning the Licensed Premises, and shall supersede any and all prior correspondence, agreements and understandings concerning the Licensed Premises, both oral and written. No addition or modification of any term or provision of this Agreement shall be effective unless set forth in writing and signed by both SmartLabs and Licensee.

(g) **Notices.** Any notice required or permitted under this Agreement shall be effective if in writing and delivered to the other party at the following address.

SMARTLABS
40 Guest Street
Boston, Massachusetts 02135
Attn: Legal Department

LICENSEE
Two Tower Place
South San Francisco, CA 94080
Attn: Faisal Shawwa

(h) **Governing Law and Jurisdiction.** This Agreement shall be governed by and construed in accordance with the laws of California. The parties hereby consent, in addition to the arbitration provision below, to the personal jurisdiction and venue of any state or federal court located in the county in which the Building is located and any successor court, and the service or process by any means authorized by such court.

Notwithstanding the foregoing, SmartLabs may elect to, upon written notice to Licensee, submit any dispute arising hereunder (including but not limited to any claim that all or some of this Agreement is invalid, illegal or otherwise voidable or void) to binding arbitration. Upon SmartLabs' exercise of its foregoing rights, arbitration shall be submitted to and determined in binding arbitration in Boston, Massachusetts, under the Rules for Commercial Arbitration of the American Arbitration Association ("**AAA**"). This arbitration provision shall survive the expiration or earlier termination of this Agreement and such arbitration shall be held in Boston, Massachusetts. The arbitration shall be conducted by a single neutral arbitrator. The arbitrator shall be appointed by the AAA under the Rules for Commercial Arbitration of AAA. The decision rendered by the arbitrator shall be final and binding upon the parties and may be entered as a judgment in, and enforced by, any court of competent jurisdiction.

(i) **Exhibits.** All exhibits and any schedules or riders attached to this Agreement are incorporated herein by this reference and made a part hereof, and any reference in the body of the Agreement or in the exhibits, schedules or riders to the Agreement shall mean this Agreement, together with all exhibits, schedules and riders.

(j) **Waiver of Trial by Jury**. LICENSEE HEREBY WAIVES ANY AND ALL RIGHTS IT MAY HAVE UNDER APPLICABLE LAW TO TRIAL BY JURY WITH RESPECT TO ANY DISPUTE WITH ANY SMARTLABS PARTIES ARISING DIRECTLY OR INDIRECTLY IN CONNECTION WITH THIS AGREEMENT OR THE LICENSED PREMISES.

(k) **Successors and Assigns.** Subject to the provisions of this Agreement relating to assignment and subletting, this Agreement shall be binding upon, and shall inure to the benefit of the parties' respective representatives, successors and assigns.

(l) **Relationship of Parties.** Nothing in this Agreement shall be deemed to create any joint venture or principal-agent relationship or partnership between any of the parties hereto, and no party is authorized to, and no party shall, act toward third parties or the public in any manner that would indicate any such relationship.

(m) **Access.** SmartLabs may enter the Licensed Premises at any time, in accordance with the revocable, non-exclusive, non-transferable, non-assignable license granted herein. Notwithstanding the foregoing, Landlord and SmartLabs reserve the right to enter the Licensed Premises upon reasonable prior written or oral notice to Licensee (except that in case of emergency no notice shall be necessary) in order to inspect the Licensed Premises and/or the performance by Licensee of the terms of this Agreement or to exercise SmartLabs' rights or perform SmartLabs' obligations hereunder.

(n) **Force Majeure.** Except for monetary obligations, the required time for performance of obligations of each party to this Agreement shall be subject to extension by a party if such party is prevented from performing such obligation as a result of an event of Force Majeure, provided that any party whose performance is delayed by Force Majeure must use commercially reasonable efforts to minimize any such delay and any effects of such delay.

(o) **Lease Matters**. SmartLabs represents and warrants to Licensee that no consent of the Landlord under the Lease is required for the execution of this Agreement or the performance of SmartLabs' obligations and the exercise of Licensee's rights under this Agreement. SmartLabs covenants to maintain the Lease in full force and effect for the Term of this Agreement.

LICENSEE UNDERSTANDS AND ACKNOWLEDGES THAT THIS AGREEMENT DOES NOT GRANT ANY INTEREST IN REAL PROPERTY. RIGHTS UNDER THIS AGREEMENT ONLY CONSTITUTE A LICENSE FOR USE OF THE LICENSED PREMISES AND DO NOT INVOLVE THE GRANT OF ANY INTEREST IN REAL ESTATE. LICENSEE SPECIFICALLY DISCLAIMS ANY RIGHTS TO SUMMARY PROCESS AND, PROVIDED THAT SMARTLABS COMPLIES WITH ALL OBLIGATIONS (INCLUDING WITHOUT LIMITATION NOTICE AND CURE REQUIREMENTS) HEREUNDER, EXPLICITLY PERMITS SMARTLABS TO USE SELF-HELP REMEDIES PROVIDED THAT SUCH SELF-HELP REMEDIES DO NOT BREACH THE PEACE.

IN WITNESS WHEREOF, SmartLabs and Licensee have duly executed this Agreement as of the day and year first above written.

SMARTLABS:

/s/ Cole Young
By: Cole Young
Title: Corporate Counsel

LICENSEE:

/s/ Nassim Usman
By: Nassim Usman
Title: President & CEO

LICENSEE:

/s/ Clinton J. Musil
By: Clinton J. Musil
Title: Chief Financial Officer

Exhibit 31.1

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

I, Nassim Usman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Catalyst Biosciences, Inc. for the period ended September 30, 2021;

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

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

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

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

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

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

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

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

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

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

Date: November 12, 2021

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

Exhibit 31.2

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

I, Seline Miller, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Catalyst Biosciences, Inc. for the period ended September 30, 2021;

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

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

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

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

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

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

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

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

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

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

Date: November 12, 2021

/s/ Seline Miller
Seline Miller
Interim Chief Financial Officer
(Interim Financial and Principal Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Catalyst Biosciences, Inc. (the "Company") for the period ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Nassim Usman, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2021

/s/ Nassim Usman, Ph.D.

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

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Catalyst Biosciences, Inc. (the "Company") for the period ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Seline Miller, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2021

/s/ Seline Miller

Seline Miller
Interim Chief Financial Officer
(*Interim Financial and Principal Accounting Officer*)