UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K	

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 1, 2018

CATALYST BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 000-51173 (Commission File Number) 56-2020050 (IRS Employer Identification No.)

611 Gateway Blvd., Suite 710 South San Francisco, California (Address of principal executive offices)

94080 (Zip Code)

 $\begin{tabular}{ll} \textbf{(650) 871-0761} \\ \textbf{Registrant's telephone number, including area code} \\ \end{tabular}$

	appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the provisions:
	Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
	Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
	Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
	Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
	check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).
Emerging	growth company
,	ging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any ised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. \Box

Item 2.02 Results of Operation and Financial Condition

On November 1, 2018, Catalyst Biosciences, Inc., a Delaware corporation (the "Company"), announced its third quarter 2018 financial results. A copy of the Company's press release is attached as Exhibit 99.1 hereto and incorporated by reference herein.

The information concerning financial results in this Form 8-K and in Exhibit 99.1 shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information concerning financial results in this Form 8-K and in Exhibit 99.1 shall not be incorporated into any registration statement or other document filed with the Securities and Exchange Commission by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No. Description

99.1 <u>Press Release dated November 1, 2018.</u>

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 hereunto duly authorized.

CATALYST BIOSCIENCES, INC.

Date: November 1, 2018

/s/ Fletcher Payne

Fletcher Payne

Chief Financial Officer



Catalyst Biosciences Reports Third Quarter Operating & Financial Results and Provides a Corporate Update

Presented Updated Positive Interim Data from the Phase 2/3 Study of Marzeptacog Alfa (Activated) (FVIIa) at Two Scientific Meetings

Published Data from Phase 1 Study of Marzeptacog Alfa (Activated) in the Journal of Thrombosis & Haemostasis

Ended Q3 with a cash balance of ~\$129M

SOUTH SAN FRANCISCO, Calif. – November 1, 2018 – Catalyst Biosciences, Inc. (NASDAQ: CBIO), today announced operating and financial results for the third quarter ending September 30, 2018 and provided a corporate update.

Recent Milestones:

- Reported positive interim data from its Phase 2/3 study of subcutaneous (SQ) prophylactic Factor VIIa (FVIIa) variant marzeptacog alfa (activated) (MarzAA), being developed for the treatment of hemophilia A or B with inhibitors at the 2018 meeting of the International Society for Thrombosis & Hemostasis (ISTH) in Dublin, Ireland on July 18th and presented updated data in the Subcutaneous Delivery of Coagulation Factors session at the 2018 Hemophilia Drug Development Summit (HDDS) in Boston, MA on August 15th.
- Published data from the Phase 1 trial of MarzAA in individuals with hemophilia A or B with or without inhibitors in the peer-reviewed *Journal of Thrombosis & Haemostasis*. The paper, entitled: "Phase 1, single-dose escalating study of marzeptacog alfa (activated), a recombinant factor VIIa variant, in patients with severe hemophilia," described the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of single ascending intravenous (IV) bolus doses of MarzAA.
- Initiated a comprehensive review of the Cohort 6 neutralizing antibody (nAb) observation from the Phase 1/2 study of Factor IX (FIX) variant dalcinonacog alfa (DalcA). We are planning to provide further updates on these analyses later in 2018.

"We had an active third quarter in which we presented interim data on our ongoing Phase 2/3 SQ study of MarzAA at the 2018 ISTH & HDDS meetings and published data from our Phase 1 IV trial of MarzAA in the *Journal of Thrombosis & Haemostasis*," said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. "We are very encouraged by the interim data from the Phase 2/3 study of MarzAA and plan to complete enrollment of the Phase 2 portion by the end of 2018. Simultaneously, we initiated an analysis of the nAb results from the Phase 1/2 study of dalcinonacog alfa (DalcA) (formerly CB 2679d/ISU304) Factor IX program. Our Q3 ending cash balance of \$129M allows us to continue the independent development of our subcutaneous prophylactic MarzAA and DalcA candidates."



Upcoming Milestones

- Interim analysis from the Phase 2/3 MarzAA study at ASH 2018.
- Additional data and analysis of the cause and impact of the antibody observations in Cohort 6 of the dalcinonacog alfa (DalcA) Phase 1/2 trial in December 2018.

Second Quarter 2018 Results and Financial Highlights

- Cash, cash equivalents and short-term investments, as of September 30, 2018 were \$129.2 million due primarily to the approximately \$106.8 million in net financing in February 2018 and \$9.5 million in proceeds from the exercise of warrants during the first quarter 2018.
- Research and development expense for the three months ended September 30, 2018 was \$5.6 million, compared with \$3.8 million for the prior year period. The increase was due primarily to personnel-related costs, preclinical third-party research and development service contracts and manufacturing expenses for MarzAA and DalcA.
- General and administrative expense for the three months ended September 30, 2018 was \$2.8 million compared with \$2.4 million for the prior year period. The increase was due primarily to personnel related expenses and professional service costs.
- Interest and other income for the three months ended September 30, 2018 was \$0.7 million, compared with \$0.1 for the prior year period. The increase was due primarily to investment and dividend income.
- Net loss attributable to common stockholders for the three months ended September 30, 2018 was \$7.7 million, or (\$0.64) per basic and diluted share, compared with \$5.8 million, or (\$1.34) per basic and diluted share, for the prior year period.
- On February 19, 2018, the final \$5 million of the company's redeemable convertible notes matured and were repaid in full with \$5 million from the company's restricted cash. The Company has no outstanding notes or debt.
- As of September 30, 2018, the Company had 11,942,729 shares of common stock outstanding.

About Catalyst Biosciences

Catalyst is a clinical-stage biopharmaceutical company developing novel medicines to address hematology indications. Catalyst is focused on the field of hemostasis, including the subcutaneous prophylaxis of hemophilia and facilitating surgery in individuals with hemophilia. For more information, please visit www.catalystbiosciences.com.



Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements about development plans for Catalyst's MarzAA and DalcA, including the potential completion of the Phase 2 portion of the Phase 2/3 trial of MarzAA by the end of 2018, plans to present interim analysis from this trial at ASH 2018, plans to complete the ongoing analysis of nAbs for DalcA by December 2018, and the potential resumption of clinical trials of DalcA. Actual results or events could differ materially from the plans, intentions, expectations and projections disclosed in the forward-looking statements. Various important factors could cause actual results or events to differ materially from the forward-looking statements that the Company makes, including, but not limited to, the risk that trials and studies may be delayed and may not have satisfactory outcomes, that the ongoing Phase 2/3 efficacy trial may not replicate the results from earlier studies, that potential adverse effects may arise from the testing or use of MarzAA, including the generation of antibodies, that the analysis of the nAbs observed in the Phase 1/2 trial of DalcA or other factors lead us not to resume clinical trials of DalcA, the risk that costs required to develop or manufacture the Company's products will be higher than anticipated, competition and other factors that affect our ability to establish collaborations on commercially reasonable terms and other risks described in the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, filed with the Securities and Exchange Commission on August 2, 2018, along with other filings with the Securities and Exchange Commission. The Company does not assume any obligation to update any forward-looking statements, except as required by law.

Contacts:

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Catalyst Biosciences, Inc. Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	September 30, 2018 (Unaudited)		Dec	ember 31, 2017
Assets				
Current assets:				
Cash and cash equivalents	\$	35,998	\$	14,472
Short-term investments		93,223		17,971
Restricted cash		50		5,333
Prepaid and other current assets		3,538	_	1,333
Total current assets		132,809		39,109
Other assets, noncurrent		352		128
Property and equipment, net		255		276
Total assets	\$	133,416	\$	39,513
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable	\$	369	\$	747
Accrued compensation		1,082		1,366
Other accrued liabilities		1,840		1,322
Deferred revenue		_		212
Deferred rent, current portion		13		7
Redeemable convertible notes				5,085
Total current liabilities		3,304		8,739
Deferred rent, noncurrent portion		161		_
Total liabilities		3,465		8,739
Stockholders' equity:				
Preferred stock, \$0.001 par value, 5,000,000 shares authorized; 0 and 3,680 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively		_		_
Common stock, \$0.001 par value, 100,000,000 shares authorized; 11,942,729 and 6,081,230 shares issued				
and outstanding at September 30, 2018 and December 31, 2017, respectively		12		6
Additional paid-in capital		322,468		204,262
Accumulated other comprehensive income		(24)		
Accumulated deficit		(192,505)		(173,494)
Total stockholders' equity		129,951		30,774
Total liabilities and stockholders' equity	\$	133,416	\$	39,513



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,				
		2018		2017		2018		2017	
Contract revenue	\$		\$	318	\$	6	\$	700	
Operating expenses:									
Research and development		5,575		3,805		13,235		9,286	
General and administrative		2,770		2,391		8,909		7,407	
Total operating expenses		8,345		6,196		22,144		16,693	
Loss from operations		(8,345)		(5,878)		(22,138)		(15,993)	
Interest and other income, net		651		85		2,920		185	
Net loss	\$	(7,694)	\$	(5,793)		(19,218)		(15,808)	
Deemed dividend for convertible preferred stock beneficial conversion feature						_		(3,951)	
Net loss attributable to common stockholders	\$	(7,694)	\$	(5,793)	\$	(19,218)	\$	(19,759)	
Net loss per share attributable to common stockholders, basic and diluted	\$	(0.64)	\$	(1.34)	\$	(1.75)	\$	(6.49)	
Shares used to compute net loss per share attributable to common stockholders, basic and diluted	11	1,942,729	4	,310,561	1	0,967,750	3	3,043,919	