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): March 7, 2019

CATALYST BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

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

611 Gateway Blvd., Suite 710 **South San Francisco, California** **(Address of principal executive offices)**	**94080** **(Zip Code)**

(650) 871-0761
Registrant's telephone number, including area code

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following 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))

Indicate by 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 chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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. ☐

Item 2.02. Results of Operations and Financial Condition.

On March 7, 2019, Catalyst Biosciences, Inc., a Delaware corporation (the "Company"), announced its fourth quarter and full year 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	Press release issued on March 7, 2019 by Catalyst Biosciences, Inc.

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: March 7, 2019

/s/ Nassim Usman

Nassim Usman, Ph.D.
President and Chief Executive Officer

Exhibit 99.1

Catalyst Biosciences Reports Fourth Quarter and Full-Year 2018 Operating & Financial Results and Provides a Corporate Update

Completed enrollment of the MarzAA SQ Phase 2 trial and demonstrated safety and clinical efficacy, with >90% reduction in bleeding

Completed a full immunogenicity analysis for DalcA, plan to initiate a Phase 2b 28-day SQ trial in March 2019

SOUTH SAN FRANCISCO, Calif. – Mar. 7, 2019 – Catalyst Biosciences, Inc. (NASDAQ: CBIO), today announced its operating and financial results for the fourth quarter and full-year ending December 31, 2018 and provided a corporate update.

"2019 will be a very exciting year for Catalyst with several clinical and regulatory read outs expected throughout the year," said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. "Both Phase 2 trials demonstrate that our therapies are clinically efficacious when dosed subcutaneously, which we believe is the future for hemophilia treatments. Subcutaneous MarzAA and DalcA have the potential to be disruptive to current intravenous products, an approximately $3.4 billion market, and they are especially well-suited for children."

Recent Milestones:

- **Marzeptacog alfa (activated) – MarzAA**, subcutaneously administered next-generation engineered coagulation Factor VIIa: Completed enrollment of 11 individuals, with hemophilia and an inhibitor in a Phase 2 efficacy trial. The trial is evaluating the ability of MarzAA to eliminate, or minimize, spontaneous bleeding episodes in individuals with hemophilia A or B with an inhibitor. As of February 2019, seven of 11 subjects had completed dosing with a reduction in annual bleed rates (ABR) from 18.2 to 2.1 (>90% reduction) and five of the seven had no bleeds for 50 days at their final dose. The Company's interim data indicates MarzAA is safe and well tolerated. Subcutaneous half-life increased to 13.1 hours compared with intravenous half-life of 3.9 hours.
- **Dalcinonacog alfa – DalcA**, subcutaneously administered next-generation engineered coagulation Factor IX: Completed a Phase 1/2 subcutaneous dosing trial. The trial evaluated the safety and efficacy of DalcA in individuals with severe hemophilia B. Data from the study demonstrated that DalcA is highly efficacious, achieving activity levels well above that required for prevention of spontaneous bleeding. Two subjects developed neutralizing antibodies, one transiently, that did not interfere with their ability for continued use of other FIX products. The Company completed a full investigation and concluded that DalcA has a similar low immunogenicity potential as do BeneFIX and other commercial wildtype Factor IX products. The Company is moving forward in clinical development of DalcA and will start a Phase 2b trial in March 2019, enrolling up to six patients each with 28 days of dosing.

- **DalcA:** Amended the ISU Abxis license and collaboration agreement to replace the original profit-sharing arrangement with a low single-digit royalty, 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.
- **CB 2679d-GT – Factor IX Gene Therapy:** Demonstrated 3-fold superior clotting activity and a 4 to 5-fold reduction in bleeding time in a hemophilia B mouse model of AAV gene therapy delivery containing the DalcA sequence compared with a gene therapy construct containing the Padua variant, that is the current lead clinical variant in development.
- **Financial:** Strong cash and short-term investments balance of $120.1 million, which positions the Company to fund the clinical development of the MarzAA and DalcA programs.

Expected Milestones

- Complete the MarzAA Phase 2 open-label subcutaneous efficacy trial with topline data read out in Q3 2019 and final data read out in Q4 2019; initiate a MarzAA Phase 1 PK/PD study in Q2 2019 with final data read out in Q4 2019; initiate an End of Phase 2 meeting with the FDA in Q4 2019
- Initiate a DalcA Phase 2b study in Q1 2019 with topline data readout in Q3 2019 and final data readout in Q4 2019
- Demonstrate prolonged PK/PD for the anti-C3 protease in the dAMD program in Q2 2019

Fourth Quarter and Full-year 2018 Results and Financial Highlights

- Cash, cash equivalents and short-term investments, as of December 31, 2018 were $120.1 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 and full-year ended December 31, 2018 was $8.2 million and $21.5 million, respectively, compared with $3.6 million and $12.8 million for the prior year periods, respectively. The increase was due primarily to investments in the development of the MarzAA and DalcA clinical programs.
- General and administrative expense for the three-months and year-ended December 31, 2018 was $3.4 million and $12.4 million, respectively, compared with $2.6 million and $10.0 million for the prior year periods, respectively. The increase was due primarily to increases in personnel and non-cash stock-based compensation expense.
- Interest and other income for the three-months and the year ended December 31, 2018 was $0.8 million and $3.8 million, respectively, compared with $0.1 million and $0.3

million for the prior year periods, respectively. Interest income increased by $2.0 million in 2018 due to the higher cash balances from the financing and the exercise of warrants. The Company also received a $1.5 million milestone payment under an asset sale agreement in 2018.

- Net loss attributable to common stockholders for the three-months and year-ended December 31, 2018 was $10.9 million, or ($0.91) per basic and diluted share, and $30.1 million, or ($2.68) per basic and diluted share, respectively, compared with $5.8 million, or ($1.26) per basic and diluted share, and $25.5 million, or ($7.45) per basic and diluted share, for the prior year periods, respectively.
- On February 19, 2018, the final $5.1 million of the Company's redeemable convertible notes matured and were repaid in full.
- As of December 31, 2018, the Company had 11,954,528 shares of common stock outstanding.

About Catalyst Biosciences

Catalyst is a clinical-stage biopharmaceutical company focused on developing novel medicines to address serious medical conditions for individuals who need new or better treatment options. We are focusing our product development efforts in the field of hemostasis (the process that regulates bleeding) and have a mission to develop valuable therapies for 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 the potential commercial market for DalcA and MarzAA, the relative safety of DalcA compared with BeneFIX and other recombinant Factor IX products, Catalyst's plans to commence a Phase 2b clinical trial of DalcA in March 2019 and have top-line and final data readouts in Q3 and Q4, 2019, respectively, the potential for DalcA to provide a conveniently-dosed subcutaneous prophylactic treatment option for patients suffering from hemophilia B, the potential for MarzAA to provide prophylaxis therapy in patients with hemophilia A or B with inhibitors, and plans to complete the Phase 2 clinical trial and a Phase 1 PK/PD study of MarzAA in 2019. Forward looking statements also include Catalyst's plans to determine preclinical efficacy for CB 2679d-GT in 2019 and develop CB2782 towards a pre-clinical candidate in 2019. 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 additional human trials will not replicate the results from earlier trials, that potential adverse effects may arise from the testing or use of MarzAA or DalcA, including the generation of antibodies, which has been observed in patients treated with 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 Annual Report on Form 10-K for the quarter and the year ended December 31, 2018 filed with the Securities and Exchange Commission on March 7, 2019, and 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.

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

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 31,213	$ 14,472
Short-term investments	88,914	17,971
Restricted cash	50	5,333
Prepaid and other current assets	3,814	1,333
Total current assets	123,991	39,109
Other assets, noncurrent	543	128
Property and equipment, net	386	276
Total assets	$ 124,920	$ 39,513
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,248	$ 747
Accrued compensation	1,495	1,366
Other accrued liabilities	2,043	1,322
Deferred revenue, current portion	—	212
Deferred rent, current portion	15	7
Redeemable convertible notes	—	5,085
Total current liabilities	4,801	8,739
Deferred rent, noncurrent portion	174	—
Total liabilities	4,975	8,739
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized; 0 and 3,680 shares issued and outstanding at December 31, 2018 and 2017, respectively	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized; 11,954,528 and 6,081,230 shares issued and outstanding at December 31, 2018 and 2017, respectively	12	6
Additional paid-in capital	323,279	204,262
Accumulated other comprehensive loss	(4)	—
Accumulated deficit	(203,342)	(173,494)
Total stockholders' equity	119,945	30,774
Total liabilities and stockholders' equity	$ 124,920	$ 39,513

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

	Year Ended December 31,	
	2018	2017
Contract revenue	$ 6	$ 1,018
Operating expenses:		
Research and development	21,474	12,847
General and administrative	12,354	9,993
Total operating expenses	33,828	22,840
Loss from operations	(33,822)	(21,822)
Interest and other income, net	3,767	261
Net loss	(30,055)	(21,561)
Deemed dividend for convertible preferred stock beneficial conversion feature	—	(3,951)
Net loss attributable to common stockholders	$ (30,055)	$ (25,512)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.68)	$ (7.45)
Shares used to compute net loss per share attributable to common stockholders, basic and diluted	11,213,884	3,423,901