UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): October 3, 2019

CATALYST BIOSCIENCES, INC.
(Exact Name of Registrant as Specified in its Charter)

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

611 Gateway Blvd, Suite 710, South San Francisco, CA 94080
(Address of principal executive offices)

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

Not Applicable
(Former name or former address, if changed since last report.)

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 (see General Instruction A.2. below):

☐ 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))

Securities 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 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 8.01. Other Events.

On October 3, 2019, Catalyst Biosciences, Inc. (the "Company") issued a press release providing an update on enrollment in the Company's Phase 2b study of dalcinonacog alfa (DalcA), a next-generation subcutaneously (SQ) administered Factor IX (FIX) therapy being developed for the treatment of hemophilia B. DalcA. The commencement of enrollment under the DalcA clinical trial was originally announced on April 2, 2019. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated October 3, 2019.

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: October 3, 2019

By: /s/ Nassim Usman

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

Exhibit 99.1

Catalyst Biosciences Provides DalcA Phase 2b Trial Update

Two subjects have successfully completed dosing, exceeded the FIX activity efficacy endpoint and no anti-drug antibodies were detected

SOUTH SAN FRANCISCO, Calif. – October 3, 2019 – Catalyst Biosciences, Inc. (NASDAQ: CBIO), today provided an update on enrollment in its Phase 2b study of dalcinonacog alfa (DalcA), a next-generation subcutaneously (SQ) administered Factor IX (FIX) therapy being developed for the treatment of hemophilia B. Two subjects have completed dosing and washout, Factor IX levels in these two subjects exceeded the trial efficacy endpoint of >12% activity and no anti-drug antibodies were detected. Enrollment is ongoing and the Company anticipates reporting final data in the first half of 2020.

“We believe that DalcA may offer a conveniently-dosed subcutaneous prophylactic treatment option that could significantly improve the quality of life for those suffering from severe hemophilia B,” said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. “We are very pleased with the FIX activity and lack of ADAs obtained and look forward to providing final data in the first half of 2020.”

The open-label Phase 2b study is evaluating the ability of DalcA to maintain steady state FIX levels above 12% in individuals with severe hemophilia B. The trial is expected to enroll up to six completing subjects who will receive a single intravenous dose, followed by daily subcutaneous (SQ) doses of DalcA for 28 days. Pharmacokinetics, pharmacodynamics, safety and tolerability of daily SQ dosing and anti-drug antibody formation are being monitored. The trial is actively enrolling and study participants have been identified.

Nassim Usman, Ph.D., president and chief executive officer of Catalyst Biosciences, is presenting a corporate overview at the Cantor 2019 Global Healthcare Conference at 8:20 a.m. ET today, October 3, 2019, in New York. To access a live webcast of the presentation, please visit http://wsw.com/webcast/cantor10/cbio/. An archived webcast of the presentation will be available for 90 days on the Events and Presentations section on the Company’s website.

About Catalyst Biosciences

Catalyst is a clinical-stage biopharmaceutical company developing novel medicines to address hematology indications. Catalyst has engineered a portfolio of compounds that have increased potency over the naturally occurring proteases. Catalyst is focused on the field of hemostasis, including the subcutaneous treatment of hemophilia and facilitating surgery in individuals with hemophilia. For more information, please visit www.catalystbiosciences.com.

Forward-Looking Statements

This press release may contain forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements about the potential uses and benefits of Catalyst’s products in development to address hemophilia indications, statements about Catalyst’s clinical trial plans for DalcA, the timing of the clinical trial, anticipated reporting of data in the first half of 2020, and the potential for the DalcA 2b trial to meet its endpoints. 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, 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 DalcA or MarzAA, including the generation of antibodies, which has been observed in patients previously 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 the Company's ability to establish collaborations on commercially reasonable terms and other risks described in the "Risk Factors" section of the Company's annual report filed with the Securities and Exchange Commission on March 8, 2019, and in 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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