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): June 15, 2020

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, 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:

☐ 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.

DalcA Developments

On June 15, 2020, Catalyst Biosciences, Inc. ("the Company") announced final efficacy and safety data from its Phase 2b trial of DalcA, a next-generation subcutaneously (SQ) administered Factor IX (FIX) therapy being developed for the treatment of Hemophilia B. The data was presented at the World Foundation of Hemophilia Virtual Summit, taking place from June 14 -19, 2020.

Data from the trial showed that 28 days of daily SQ dosing of DalcA achieved protective target FIX levels of >12% in all participants, with FIX levels of up to 27% and a half-life of 2.5 to 5.1 days with no bleeds, demonstrating effective prophylaxis and the potential for lower or less frequent dosing. Injection volumes were less than 1 mL. One subject withdrew on day 7 after reporting injection site reactions (ISR) from the first 3 SQ doses. No neutralizing anti-drug antibodies were detected and no serious adverse events were reported. Some subjects reported mild ISR of pain and/or redness, primarily with the initial injections. No thrombotic events occurred and blood coagulation markers of d-dimer, prothrombin fragment 1+2, thrombin-antithrombin and fibrinogen did not show any prothrombotic signals.

The trial was designed to evaluate daily SQ dosing and the ability to maintain protective steady state FIX levels above 12% in six individuals with severe Hemophilia B. Each subject received a single intravenous dose, followed by daily SQ doses of DalcA for 28 days whereby the pharmacokinetics, pharmacodynamics, safety, tolerability and anti-drug antibody formation were monitored.

SQ Systemic Complement Inhibitors

The Company also announced that it has initiated discovery research to identify novel complement pathway regulating proteases and expects to have its first development candidate in Q4 2020.

MarzAA Developments

The Company also plans to initiate a Phase 1/2 trial of MarzAA in Factor VII deficiency, Glanzmann Thrombasthenia, and Hemlibra patients for treatment of bleeding in the fourth quarter of 2020.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements about the potential uses and benefits of DalcA to provide benefits and change the treatment paradigm for patients with hemophilia B, the potential benefits of SQ dosing, statements about the Company's clinical trial status for DalcA, the potential for lowering and reducing the frequency of SQ dosing and the Company's expectation for a development candidate related to its SQ systemic complement inhibitor. 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, 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, the impact of the COVID-19 pandemic, competition and other risks described in the "Risk Factors" section of the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 20, 2020 and Quarterly report on Form 10-Q filed with the SEC on May 11, 2020, and in other filings with the SEC. The Company does not assume any obligation to update any forward-looking statements, except as required by law.

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: June 17, 2020

/s/ Nassim Usman

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