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): February 7, 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 February 7, 2020, Catalyst Biosciences, Inc. ("the Company") announced positive 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 were presented by Johnny Mahlangu, M.B.B.Ch., M.Med, F.C.Path, professor of haematology, faculty of health sciences, head of the School of Pathology at the University of Witwatersrand in Johannesburg, South Africa, and principal investigator in the clinical trial in an oral presentation at the 13th Annual Congress of the European Association for Haemophilia and Allied Disorders (EAHAD) in The Hague, Netherlands (the "EAHAD Conference").

Data from the trial showed that 28 days of daily SQ dosing of DalcA achieved protective target FIX levels of >12%, with steady state FIX levels of up to 27% after 14 days with no bleeds, demonstrating effective prophylaxis and the potential for lower or less frequent dosing. One subject withdrew on day 7. No anti-drug antibodies were detected and no serious adverse events were reported. Three subjects reported injection site reactions (ISRs), the majority of which were mild in severity and resolved without sequelae.

The open-label Phase 2b study was designed to evaluate the ability of DalcA to maintain steady state protective 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. Pharmacokinetics, pharmacodynamics, safety and tolerability of daily SQ dosing and anti-drug antibody formation are being monitored.

MarzAA Developments

At the EAHAD Conference, the Company also presented data from a Phase 1 study to evaluate the pharmacokinetics, pharmacodynamics, and safety of ascending doses of SQ MarzAA in adult subjects with hemophilia, which showed that SQ dosing reaches target levels to treat ongoing bleeding and presented data on SQ MarzAA demonstrating that on-demand treatment in Hemophilia A mice treated after a tail clip injury was as efficient as intravenous NovoSeven at reducing bleeding.

Factor IX Gene Therapy Developments

At the EAHAD Conference, the Company also presented data on Hemophilia B gene therapy in mice demonstrating that a novel chimeric AAV capsid combined with the Company's proprietary potency enhanced CB 2679d-GT FIX variant may reduce the vector dose required in gene therapy while maintaining high FIX levels.

Collaboration with Biogen International GmbH

As previously disclosed, the Company entered into an exclusive worldwide license and collaboration agreement with Biogen International GmbH ("Biogen") on December 18, 2019, for the development and commercialization of CB 2782-PEG. In connection with this license and collaboration agreement with Biogen, the Company received a $15 million upfront payment from Biogen in January 2020. As a result of a collaboration, Mosaic Biosciences, Inc. is entitled to receive a double digit percentage of funds that the Company receives from Biogen.

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 and for MarzAA to treat patients with hemophilia A or B with inhibitors, the potential benefits of SQ dosing, statements about the Company's clinical trial status for DalcA, the potential for CB 2679d-GT to be a promising asset and the potential use of MarzAA as an on-demand therapy. 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 risks described in the "Risk Factors" section of the Company's quarterly report filed with the Securities and Exchange Commission on November 7, 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.

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: February 7, 2020

/s/ Nassim Usman

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