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): December 2, 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.

On December 2, 2020, Catalyst Biosciences, Inc. (the "Company") announced that the U.S. Food and Drug Administration has granted Fast Track Designation for Marzeptacog alfa (activated) – or MarzAA, the Company's subcutaneously (SQ) administered next-generation engineered coagulation Factor VIIa (FVIIa) for the treatment of episodic bleeding in subjects with Hemophilia A or B with inhibitors. The press release is filed as Exhibit 99.1 hereto, the contents of which are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled "Catalyst Biosciences Receives Fast Track Designation for Subcutaneous MarzAA for the Treatment of Episodic Bleeding in Hemophilia A or B with Inhibitors" dated December 2, 2020.
104	Cover Page Interactive Data File (formatted as Inline XBRL).

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: December 2, 2020

/s/ Clinton Musil
Clinton Musil
Chief Financial Officer

Catalyst Biosciences Receives FDA Fast Track Designation for Subcutaneous MarzAA for the Treatment of Episodic Bleeding in Hemophilia A or B with Inhibitors

SOUTH SAN FRANCISCO, Calif. – Dec. 2, 2020 – Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for Marzeptacog alfa (activated) – or MarzAA, the Company's subcutaneously (SQ) administered next-generation engineered coagulation Factor VIIa (FVIIa) for the treatment of episodic bleeding in subjects with Hemophilia A or B with inhibitors that will enter a pivotal Phase 3 study CRIMSON 1 this month.

The Fast Track program is designed to facilitate and expedite the development and review of drug candidates that have demonstrated the potential to address an unmet medical need in treating serious diseases or conditions. A drug candidate with Fast Track designation is eligible for greater access to the FDA as well as a priority review and rolling review of the marketing application.

"We believe the FDA Fast Track Designation validates MarzAA's potential to improve patient care. As the only SQ delivered therapy in development for on-demand treatment of bleeding events, MarzAA is uniquely positioned to become an important addition to the treatment landscape." said Nassim Usman, Ph.D., president and chief executive officer of Catalyst.

The Phase 3 CRIMSON 1 study is an open-label, global, multi-center, randomized, cross-over study, designed to evaluate the safety and efficacy of MarzAA for on-demand treatment of spontaneous or traumatic bleeding episodes, in adolescents and adults with congenital Hemophilia A or B with inhibitors, compared to the Standard of Care. The study will enroll approximately 60 subjects to treat 244 eligible bleeding episodes with each treatment. The primary endpoint for the trial is the percentage of treated bleeds resulting in effective hemostasis at the 24-hour timepoint. The objective of the trial is to demonstrate non-inferiority of MarzAA compared with Standard of Care.

About Catalyst Biosciences

Catalyst is a research and clinical development biopharmaceutical company focused on addressing unmet medical needs in rare hematologic and complement-mediated disorders. Our protease engineering platform has generated two late-stage clinical programs in hemophilia; a research program on engineering of subcutaneous (SQ) complement inhibitors; a discovery stage Factor IX gene therapy construct—CB 2679d-GT—for Hemophilia B, and a partnered preclinical development program with Biogen for dry age-related macular degeneration (AMD). The product candidates generated by our protease engineering platform have improved functionality and potency that allow for: SQ administration of recombinant coagulation factors and complement inhibitors; low-dose, high activity gene therapy constructs; and less frequently dosed intravitreal therapeutics.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements about Catalyst's plans for a Phase 3 study of MarzAA for on-demand treatment of spontaneous or traumatic bleeding episodes, the potential for MarzAA to effectively and therapeutically treat hemophilia subcutaneously, the potential benefits of Fast Track Designation, and the Company's collaboration with Biogen for the development and commercialization of pegylated CB 2782 for the potential treatment of geographic atrophy-associated dry age-related macular degeneration. 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 as a result of COVID-19 and other factors, that trials 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, including the generation of neutralizing antibodies, the risk that costs required to develop or manufacture the Company's products will be higher than anticipated, including as a result of delays in development and manufacturing resulting from COVID-19 and other factors, the risk that Biogen will terminate Catalyst's agreement, 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 5, 2020, 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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