

**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 28, 2021**

**CATALYST BIOSCIENCES, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**000-51173**  
(Commission  
File Number)

**56-2020050**  
(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 June 28, 2021, 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 Factor VII deficiency. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release titled “Catalyst Biosciences Receives FDA Fast Track Designation for Subcutaneous MarzAA for the Treatment of Episodic Bleeding in Factor VII Deficiency” dated June 28, 2021.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

**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.

Date: June 29, 2021

**CATALYST BIOSCIENCES, INC.**

/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 Factor VII Deficiency  
Second Fast Track Designation for MarZAA**

**SOUTH SAN FRANCISCO, Calif. – June 28, 2021** – Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for Marzeptacog alfa (activated), MarZAA, the Company’s subcutaneously (SQ) administered next-generation engineered coagulation Factor VIIa (FVIIa) for the treatment of episodic bleeding in subjects with Factor VII deficiency. Catalyst is currently enrolling patients with FVII deficiency in a Phase 1/2 open-label study. This trial is being conducted in parallel with the ongoing Phase 3 registration trial evaluating MarZAA for the treatment of episodic bleeds in patients with Hemophilia A or B with inhibitors.

Fast Track is an FDA process 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.

“Receiving a second Fast Track designation is another important milestone in our MarZAA development program. We look forward to our continued collaboration with the FDA to bring a safe and effective treatment to patients with Factor VII deficiency, Hemophilia A or B with inhibitors, Glanzmann Thrombasthenia and other severe bleeding disorders.” said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. “MarZAA is the only subcutaneously administered bypassing agent under development for the episodic treatment of bleeding events and has the potential to significantly improve the lives of patients with several inherited or acquired bleeding disorders.”

FDA granted Fast Track Designation for MarZAA for the SQ treatment and control of episodic bleeding in subjects with Hemophilia A or B with inhibitors in December 2020.

**About Catalyst Biosciences, the Protease Medicines company**

Catalyst is a research and clinical development biopharmaceutical company focused on addressing unmet medical needs in rare disorders of the complement and coagulation systems. Our protease engineering platform has generated two late-stage clinical programs, including MarZAA, an SQ administered next-generation engineered rFVIIa for the episodic treatment of bleeding in subjects with rare bleeding disorders. Our complement pipeline includes a preclinical C3-degrader program licensed to Biogen for dry age-related macular degeneration, an improved complement factor I protease for SQ replacement therapy in patients with CFI deficiency, and C4b-degraders designed to target disorders of the classical complement pathway, as well as other complement programs in discovery.

**Forward-Looking Statements**

This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements about the potential for MarZAA to treat and control episodic bleeding in subjects with Factor VII deficiency, Hemophilia A or B with inhibitors, Glanzmann Thrombasthenia and other severe bleeding disorders, the benefits of Fast Track designation, and the benefits and uses of MarZAA and Catalyst’s other product candidates. 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 the one or both of the clinical trials of MarZAA may be delayed or terminated as a result of COVID-19, competitive products 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 Fast Track designation will not lead to a faster or less costly product approval process, 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 trial enrollment, development and manufacturing resulting from COVID-19 and other factors, competition and other risks described in the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 6, 2021, 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.

**Contact:**

Ana Kapor  
Catalyst Biosciences, Inc.  
[investors@catbio.com](mailto:investors@catbio.com)