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): May 18, 2021

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 May 18, 2021, Catalyst Biosciences, Inc. (the "Company") announced the initiation of dosing in the Company's Phase 1/2 study (MAA-202) of marzeptacog alfa (activated) – known as "MarzAA," a subcutaneously (SQ) administered next-generation engineered coagulation Factor VIIa (FVIIa). 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 Announces First Patient Dosed in Marzeptacog Alfa (Activated) Phase 1/2 Study in Factor VII Deficiency, Glanzmann Thrombasthenia and Hemophilia A treated with Hemlibra" dated May 18, 2021.
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.

CATALYST BIOSCIENCES, INC.

Date: May 18, 2021

/s/ Clinton Musil
Clinton Musil
Chief Financial Officer

Catalyst Biosciences Announces First Patient Dosed in Marzeptacog Alfa (Activated) Phase 1/2 Study in Factor VII Deficiency, Glanzmann Thrombasthenia and Hemophilia A treated with Hemlibra

SOUTH SAN FRANCISCO, Calif. – May 18, 2021 – Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced the initiation of dosing in the Company's Phase 1/2 study (MAA-202) of marzeptacog alfa (activated) – known as "MarzAA." MarzAA is a subcutaneously (SQ) administered next-generation engineered coagulation Factor VIIa (FVIIa). MAA-202 is a Phase 1/2 open-label study designed to evaluate the pharmacokinetics (PK), pharmacodynamics (PD), safety and efficacy of SQ MarzAA for treatment of bleeding in FVII deficiency, Glanzmann Thrombasthenia, and Hemophilia A with inhibitor patients receiving Hemlibra® prophylaxis. This study, along with Catalyst's ongoing Phase 3 study MAA-304 evaluating MarzAA for the treatment of bleeding epsisodes in patients with Hemophilia A or B with inhibitors, is a key part of the Company's strategy to realize the full potential of MarzAA to improve the lives of patients with inherited bleeding disorders.

"MarzAA is the only bypassing agent under development for the episodic treatment of bleeding events that can be rapidly administered subcutaneously and, if successful, will address a significant unmet medical need," said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. "We look forward to providing updates on the MarzAA clinical development program, including reporting interim data from MAA-202 later this year."

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 benefits of products based on Catalyst's engineered protease platform, and plans to conduct the MAA-202 and MAA-304 clinical trials of MarzAA. 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 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:

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