# 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 5, 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 7.01 Regulation FD Disclosure.**

On May 5, 2021, Catalyst Biosciences, Inc. (the "Company") announced the dosing of the first patient in the Crimson 1 Study, the Company's Phase 3 registration trial (MAA-304 - Crimson 1) of Marzeptacog alfa (activated) – or MarzAA, the Company's subcutaneously (SQ) administered next-generation engineered recombinant coagulation Factor VIIa (rFVIIa). The press release is filed as Exhibit 99.1 hereto, the contents of which are incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. The information in this Current Report shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release titled "Catalyst Biosciences Announces First Patient Dosed in Pivotal Phase 3 Registration Study of SQ MarzAA in Individuals with Hemophilia A or B with Inhibitors" dated May 5, 2021. |
| 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: May 5, 2021

/s/ Clinton Musil
Clinton Musil
Chief Financial Officer

**Catalyst Biosciences Announces First Patient Dosed in Pivotal Phase 3 Registration Study of SQ MarzAA in Individuals with Hemophilia A or B with Inhibitors**

**SOUTH SAN FRANCISCO, Calif. – May 5, 2021** – Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced the dosing of the first patient in the Crimson 1 Study, the Company's Phase 3 registration trial (MAA-304 - Crimson 1) of Marzeptacog alfa (activated) – or MarzAA, the Company's subcutaneously (SQ) administered next-generation engineered recombinant coagulation Factor VIIa (rFVIIa).

"Dosing the first patient in our pivotal Phase 3 study of MarzAA is an important milestone for Catalyst given the significant challenges encountered in conducting clinical trials during the ongoing global Covid-19 pandemic," said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. "MarzAA is the only SQ-delivered therapy in development for the episodic treatment of bleeding events and if successful, could fundamentally change patients' lives. We look forward to providing further updates on the MAA-304 study, the associated Phase 1/2 study (MAA-202) in other rare bleeding disorders, and in our growing complement pipeline later this year."

Crimson 1 is an open-label, global, multi-center, randomized, cross-over study, designed to evaluate the safety and efficacy of SQ MarzAA for episodic treatment of spontaneous or traumatic bleeding episodes, in adults and adolescents with congenital Hemophilia A or B with inhibitors, compared with standard of care. The study will assess the effectiveness of SQ MarzAA, using up to three doses to treat a bleeding episode, compared with IV FEIBA or up to three doses of IV rFVIIa. Catalyst anticipates the submission of its first report to the Data and Safety Monitoring Board (DSMB) in 2021.

**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, plans to enroll the Phase 3 open-label trial of MarzAA, and plans to submit the first report to the Data and Safety Monitoring Board (DSMB) in 2021. 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 Phase 3 trial of MarzAA and other trials may be delayed or terminated as a result of COVID-19, competitive products and other factors, that Catalyst may not submit its first report to the DSMB as planned, 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 4, 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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