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): September 28, 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 September 28, 2021, Catalyst Biosciences, Inc. (the "Company") announced that the U.S. Food and Drug Administration has granted Orphan Drug Disease Designation ("ODD") for its lead product candidate, subcutaneous Marzeptacog alfa (activated), or MarzAA, for the treatment of Factor VII Deficiency ("FVIID"). MarzAA was previously granted ODD and Fast Track Designation for treatment of Hemophilia A/B with inhibitors and Fast Track Designation for the treatment of FVIID. 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 "FDA Grants Catalyst Biosciences Orphan Drug Designation for MarzAA for the Treatment of Factor VII Deficiency" dated September 28, 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: September 29, 2021

/s/ Clinton Musil
Clinton Musil
Chief Financial Officer

FDA Grants Catalyst Biosciences Orphan Drug Designation for MarzAA for the Treatment of Factor VII Deficiency

SOUTH SAN FRANCISCO, Calif. – September 28, 2021 – Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Disease Designation (ODD) for its lead product candidate, subcutaneous Marzeptacog alfa (activated), or MarzAA, for the treatment of Factor VII Deficiency (FVIID). MarzAA was previously granted ODD and Fast Track Designation (FTD) for treatment of Hemophilia A/B with inhibitors and FTD for the treatment of FVIID.

“Receiving a second orphan drug designation in addition to two FTDs for MarzAA demonstrates its potential in treating multiple rare bleeding disorders” said Nassim Usman, Ph.D., president and chief executive officer of Catalyst.

The FDA grants Orphan Drug Designation to drugs and biologics intended for the safe and effective treatment, diagnosis or prevention of rare diseases or conditions affecting fewer than 200,000 people in the United States. Orphan Drug Designation provides benefits to drug developers designed to support the developments of drugs and biologics for small patient populations with unmet medical needs. These benefits include assistance in the drug development process, tax credits for clinical costs, exemptions from certain FDA fees and seven years of marketing exclusivity.

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, a subcutaneously (SQ) administered next-generation engineered coagulation Factor VIIa (FVIIa) for the treatment of episodic 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 proteases from our ProTUNE™ C3b-C4b degrader and ImmunoTUNE™ C3a-C5a degrader platforms designed to target specific disorders of the complement or inflammatory pathways as well as other complement programs in development.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include, without limitation, statements about the product candidates of Catalyst and the benefits of its protease engineering platform; potential benefits of MarzAA and plans to commercialize 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 trials and studies may be delayed as a result of COVID-19, competitive products and other factors, that trials may not have satisfactory outcomes, the significance of the second orphan drug designation for MarzAA, the risk Catalyst may elect to terminate or postpone ongoing development programs, including development of MarzAA, the risk that Catalyst will need to raise additional capital, which may not be available on favorable terms if at all; the risk that costs required to develop or manufacture Catalyst’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, the risk that Biogen may terminate the agreement with Catalyst, and other risks described in the “Risk Factors” section of Catalyst’s Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”) on March 4, 2021, the Quarterly Report on Form 10-Q filed with the SEC on August 5, 2021 and in other filings filed from time to time with the SEC. Catalyst 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