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): July 22, 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 \Box

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 July 22, 2021, Catalyst Biosciences, Inc. (the "Company") announced the screening of the first patient in the Company's CFI-deficiency study in the CB 4332 program, its wholly-owned, first-in-class, enhanced Complement Factor I (CFI), intended for prophylactic subcutaneous (SQ) administration in individuals with CFI 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

Exhibit <u>Description</u>

99.1 Press Release titled "Catalyst Biosciences Announces First Patient Screened for CFI deficiency in its CB 4332 Screening and Natural History of Disease Studies" dated July 22, 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.

Date: July 22, 2021

CATALYST BIOSCIENCES, INC.

/s/ Clinton Musil

Clinton Musil Chief Financial Officer



Catalyst Biosciences Announces First Patient Screened for CFI deficiency in its CB 4332 Screening and Natural History of Disease Studies

Launching the ConFIrm study to identify patients with Complement Factor I deficiencies

SOUTH SAN FRANCISCO, Calif. – July 22, 2021 – Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced the screening of the first patient in its CFI-deficiency study in the CB 4332 program, its wholly-owned, first-in-class, enhanced Complement Factor I (CFI), intended for prophylactic subcutaneous (SQ) administration in individuals with CFI deficiency.

"The findings from the CFI deficiency screening and natural history of disease studies will be instrumental in identifying patients for the Phase 1/2 trial of CB 4332, planned for mid-year 2022," said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. "Following the disease manifestations and biomarkers of this complement disorder will be important in unlocking the full therapeutic potential of CB 4332."

The ConFIrm screening study will measure CFI levels and activity in patients who have diseases related to a CFI deficiency and who may potentially benefit from CB 4332 treatment. The ConFIdence natural history of disease study will follow these CFI-deficient subjects, who often present with repetitive bacterial infections, immune-related diseases, and/or glomerulopathies, for clinical biomarkers and safety of current treatments. The findings from these studies will identify opportunities to potentially develop CB 4332 for treatment in multiple indications.

Catalyst's complement portfolio is led by the development candidates CB 4332 and CB 2782-PEG, originating from the company's internal discovery platform, which has generated a rich pipeline of leads. CB 4332 is an engineered CFI protease with the potential to address multiple complement related disorders. CB 2782-PEG is designed as a long-acting anti-C3 protease in preclinical development for the treatment of dry AMD that Catalyst has licensed to Biogen. Catalyst has several engineered protease programs in discovery or early non-clinical development. These programs all target diseases caused by deficient regulation of the complement system.

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 Biosciences, Inc. (the "Company") and the benefits of its protease engineering platform; plans to complete the ConFIrm and ConFIdence studies and the expectation that the studies will inform opportunities to develop CB 4332; the potential markets for and advantages of the Company's complement product candidates, including CB 2782-PEG, CB 4332 and complement degraders; plans for the Company's collaboration with Biogen; and plans to conduct for a Phase 1/2 clinical trial of CB 4332 in 2022.

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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 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, the risk that Biogen will terminate Catalyst's agreement, 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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