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): January 25, 2022

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 January 25, 2022, Catalyst Biosciences, Inc. announced that the U.S. Food and Drug Administration has granted Rare Pediatric Disease Designation for CB 4332 for the treatment of Complement Factor I 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 No.	Description
99.1	Press Release titled "Catalyst Biosciences Receives Rare Pediatric Disease Designation for CB 4332 for the Treatment of CFI Deficiency" dated January 25, 2022.
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: January 25, 2022

/s/ Nassim Usman

Nassim Usman, Ph.D.
President and Chief Executive Officer

Catalyst Biosciences Receives Rare Pediatric Disease Designation for CB 4332 for the Treatment of CFI Deficiency

SOUTH SAN FRANCISCO, Calif. – January 25, 2022 – Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced the U.S. Food and Drug Administration (FDA) has granted Rare Pediatric Disease Designation (RPDD) for CB 4332 for the treatment of Complement Factor I (CFI) deficiency (CFID).

“The granting of the Rare Pediatric Disease Designation for CB 4332 underscores the significant unmet medical need in pediatric patients with CFID. We are focused on efficiently advancing the development of CB 4332 and our complement medicines portfolio in a number of complement-driven diseases in hematology, nephrology and ophthalmology. We are pleased with the FDA’s assessment of CB 4332 as a potential therapy for underserved pediatric patients with CFID and the granting of the RPDD,” said Nassim Usman, Ph.D., chief executive officer of Catalyst Biosciences.

Under the FDA’s rare pediatric disease designation program, the FDA may grant a priority review voucher to a sponsor who receives a product approval for a rare pediatric disease. A rare pediatric disease is defined as a serious or life-threatening condition that affects less than 200,000 individuals in the U.S. per year and who are primarily less than 18 years of age.

About Catalyst Biosciences, the Protease Medicines company

Catalyst is a research and clinical development biopharmaceutical company focused on developing protease therapeutics to address unmet medical needs in disorders of the complement system. Proteases are natural regulators of this biological system. We engineer proteases to create improved or novel molecules to treat diseases that result from dysregulation of the complement cascade. Our complement pipeline consists of several proteases that regulate the complement cascade including our improved Complement Factor I protease CB 4332 for patients with deficiencies in CFI, a preclinical C3-degrader program licensed to Biogen for dry age-related macular degeneration (dAMD), and proteases from our ProTUNE™ C3b/C4b degrader and ImmunoTUNE™ C3a/C5a degrader platforms designed to target other disorders of the complement or inflammatory pathways.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include, without limitation, those regarding plans for clinical development of CB 4332, the potential to receive a priority review voucher, and the continued generation of candidates to treat diseases that result from dysregulation of the complement cascade, as well as statements about the benefits of our protease engineering platform. 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 clinical trials and preclinical studies may be delayed as a result of COVID-19, competitive products, and other factors, that Biogen could terminate our agreement for the development of CB 2782-PEG, that the Company’s complement degraders are not yet in human clinical trials and will require additional manufacturing validation and preclinical testing before entering human clinical trials and multiple clinical trials before being approved, that the Company may need to raise additional capital, 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 (the “SEC”) on March 4, 2021, the Quarterly Report on Form 10-Q filed with the SEC on November 12, 2021, and in other filings filed from time to time with the SEC. The Company does not assume any obligation to update any forward-looking statements, except as required by law.

Contact:

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