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): April 1, 2019

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, California** **(Address of principal executive offices)**	**94080** **(Zip Code)**

(650) 871–0761
Registrant's telephone number, including area code

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))

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

Receipt of Orphan Designation from the European Commission for Marzeptacog Alfa (Activated)

On April 1, 2019, Catalyst Biosciences, Inc. (the "Company") issued a press release announcing that the European Commission has awarded orphan designation of its Factor VIIa (FVIIa) variant marzeptacog alfa (activated) (MarzAA) for the treatment of haemophilia B (with or without inhibitors). A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Initiation of a Phase 2b Trial of Dalcinonacog Alfa for the Treatment of Hemophilia B

On April 2, 2019, the Company issued a press release announcing the initiation of enrollment in a Phase 2b study of dalcinonacog alfa (DalcA), a next-generation subcutaneously (SQ) administered Factor IX (FIX) therapy being developed for the treatment of hemophilia B. A copy of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated April 1, 2019.
99.2	Press Release dated April 2, 2019.

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: April 2, 2019

/s/ Fletcher Payne
Fletcher Payne
Chief Financial Officer

Exhibit 99.1

Catalyst Biosciences Receives Orphan Designation from the European Commission for Marzeptacog Alfa (Activated)

Dosing successfully completed in the Phase 2 portion of the Phase 2/3 MarzAA trial for the treatment of hemophilia A or B with inhibitors

SOUTH SAN FRANCISCO, Calif., April 01, 2019 (GLOBE NEWSWIRE) — Catalyst Biosciences, Inc. (Nasdaq:CBIO) today announced that the European Commission has awarded orphan designation of its Factor VIIa (FVIIa) variant marzeptacog alfa (activated) (MarzAA) for the treatment of haemophilia B (with or without inhibitors).

Catalyst has also completed dosing in the Phase 2 portion of the Phase 2/3 subcutaneous trial of MarzAA for the treatment of hemophilia A or B with inhibitors. Nine subjects successfully completed dosing and top-line results will be presented in the third quarter of 2019.

“Orphan designation is another important acknowledgement of the significant benefits of subcutaneous MarzAA and will complement our orphan drug designation already granted in the U.S. by the Food and Drug Administration,” said Nassim Usman, Ph.D., chief executive officer of Catalyst. “We have completed dosing in the Phase 2 portion of the Phase 2/3 trial for the treatment of hemophilia A or B with inhibitors and have clearly demonstrated efficacy as measured by greater than 90% reduction in annualized bleed rate (ABR), as well as bleeding density. We expect to present top-line results from the study in the third quarter of 2019. We also plan to initiate a Phase 3 MarzAA registrational study in 2020 and believe that subcutaneous MarzAA has significant commercial potential in the $2.2 billion hemophilia inhibitor market.”

About 30 million people living in the European Union (EU) suffer from a rare disease. The European Medicines Agency (EMA) plays a central role in facilitating the development and authorization of medicines for rare diseases. Orphan medicinal products, orphan designation, is given to products that are intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating, where prevalence of the condition in the EU is less than 5 in 10,000 persons and where the product represents a significant benefit over existing treatments. Orphan designation benefits include protocol assistance, reduced EU regulatory filing fees and 10 years of market exclusivity. Designated orphan medicines are also eligible for conditional marketing authorization. Detailed information on orphan designation can be found here.

About Catalyst Biosciences

Catalyst is a clinical-stage biopharmaceutical company developing novel medicines to address hematology indications. Catalyst is focused on the field of hemostasis, including the subcutaneous prophylaxis of hemophilia and facilitating surgery in individuals with hemophilia. For more information, please visit www.catalystbiosciences.com.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statement of historical facts, including, but not limited to, statements about the potential for MarzAA to treat patients with hemophilia B with or without inhibitors, and plans to announce top-line results for the Phase 2/3 trial in the third quarter of 2019 and to initiate a Phase 3 MarzAA registration study in 2020 are forward-looking statements. 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 from the forward-looking statements that the Company makes, including, but not limited to, the risk that ongoing or planned trials may be delayed and may not have satisfactory outcomes, that such trials will not replicate the results from earlier trials, that potential adverse effects may arise from the testing or use of the Company's products, including the generation of antibodies, and other risks described in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2018 filed with the Securities and Exchange Commission on March 8, 2019, and with 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.

Contacts:
Investors:
Fletcher Payne, CFO
Catalyst Biosciences, Inc.
1.650.871.0761
investors@catbio.com

Media:
Josephine Belluardo, Ph.D.
LifeSci Public Relations
1.646.751.4361
jo@lifescipublicrelations.com

Exhibit 99.2

Catalyst Biosciences Initiates a Phase 2b Trial of Dalcinonacog Alfa for the Treatment of Hemophilia B

Currently enrolling individuals with severe hemophilia B

SOUTH SAN FRANCISCO, Calif., April 02, 2019 (GLOBE NEWSWIRE) — Catalyst Biosciences, Inc. (Nasdaq:CBIO), today announced the initiation of enrollment in a Phase 2b study of dalcinonacog alfa (DalcA), a next-generation subcutaneously (SQ) administered Factor IX (FIX) therapy being developed for the treatment of hemophilia B.

"The data from our Phase 1/2 clinical study demonstrated that DalcA is highly efficacious for the treatment of hemophilia B and can achieve Factor IX activity levels well above the 12% expected to prevent spontaneous bleeding," said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. "We anticipate that this Phase 2b study will further demonstrate DalcA's safety and efficacy as a subcutaneous prophylactic treatment option. Individuals with severe hemophilia B face a lifetime of complicated intravenous treatment regimens. We believe that DalcA may offer a conveniently-dosed subcutaneous prophylactic treatment option that could significantly improve the quality of life for those suffering from severe hemophilia B."

The open-label Phase 2b study will evaluate the ability of DalcA to maintain steady state FIX levels above 12% in individuals with severe hemophilia B. The trial will enroll up to six subjects who will receive a single intravenous dose, followed by daily subcutaneous (SQ) doses of DalcA for 28 days. Pharmacokinetics, pharmacodynamics, safety and tolerability of daily SQ dosing and anti-drug antibody formation will also be monitored. The trial is expected to be completed in the second half of 2019.

About Catalyst

Catalyst is a clinical-stage biopharmaceutical company focused on developing novel medicines to address hematology indications. Catalyst is focused on the field of hemostasis, including the subcutaneous prophylaxis of hemophilia and facilitating surgery in individuals with hemophilia. For more information, please visit http://www.catalystbiosciences.com/.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements about Catalyst's clinical trial plans for DalcA, the timing of the clinical trial and anticipated completion in the second half of 2019, and the potential for DalcA to safely treat patients with hemophilia and maintain steady state FIX levels above 12% in individuals with severe hemophilia B. 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 and 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 DalcA, including the generation of antibodies, which has been observed in patients treated with DalcA, the risk that costs required to develop or manufacture the Company's products will be higher than anticipated, competition and other factors that affect our ability to establish collaborations on commercially reasonable terms and other risks described in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the quarter and the year ended December 31, 2018 filed with the Securities and Exchange Commission on March 8, 2019, and with 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.

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