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 18, 2018

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 **94080**
(Address of principal executive offices) **(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

On July 18, 2018, Catalyst Biosciences, Inc. (the "Company") issued a press release announcing interim data from the Company's ongoing Phase 2/3 study of marzeptacog alfa (activated) in individuals with hemophilia A or B with inhibitors, a copy of which is attached as Exhibit 99.1 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 July 18, 2018

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: July 18, 2018

/s/ Fletcher Payne
Fletcher Payne
Chief Financial Officer

Catalyst Biosciences Announces Positive Interim Data from a Phase 2/3 Study of Marzeptacog Alfa (Activated) in Individuals with Hemophilia A or B with Inhibitors

Interim data support goal of significantly reducing annualized bleed rates with daily subcutaneous injections of marzeptacog alfa (activated)

Conference call and webcast to be held today, July 18, 2018 at 8:30 a.m. EDT

SOUTH SAN FRANCISCO, Calif. – July 18, 2018 – Catalyst Biosciences, Inc. (NASDAQ: CBIO), a clinical-stage biopharmaceutical company focused on developing novel medicines to address hematology indications, today announced interim data from its Phase 2/3 study of subcutaneous (SQ) prophylactic Factor VIIa (FVIIa) variant marzeptacog alfa (activated) (MarzAA) being developed for the treatment of hemophilia A or B with inhibitors in a poster presentation at the 64th Annual Scientific and Standardization Committee (SSC) Meeting of the International Society on Thrombosis and Haemostasis (ISTH) in Dublin. The Company also presented the most current data from the Phase 1/2 trial of SQ prophylactic Factor IX (FIX) candidate CB 2679d/ISU304 being developed for the treatment of hemophilia B.

“We are very pleased with the efficacy with our subcutaneous FVIIa variant MarzAA for the treatment of hemophilia A or B with inhibitors,” said Nassim Usman, Ph.D., chief executive officer of Catalyst. “The interim results from the Phase 2/3 trial support our target of achieving significant reductions in annualized bleed rate with daily subcutaneous injections of MarzAA. We expect to open more trial sites and increase enrollment as the year progresses and plan to complete the Phase 2 portion of the Phase 2/3 study by the end of 2018.”

Dr. Howard Levy, chief medical officer of Catalyst, presented the interim results from the MarzAA Phase 2/3 trial in which five of 12 subjects have been enrolled. One subject, with a historical annualized bleed rate (ABR) of 26.7, has completed the study with one bleed during 96 days of prophylaxis. The subject experienced no bleeds during treatment with 60 µg/kg MarzAA for 50 days and one bleed at Day 46 during treatment with 30 µg/kg MarzAA. Two other subjects with ABRs of 15.9 and 16.6 are currently in the first 50 days of dosing. MarzAA’s intravenous (IV) half-life of 3.5 hours was increased to 9.5 hours when dosed subcutaneously. Through a cumulative 160 dosed days, no anti-drug antibodies to MarzAA have been detected to date.

Dr. Levy also presented the most current data from the CB 2679d/ISU304 Phase 1/2 trial. In Cohort 6, two subjects have been enrolled and achieved FIX trough activity levels >30% with one IV dose followed by 9 daily SQ doses. The two subjects, who were cousins, developed neutralizing antibodies (nAbs) to CB 2679d. The nAb was transient in subject C5-01-S02 and was below the level of quantification at a follow up visit. The nAb in subject C5-01-S01 fell below 1 Bethesda Unit at a follow up visit. The nAbs bind to CB 2679d, but not to wildtype FIX. Both Cohort 6 subjects returned to their prior prophylaxis treatment (BeneFIX® or RIXUBIS) with continued efficacy.

Dr. Usman added, “We are moving forward with our analysis to determine the cause of the nAb development we observed in Cohort 6 and will provide further updates once the analysis has been completed.”

Conference Call Details

The management team will host a conference call for investors today, July 18, 2018, at 8:30 a.m. EDT to discuss the Factor VIIa and Factor IX clinical data. Conference call, webcast and post-conference call replay details are as follows:

Domestic: +1.877.425.9470
International: +1.201.389.0878
Conference ID: 13681615
Webcast: http://public.viavid.com/index.php?id=130521

A replay will be available two hours after completion of the call through August 1, 2018:

Domestic: +1.844.512.2921
International: +1.412.317.6671
Replay ID: 13681615

The call will also be archived on the Company's website for 30 days at www.catalystbiosciences.com.

About the FVIIa Phase 2/3 Trial

Marzeptacog alfa (activated) (MarzAA) is a potent, subcutaneous Factor VIIa therapy being developed for prophylaxis in hemophilia A or B with inhibitors. The Phase 2/3 open-label, subcutaneous efficacy trial in individuals with hemophilia A or B with inhibitors will evaluate the ability of MarzAA to eliminate, or minimize, spontaneous bleeding episodes. The primary endpoint is a reduction in annualized bleed rate that will be compared with each individual's recorded historical annualized bleed rate as the control. The trial will enroll up to 12 individuals with hemophilia and an inhibitor across approximately ten clinical trial sites globally. MarzAA has been granted orphan drug designation by the U.S. Food and Drug Administration (FDA) for routine prophylaxis to prevent bleeding episodes in individuals with hemophilia A or B with inhibitors.

About the FIX Phase 1/2 Trial

CB 2679d was designed as a best-in-class high potency recombinant Factor IX (FIX) product. Catalyst believes that CB 2679d may provide a subcutaneous prophylactic treatment for individuals with hemophilia B by achieving high-mild or normal hemophilia FIX activity levels in blood. The Phase 1/2 clinical trial of CB 2679d in patients with severe hemophilia B is being conducted at three centers in South Korea by Catalyst's collaborator, ISU Abxis, which uses ISU304 as an alternate product name. The trial is investigating the potency, subcutaneous bioavailability, half-life and clotting ability of CB 2679d achieved after single intravenous and subcutaneous dosing in the first three Cohorts, and daily subcutaneous injections of CB 2679d without and with an intravenous loading dose in the 5th and 6th cohorts, respectively. CB 2679d was awarded orphan drug designations by both the European Commission and U.S. Food and Drug Administration (FDA) in 2017.

About Catalyst

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 fact, included in this press release regarding our strategy, the efficacy of subcutaneously administered marzeptacog alfa (activated), potential uses and benefits of CB 2679d and marzeptacog alfa (activated), and development plans for these product candidates are forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and projections disclosed in the forward-looking statements as a result of various important factors, including, but not limited to, the risk that trials and studies may be delayed and may not have satisfactory outcomes, that ongoing or future trials will not replicate the results from earlier human trials or from prior animal studies, that potential adverse effects may arise from the testing or use of the Company's products, including the generation of antibodies, 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 year ended December 31, 2017, filed with the Securities and Exchange Commission on March 19, 2018, along with our 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

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