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): December 9, 2017

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.)**

260 Littlefield Ave. **South San Francisco, California** **(Address of principal executive offices)**	**94080** **(Zip Code)**

(650) 266–8674
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 7.01. Regulation FD Disclosure

On December 9, 2017, Catalyst Biosciences, Inc. delivered a presentation at the 59th American Society of Hematology (ASH) Annual Meeting in Atlanta, GA. A copy of the presentation is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section. The information in this Current Report shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events

On December 11, 2017, Catalyst Biosciences, Inc. issued a press release announcing interim Phase 1/2 data on its subcutaneously administered, prophylactic Factor IX variant CB 2679d/ISU304 that were presented at the 59th American Society of Hematology (ASH) Annual Meeting and Exposition in Atlanta, GA, on December 9, 2017.

A copy of the press release announcing the interim Phase 1/2 data is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Presentation at the 59th American Society of Hematology (ASH) Annual Meeting in Atlanta, GA, by Catalyst Biosciences, Inc. on December 9, 2017.
99.2	Press release of Catalyst Biosciences, Inc. dated December 11, 2017.

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: December 11, 2017

/s/ Nassim Usman

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

Phase 1/2 Trial of Subcutaneously Administered Factor IX Variant CB 2679d/ISU304: Pharmacokinetics and Activity

Chur Woo You, MD PhD, Ho-Jin Shin, MD, **Howard Levy** MBBCh PhD, Martin Lee, PhD, Seung-Beom Hong, PhD, Jamie Ellen Siegel, MD and June Young Park, MD

87 Session 322. Disorders of Coagulation or Fibrinolysis: Novel Therapies and Clinical Trials in Bleeding Disorders

ASH

9 December 2017

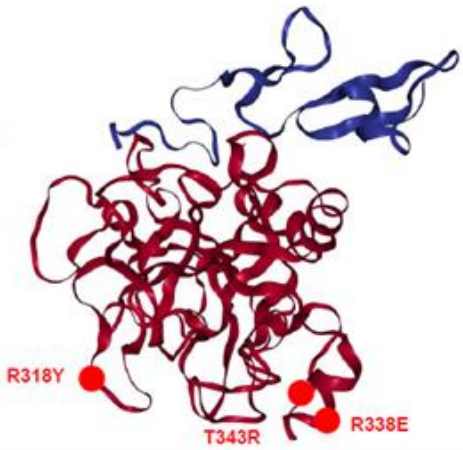
Disclosure

- Employee and Stockholder of Catalyst Biosciences

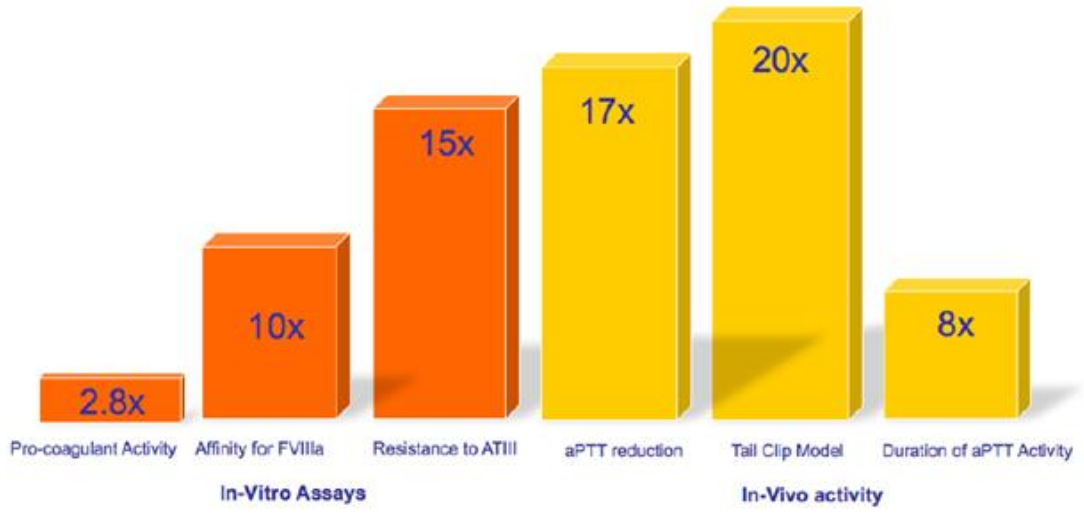
Factor IX Modified with 3 Point Mutations

- Rapid clearance of FIX necessitates frequent intravenous administrations to achieve effective prophylaxis
- Subcutaneous administration is the preferred route of administration but has been limited by low bioavailability and potency of the marketed FIX products
- Designed as best-in-class high potency recombinant FIX product
- Orphan Drug Designation in US and EU

Factor IX: CB 2679d/ISU304



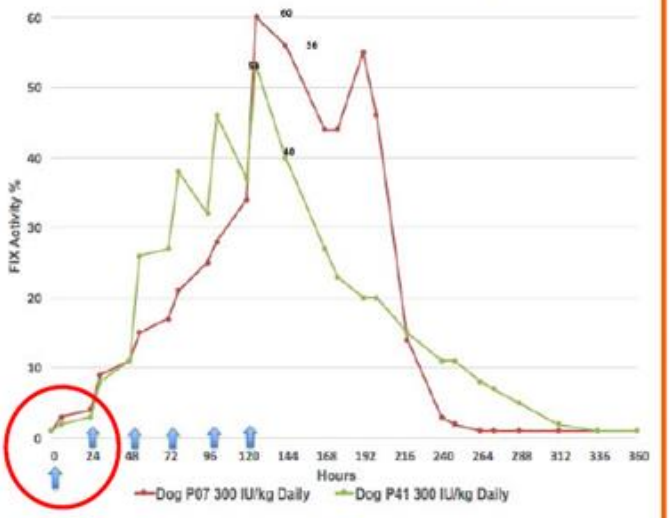
CB 2679d/ISU304 Potency Advantage over wt-FIX



- 20-fold increased potency of CB 2679d over wild-type FIX in tail clip model

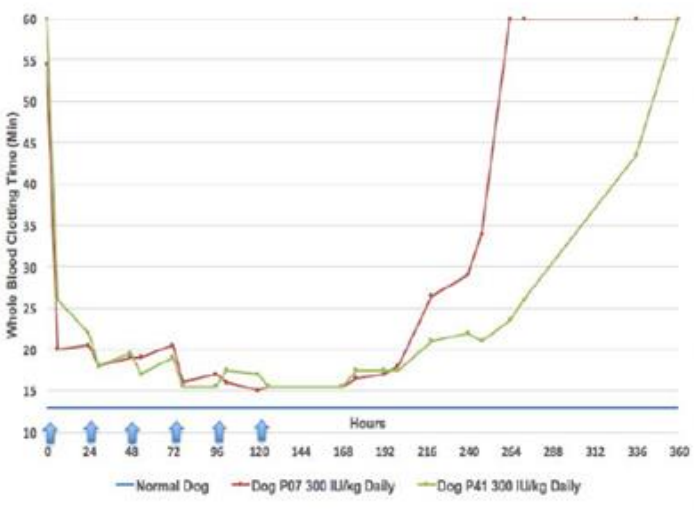
Normalization of FIX Activity and Rapid Whole Blood Clotting Time Correction with Daily SQ Dosing of CB 2679d/ISU304 (300 IU/kg) in Hemophilia B Dogs*

Increase in FIX Activity After Daily SQ Dosing



*Levy *et al*. ISTH 2017 Res Pract Thromb Haemost (2017), 1 (Suppl. 1), 142

Decrease in Whole Blood Clotting Time After Daily SQ Dose



*Levy *et al*. EAHAD 2017 Haemophilia (2017), 23 (Suppl. 2), 29-140

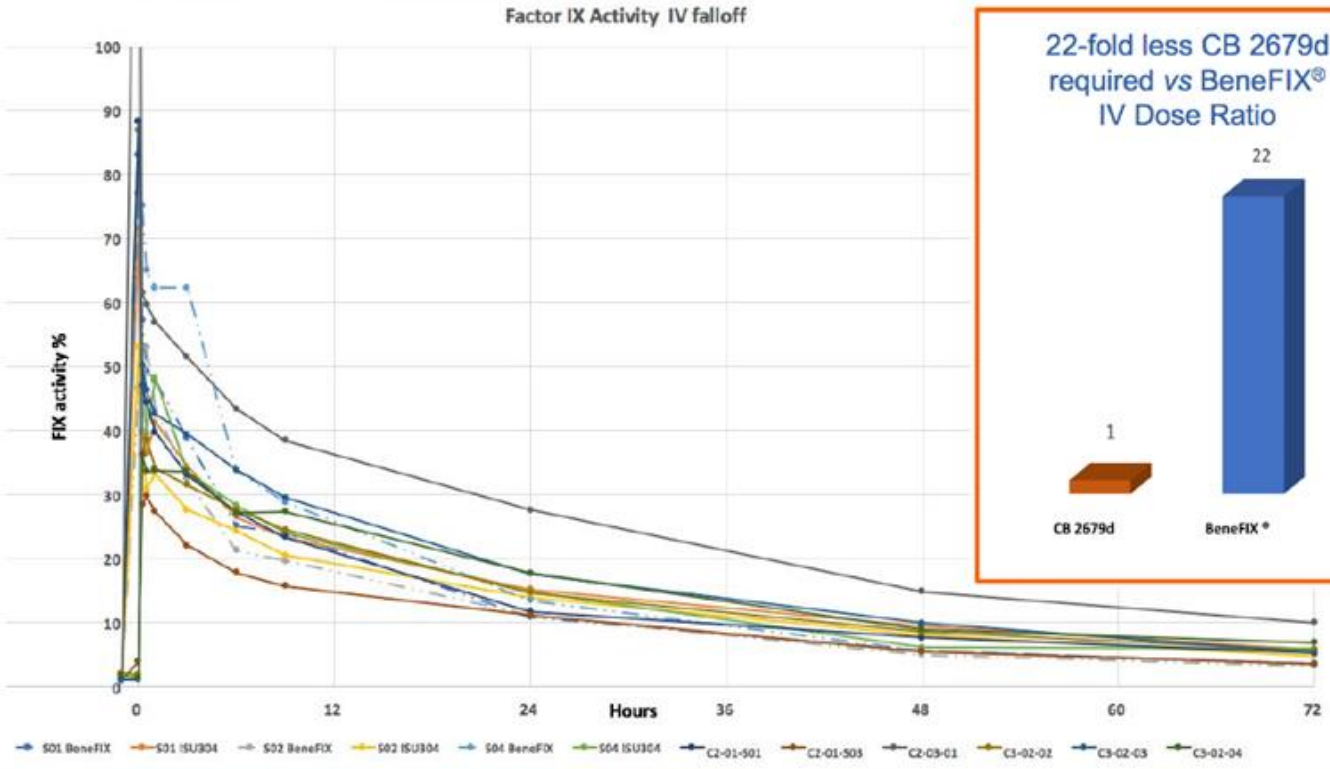
Design of Ongoing Phase 1/2 Trial

- ISU Abxis is executing the Phase 1/2 trial
- Cohort 3 has been completed

Methods

- IV PK was sampled at predose, 0, 0.25, 0.5, 1, 3, 6, 9, 24, 48 and 72 hours
- SQ PK was sampled at predose, 1, 2, 4, 6, 8, 10, 12, 24, 48 and 72 hours
- A safety follow-up was done 3 weeks after dosing
- FIX antigen and FIX activity, anti-drug antibody to BeneFIX and ISU304 and neutralizing antibody were measured at Haematologic Technologies
- FIX antigen was measured using VisuLize™ Factor IX Antigen KitAG (Affinity Biologicals) and FIX activity was measured using a one-stage clotting assay using ACL TOP 700 and Instrumentation Laboratories reagents
- Calculation of AUC was based on the trapezoidal rule
- Calculation of half-life used Demitasse 2000 which uses an iterative piecewise fitting algorithm based on a robust (M-regression) log-linear model
- All activity data were adjusted for baseline assuming exponential falloff after IV administration and a half-life of 20 hours

Cohort 1, 2 & 3:
IV BeneFIX & IV CB 2679d/ISU304 75 IU/kg



IV BeneFIX vs IV CB 2769d/ISU304 PK 75 IU/kg

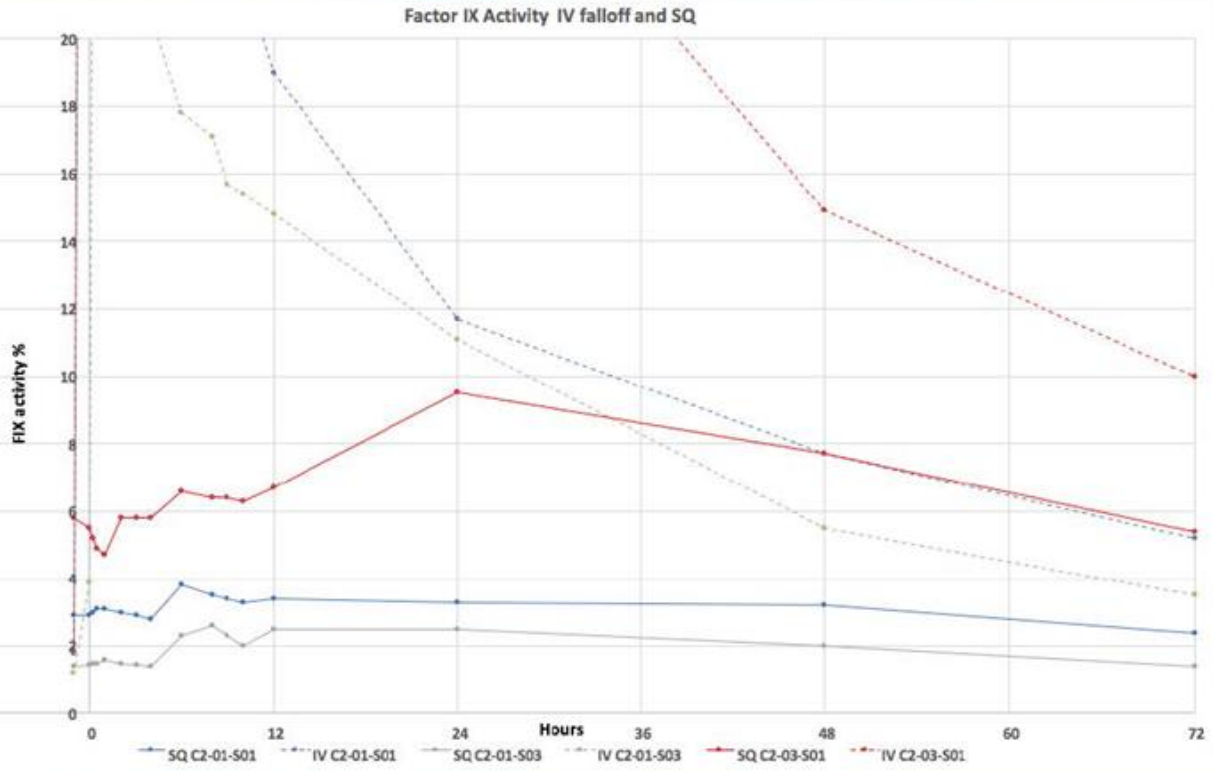
PK profiles after IV administration (mean ± SD)

Group	t-half alpha (hrs)	t-half beta (hrs)	MRT (hrs)	Cmax (mU/mL)	AUC 0-t (mU/mL*hr)	AUC 0-inf (mU/mL*hr)
BeneFIX	5.3 ± 0.8	21.0 ± 1.1	25.1 ± 1.5	70.2 ± 16.0	855 ± 163	933 ± 177
CB 2679d/ ISU304	8.5 ± 4.0	27.0 ± 2.2	35.8 ± 2.5	70.0 ± 46.9	973 ± 274	1148 ± 334
P-value by two-sample t-test*	0.22	0.0014	0.00004	0.995	0.50	0.32

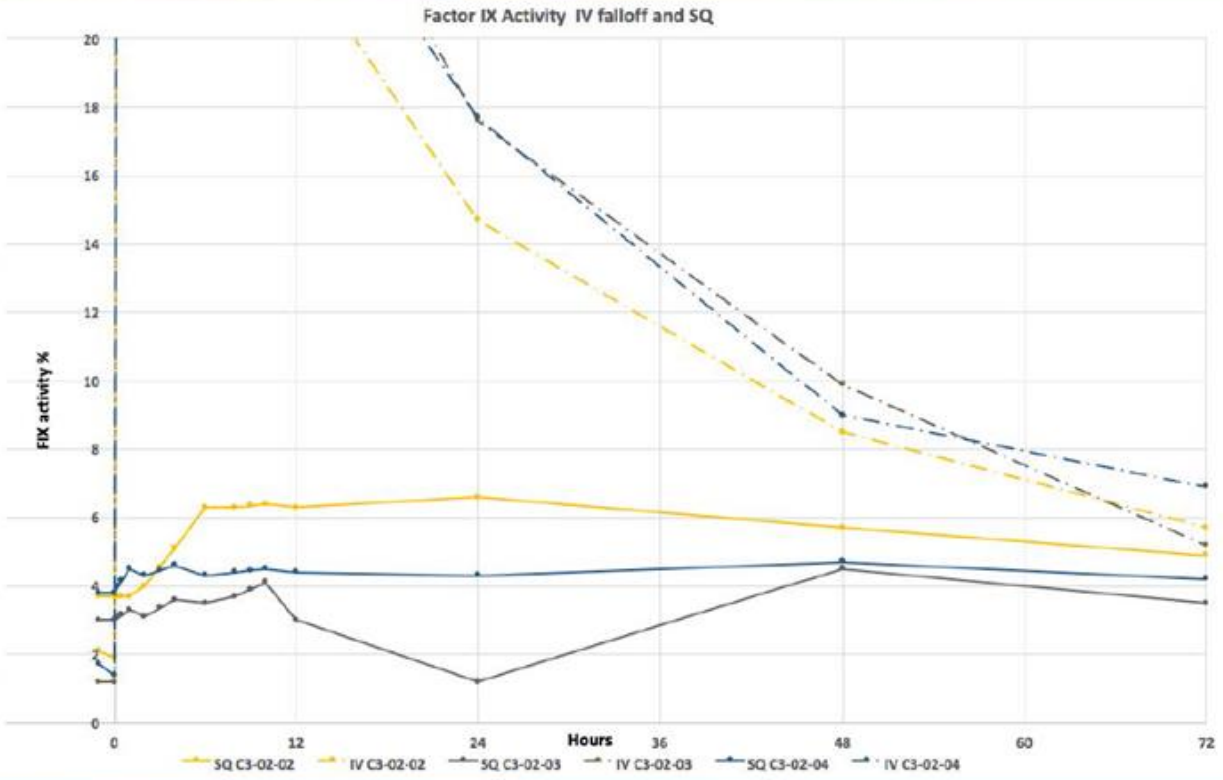
*ignoring the matching from Cohort 1

- IV CB 2679d has a significantly longer half-life and mean residence time than BeneFIX

Cohort 2: 75 IU/kg IV then 75 IU/kg SQ CB 2679d/ISU304



Cohort 3: 75 IU/kg IV then 150 IU/kg SQ CB 2679d/ISU304



CB 2769d – ISU304-001 PK: SQ *vs* IV has 3.6-fold Increase in Half-life

Cohort 2 & 3: PK activity profiles after IV and SQ CB 2679d/ISU304 administration

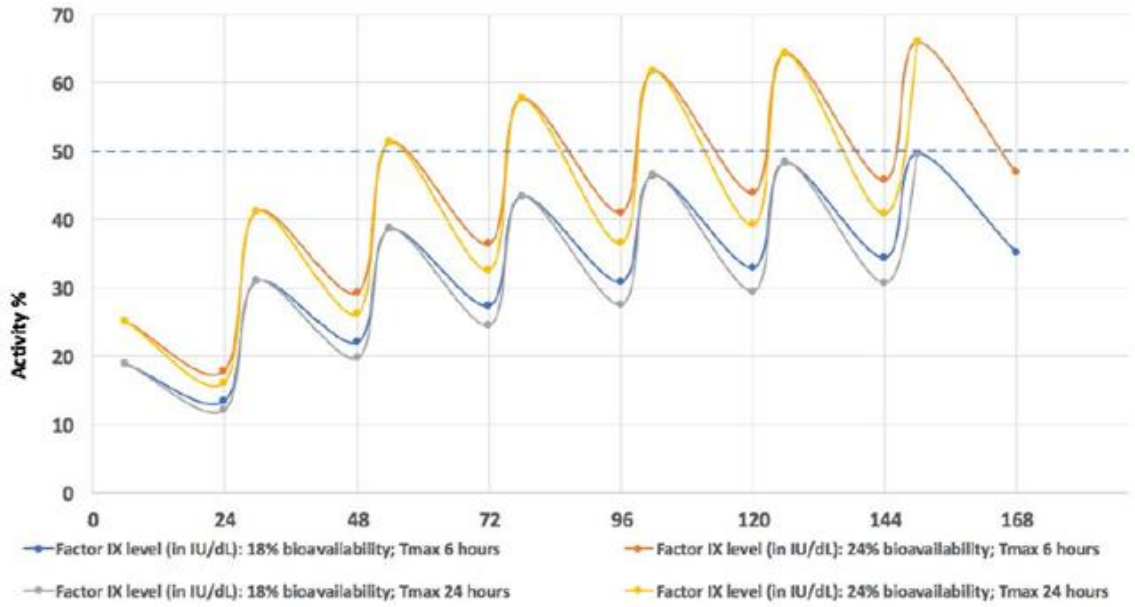
Route		t-half alpha (hrs)	t-half beta (hrs)	Tmax	AUC 0-t (mU/mL*hr)	Bioavailability
IV	Mean ± SD	9.4 ± 4.4	27.0 ± 2.2	16.7 ±11.3 mins	1026 ± 330	
	Median [25%-75%]	9.4 [6.4-13.2]	27.6 [26.4-29.2]	15 mins [5-30]	945 [780-1265]	
SQ	Mean	3.4 (n=1)	242.2 ± 365.5	29.0 ± 16.3 hrs	306 ± 148	19.8 ± 5.2%
	Median [25%-75%]		98.7 [60.0-369.4]	24 hrs [19.5-48]	352 [138-410]	18.5% [15.4-24.7%]

- 98.7 hour SQ CB 2679d half-life is similar to IV agents dosed biweekly or weekly:
  - Alprolix 86.52 hours
  - Idelvion 104-118 hours
  - Rebinyn/Refixia 114.9 hours

ISU-304-001 Safety

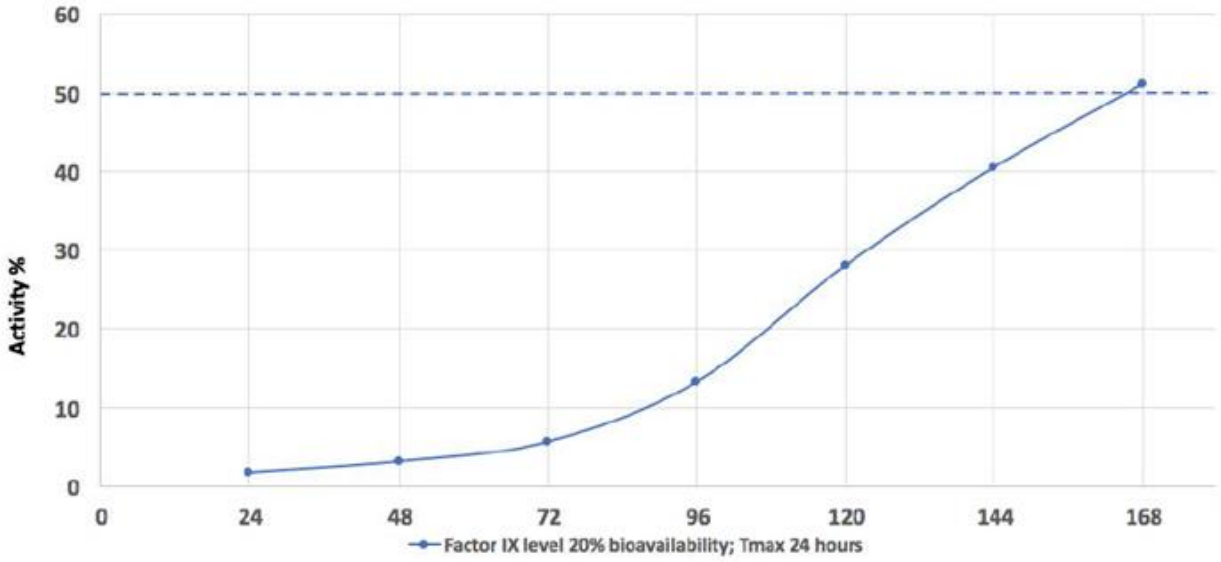
- One subject had a mild general reaction within 1 hour of injection
  - Fatigue/Boredom
  - Headache
  - Dizziness
- Transient mild AEs were reported in cohorts 2 and 3 and all resolved without sequelae:
  - Itching
  - Tenderness
  - Erythema
  - Solidification
  - Injection site discomfort
  - General ache [moderate severity]

Modeling of Daily 75 IU/kg SQ $t_{1/2}$ = 36 hours



- Modeling demonstrates that CB 2679d could achieve **stable** FIX minimum levels in the high mild hemophilia or normal range >50%

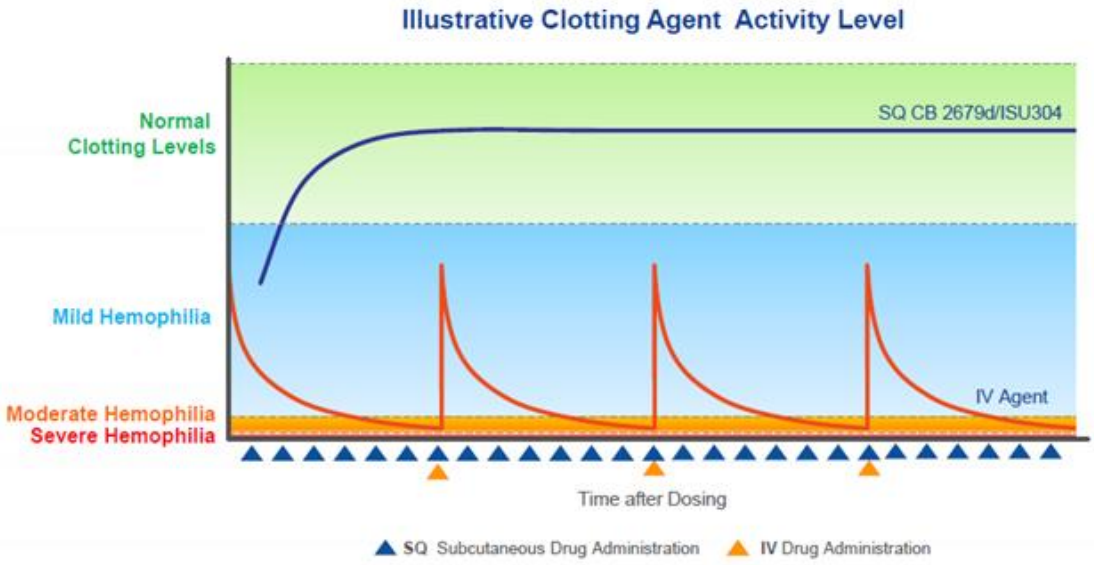
Modeling of Daily 60 IU/kg SQ $t_{1/2}$ = 100 hours



- Normal FIX activity levels of >50% are reached after 7 daily doses of CB 2679d
- No difference between peak and minimum levels when Tmax is 24 hours
- Lower doses of CB 2679d will maintain levels above 50% at all times
- Less frequent dosing is also a possibility

Modeling Predicts Subcutaneous Administration may be a Superior Prophylaxis Regimen Compared with IV Agents

Time in Mild to Normal Levels Predicts Protection from Spontaneous Bleeds



CB 2679d/ISU304 Program Conclusions

- CB 2679d is designed as best-in-class high potency recombinant Factor IX product
- 22-fold potency advantage allows subcutaneous administration
- Normal trough factor IX blood levels achieved after 6 daily subcutaneous doses in hemophilia B dogs
- Phase 1/2 subcutaneous trial is ongoing
  - Cohort 3 (150 IU/kg SQ) has been completed
  - Multi-dose SQ data anticipated Q1 2018
- IV CB 2679d has a longer half-life of 27 hours than 21 hours of wt-FIX
- SQ delivery significantly increases half-life 3.6-fold to 98.7 hours
- SQ dosing may provide superior prophylaxis to IV extended half-life agents
- Orphan drug designations have been granted in US and EU

Exhibit 99.2

Catalyst Biosciences Announces Interim Phase 1/2 CB 2679d/ISU304 Results at the American Society of Hematology Conference

Subcutaneous (SQ) delivery significantly increases half-life of CB 2679d to 98.7 hours

Data supports potential normalization of FIX activity with daily or less-frequent SQ dosing

SOUTH SAN FRANCISCO, Calif., December 11, 2017 – Catalyst Biosciences, Inc. (NASDAQ: CBIO), a clinical-stage biopharmaceutical company focused on developing novel medicines to address hematology indications, today announced interim Phase 1/2 data on its subcutaneously administered, prophylactic Factor IX variant CB 2679d/ISU304 in an oral presentation at the 59th American Society of Hematology (ASH) Annual Meeting and Exposition held on Dec. 9-12, 2017 in Atlanta. The data demonstrate that subcutaneous delivery of CB 2679d significantly increases the factor IX (FIX) activity half-life to 98.7 hours.

Dr. Howard Levy, chief medical officer of Catalyst, presented results from the first three cohorts of the Phase 1/2 trial of CB 2679d in patients with severe hemophilia B. During these first three cohorts, patients received single intravenous (IV) and subcutaneous (SQ) doses of CB 2679d. Results from cohort 1, which compared 75 IU/kg IV CB 2679d with 75 IU/kg IV BeneFIX, showed that IV CB 2679d is approximately 22 times more potent and has a significantly longer half-life (27 *vs* 21 hours, p = 0.0014) and mean residence time than BeneFIX (36 hours *vs* 25 hours, p = 0.00004). Cohorts 2 and 3 compared 75 IU/kg IV CB 2679d with 75 IU/kg and 150 IU/kg SQ CB 2679d respectively. These results showed that SQ delivery of CB 2679d had a bioavailability of 18.5% and significantly increases the FIX activity half-life to 98.7 hours *vs* 27.6 hours for a IV dose of 75 IU/kg, (p = 0.005). No serious adverse events were observed. The data to date support the potential of achieving normal FIX levels in individuals with hemophilia B with daily or less frequent subcutaneous dosing.

“The results from these first three cohorts demonstrate the promise of CB 2679d as a safe prophylactic treatment for patients with hemophilia B,” said Dr. Levy. “The significantly increased half-life of CB 2679d and bioavailability after subcutaneous dosing suggests that CB 2679d may provide superior prophylaxis capabilities compared with intravenous extended half-life agents, with the potential to normalize FIX levels. We eagerly await the results from daily subcutaneous doses of CB 2679d on Factor IX blood levels that are expected in early 2018.”

About the Phase 1/2 Trial

CB 2679d is designed as a best-in-class high potency recombinant Factor IX product. 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 the Company’s collaborator, ISU Abxis, which uses ISU304 as an alternate product name. The trial aims to measure the subcutaneous bioavailability and clotting ability of CB 2679d achieved after single intravenous and subcutaneous dosing in the first four cohorts, followed by daily subcutaneous injections of CB 2679d in the fifth, and final, cohort. In

June 2017, the European Commission and in September 2017, the U.S. Food and Drug Administration (FDA) granted orphan drug designations for CB 2679d. Complete trial results are expected in early 2018.

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. All statements, other than statement of historical facts, included in this press release regarding our strategy, the potential uses and benefits of CB 2679d and development plans for this product candidate are forward-looking statements. Examples of such statements include, but are not limited to, statements relating to Catalyst's clinical trial timelines, including the anticipated completion of a Phase 1/2 proof-of-concept study for CB 2679d, the plans to disclose complete trial results by early 2018, and the potential uses and benefits of subcutaneously dosed CB 2679d. Actual results or events could differ materially from the plans and expectations and projections disclosed in these forward-looking statements. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Catalyst makes, including, but not limited to, the risk that trials and enrollment may be delayed and may not have satisfactory outcomes, that later trials will not replicate the results from earlier trials or preclinical studies, that potential adverse effects may arise from the testing or use of Catalyst's products, including the generation of antibodies, the risk that costs required to develop or manufacture Catalyst's products will be higher than anticipated, competition, and other factors described in the "Risk Factors" section of the Company's most recent Quarterly Report on Form 10-Q filed with the SEC on November 2, 2017. Catalyst does not assume any obligation to update any forward-looking statements, except as required by law.

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