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): February 7, 2020

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 7.01 Regulation FD Disclosure.

On February 7, 2020, Catalyst Biosciences, Inc. (the "Company") posted an update to its corporate presentation (the "Presentation") on its website, ir.catalystbiosciences.com/presentations-events. A copy of the Presentation is attached hereto as Exhibit 99.1.

On February 7, 2020, the Company also announced positive data from its Phase 2b trial of subcutaneous dalcinonacog alfa (DalcA) and marzeptacog alfa (MarzAA). The data were presented at the European Association for Haemophilia and Allied Disorders (EAHAD) in The Hague, Netherlands and are summarized in the Company's press release issued on February 7, 2020. The press release also announced the details for the conference call that the Company's management team is scheduled to host for investors on February 7, 2020 to discuss the DalcA and MarzAA data presented at EAHAD. A copy of the press release is attached hereto as Exhibit 99.2.

The information in this Item 7.01 of this Current Report on Form 8-K (including Exhibits 99.1 and 99.2) 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Presentation slide deck, dated February 7, 2020.
99.2	Press release of Catalyst Biosciences, Inc., dated February 7, 2020.

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: February 7, 2020

/s/ Nassim Usman

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

Exhibit 99.1

CATALYST BIOSCIENCES

Corporate Overview
7 February 2020

CATALYST BIOSCIENCES

Forward looking statements

This presentation includes forward-looking statements that involve substantial risks and uncertainties. All statements included in this presentation, other than statement of historical facts, are forward-looking statements. Examples of such statements include, but are not limited to, potential markets for MarzAA, DalcA and CB 2782-PEG, potential benefits of subcutaneous dosing, potential use of MarzAA as a subcutaneous therapy for patients with hemophilia A or B with inhibitors and other bleeding disorders, potential use of DalcA as a subcutaneous therapy for patients with hemophilia B, potential benefits of CB 2679d-GT as gene therapy, clinical trial results, plans for a registrational trial for MarzAA in second half of 2020, plans for final Phase 2b clinical trial data for DalcA in the second quarter of 2020, plans for non-human primate data for CB 2679d-GT in the second quarter of 2020, and potential milestone and royalty payments from Biogen. Actual results or events could differ materially from the plans, expectations and projections disclosed in these forward-looking statements.

Various important factors could cause actual results or events to differ materially, including, but not limited to, the risk that additional human trials will not replicate the results from earlier trials or animal studies, that potential adverse effects may arise from the testing or use of MarzAA or DalcA, including the generation of antibodies, which has been observed in patients treated with DalcA, that clinical trials will take longer than anticipated to be completed, that costs required to develop or manufacture the Company's products will be higher than anticipated, that Biogen will discontinue development of CB 2782-PEG, 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 quarterly report on Form 10-Q filed with the Securities and Exchange Commission on November 7, 2019, 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.

CATALYST BIOSCIENCES

Essential Medicines – Superior Outcomes

Late-Stage Asset

SQ Marzeptacog alfa (activated)
MarzAA (FVIIa)

Phase 3 Ready

Hemophilia

SQ MarzAA

SQ Dalcinonacog alfa – DalcA (FIX)

Factor IX Gene Therapy

Factor Xa

Complement

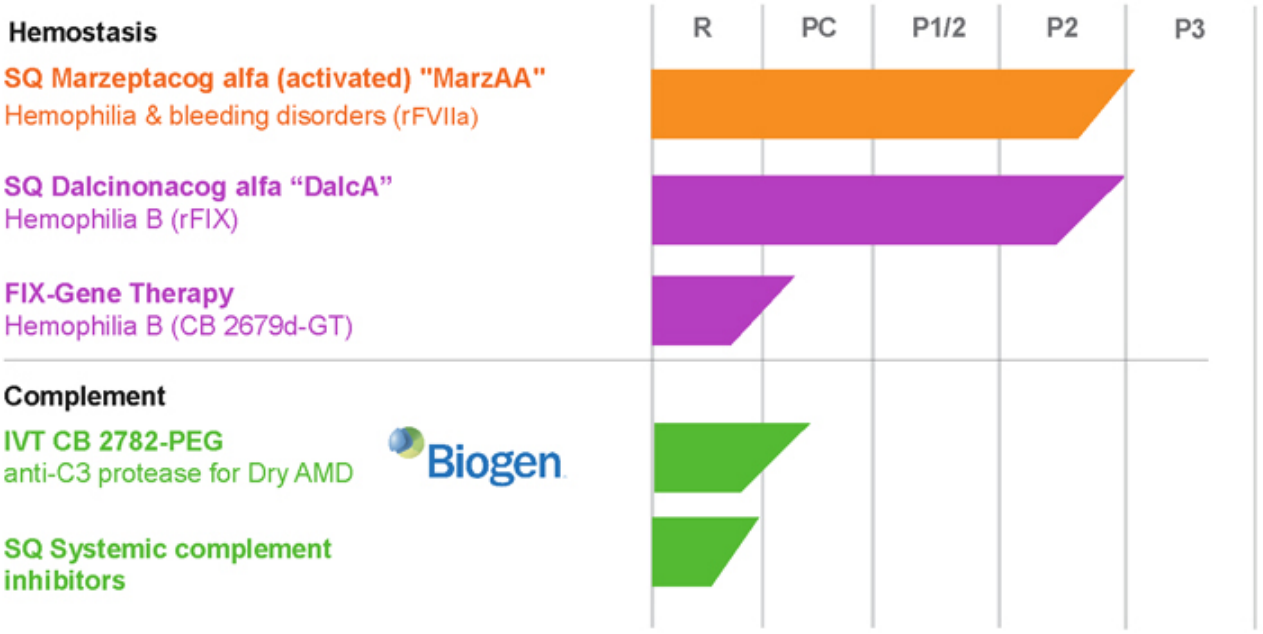
IVT Anti-C3
CB 2782-PEG

Biogen

SQ Systemic Complement Inhibitors

Protease Engineering Platform

Pipeline


R
PC
P1/2
P2
P3
Hemostasis
SQ Marzeptacog alfa (activated) "MarzAA"
Hemophilia & bleeding disorders (rFVIIa)
SQ Dalcinonacog alfa "DalcA"
Hemophilia B (rFIX)
FIX-Gene Therapy
Hemophilia B (CB 2679d-GT)
Complement
IVT CB 2782-PEG
anti-C3 protease for Dry AMD
Biogen
SQ Systemic complement inhibitors

Investment highlights

Novel subcutaneous factors with orphan drug designation, MarzAA & DalcA – SQ P2b clinical efficacy demonstrated

Multi-billion-dollar market opportunities

Anti-C3 collaboration with Biogen

SQ systemic complement inhibitors research program

Experienced team

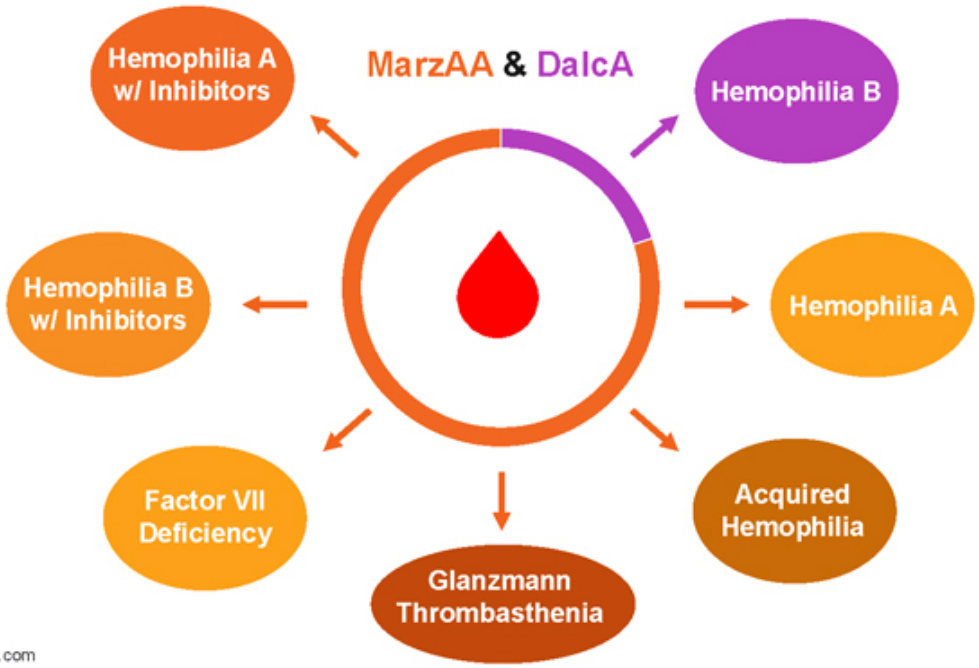
~134 worldwide patents – CBIO retains full ownership of all compounds

Well funded
$85 M cash (Q3 2019)

Addressing unmet needs in orphan bleeding disorders

Nasdaq: CBIO

SQ treatment of bleeds and prophylaxis – $3.7B market



The Catalyst Biosciences subcutaneous solution

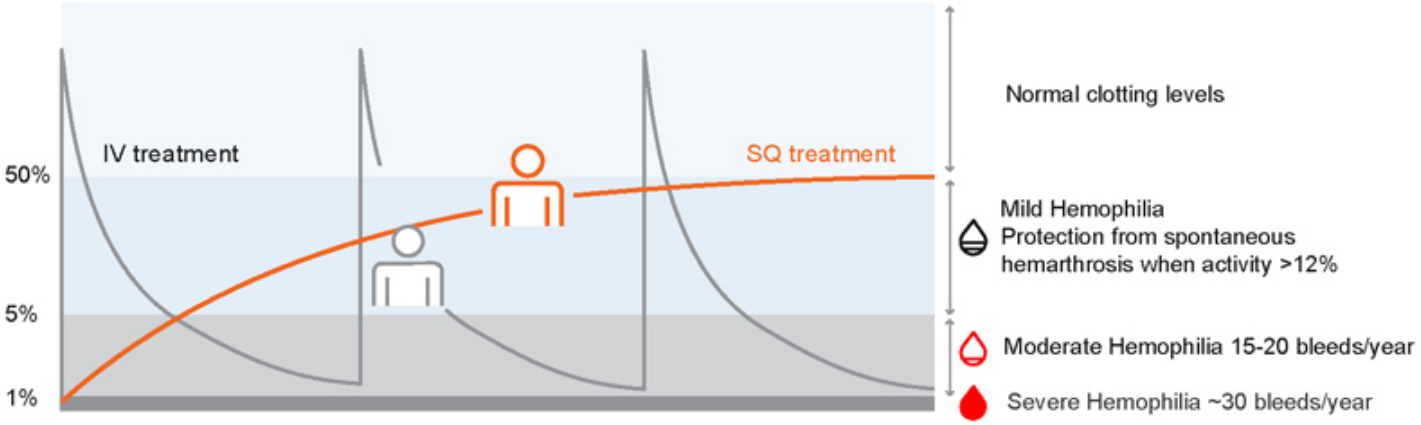
Our highly potent candidates

+ Quick & simple self-administered SQ injection
+ SQ dosing is the future in hemophilia and other rare hematology indications
+ Ideal for pediatric patients
+ Significantly increases half-life
+ Much higher & more stable factor levels for prophylaxis
+ Enable SQ treatment of bleeding

The new standard in hemophilia prophylaxis

Nasdaq: CBIO

Patients in high mild range are protected from spontaneous bleeds



- Our concept of prophylactic treatment is to keep severe & moderate hemophilia patients in the high mild range
- Subcutaneous factor treatments build up over time, offering long-term stability in clotting levels

MarzAA is only bypass agent for **both** SQ prophylaxis and SQ treatment of bleeds

Nasdaq: CBIO

Attractive commercial profile targeting an existing $2.2B bypass agent market

IV NovoSeven ($1.2B 2018 sales) validates rFVIIa in multiple rare bleeding disorders

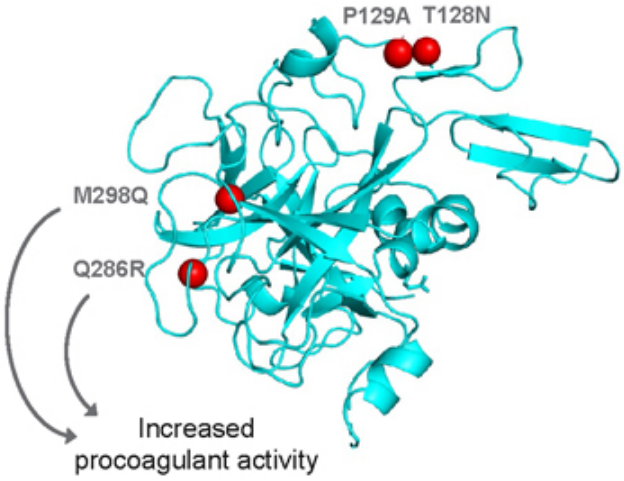
+ Hemophilia A or B with inhibitors
+ Severe Factor VII Deficiency
+ Glanzmann Thrombasthenia
+ Acquired Hemophilia A

SQ MarzAA has a superior profile to IV NovoSeven – over 100 clinicians surveyed:

+ All physicians surveyed indicated a preference for SQ MarzAA over IV N7 in one or more settings
+ SQ MarzAA can create & expand multiple prophylaxis markets

Marzeptacog alfa (activated): MarzAA rFVIIa

SQ prophylaxis and SQ treatment of a bleed are clear unmet needs in hemophilia and other bleeding disorders



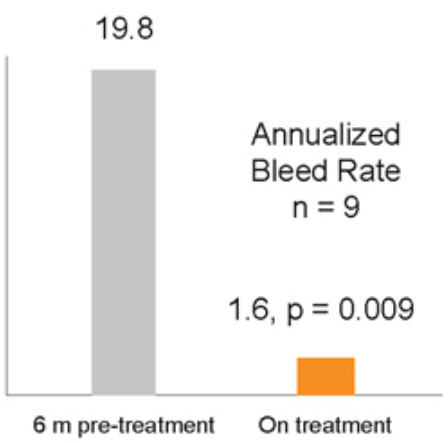
+ Four engineered amino acid substitutions within the FVIIa protein
+ 9-fold more potent catalytic activity than NovoSeven RT
+ **Allows subcutaneous dosing**
+ Half-life prolonged when using subcutaneous dosing

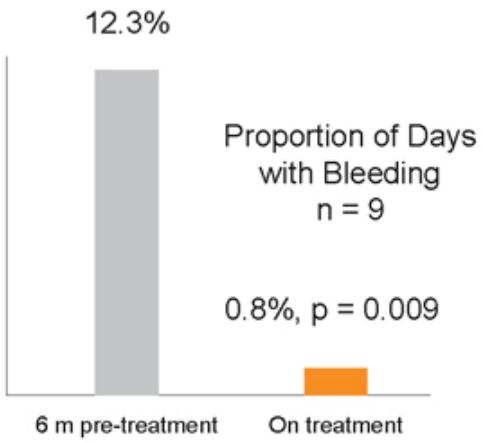
Orphan Drug Designation Granted in the US and EU

MarzAA Phase 2 demonstrates clinical efficacy

Nasdaq: CBIO

Greater than 90% reduction in all bleeding; Median ABR zero; Median bleeding days zero





Mean Annualized Bleeding Rates (ABR) significantly reduced from 19.8 to 1.6

Mean Proportion of Days with Bleeding (PDB) significantly reduced from 12.3% to 0.8%

Safe & well tolerated, ~1% ISRs (6/517 SQ doses) and **no ADAs**

In a world of SQ prophylaxis:

Patients need a SQ treatment of a bleed option

Individuals on Hemlibra® need additional treatments

NovoSeven® is safe but is administered IV

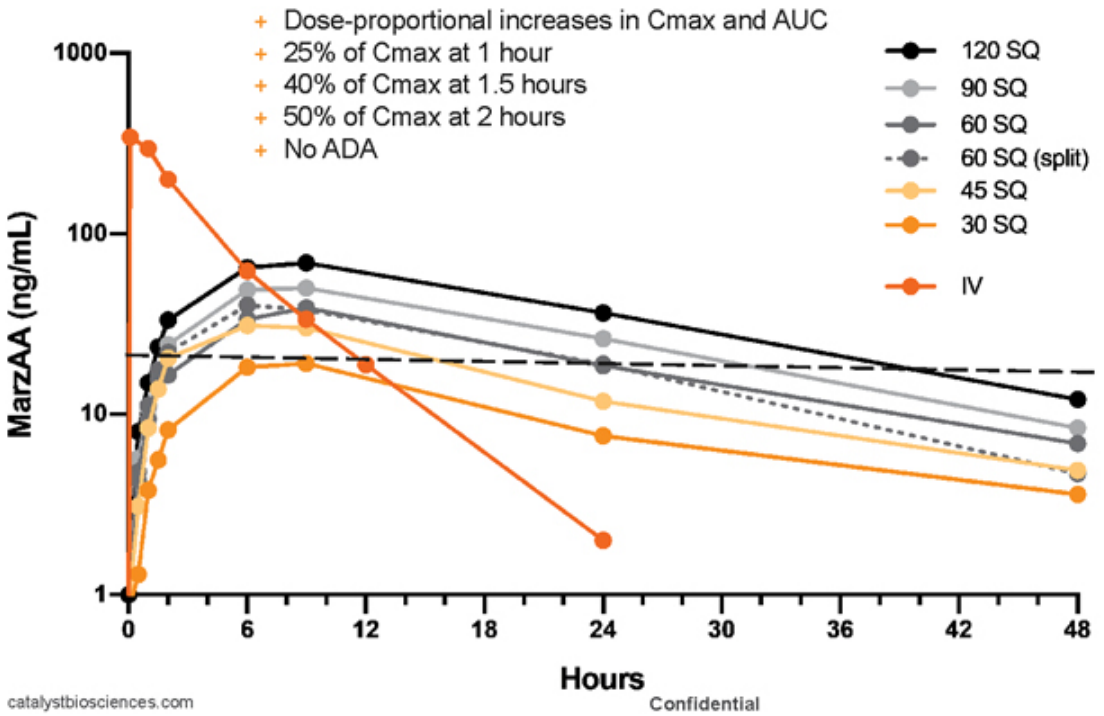
FEIBA lacks a safety margin and is administered IV

Blouse *et al.* ASH 2019

SQ MarzAA meets the profile for an **Ideal Solution**

- ✓ Fast & easy to administer
- ✓ Stops bleeding in a validated preclinical model
- ✓ Can be safely combined with Hemlibra

MAA-102 PK dose levels supports treatment of a bleed



Marzeptacog alfa (activated)

Phase 3 studies to initiate in 2020

- Large commercial opportunity across multiple rare bleeding disorders
- Demonstrated P2 Clinical efficacy & tolerability for prophylaxis indications
- Demonstrated preclinical PoC for SQ treatment of a bleed
- MarzAA can be safely combined with Hemlibra
- SQ dose escalation PK/PD study supports treatment of a bleed – final data in Q2 2020
- P3 guidance from EMA & MHRA received

Dalcinonacog alfa: a novel SQ FIX product

Nasdaq: CBIO

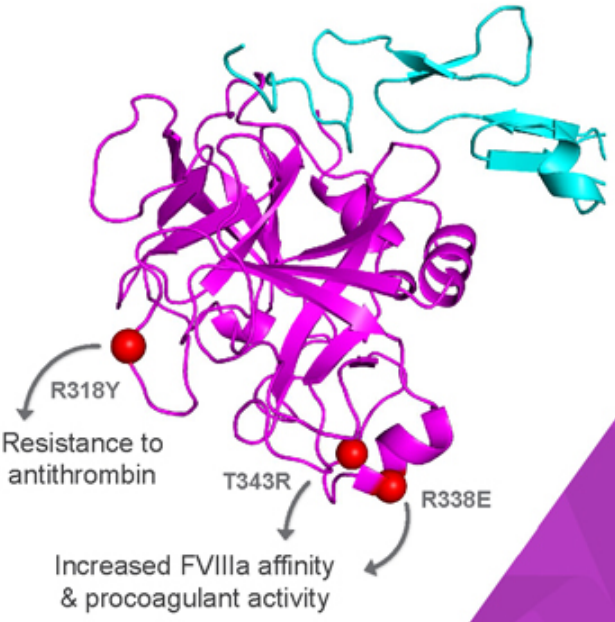
Three substitutions within the FIX protein:

+ Increased catalytic activity
+ Higher affinity for FVIIIa
+ Resistance to antithrombin inhibition
+ 22-fold increased potency over BeneFIX

Differentiated from marketed IV FIXs:

+ Simple SQ administration
+ Potential to maintain continuous protective levels
+ Small volume injection
+ Enhanced pharmacokinetics with prolonged half-life

Orphan Drug Designation in US & EU



Dalcinonacog alfa phase 2b SQ clinical trial design

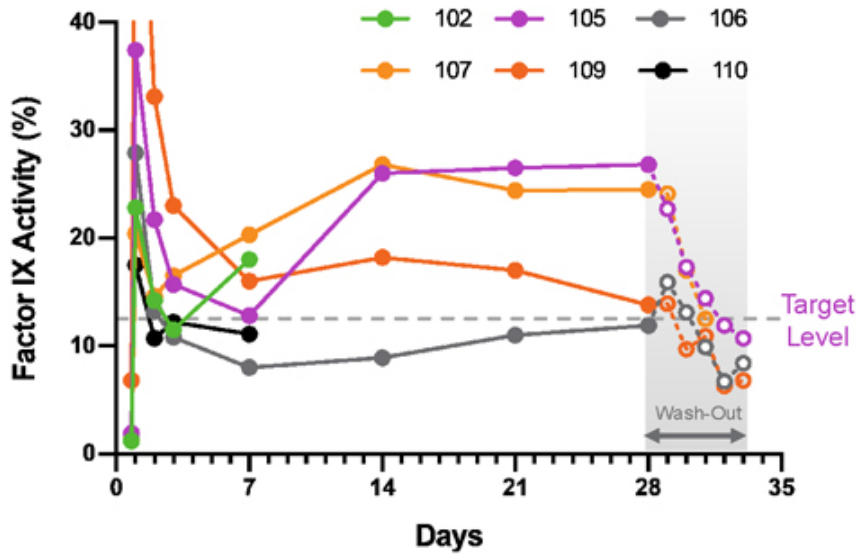
Nasdaq: CBIO

Enrollment complete

+ Primary endpoint: **Steady state FIX activity** level above 12% with daily dosing
+ Secondary endpoints: **safety including weekly ADA testing**, pharmacokinetics, pharmacodynamics, bleeding events,
+ 10 severe HB patients screened; 6 dosed
+ Rare propeptide mutation excluded

Target levels achieved with 100 IU/kg dosing for 28 Days

Nasdaq: CBIO



*Data cutoff 05 Feb 2020

Target FIX >12% Achieved

- Dosed 6 severe HB subjects
  - 110 continues dosing*
  - 102 withdrew on Day 7
- **Steady state FIX levels up to 27%** achieved after 14 days
- Consistent PK profiles
- Terminal half-life is 70-112 hr
- **No breakthrough bleeds**
- **No ADAs**

Conclusions

+ **SQ dalcinonacog alfa provides stable therapeutic levels of Factor IX**
+ **Demonstrates the potential to be an effective prophylaxis treatment for individuals with Haemophilia B**

Trial enrollment complete
Excellent & consistent therapeutic FIX activity levels attained
Prolonged half-life with SQ administration
No SAEs, systemic hypersensitivity, ADAs or nAb to DalcA or wild-type FIX
Mild to moderate ISR's primarily with initial injections
No bleeding events during treatment demonstrates effective prophylaxis

FIX gene therapy: CB 2679d-GT for hemophilia B

Nasdaq: CBIO

CB 2679d-GT in combination with a novel chimeric AAV capsid provides significant improvements

+ Stable high activity levels in a mouse hemophilia B model – **no nAbs**
+ Vector dose reduced 10-fold compared to current constructs
+ Potential for an improved efficacy & safety profile
+ AAV license and sponsored research agreement with Stanford University School of Medicine

Superior preclinical efficacy of CB 2679d-GT *vs* Padua

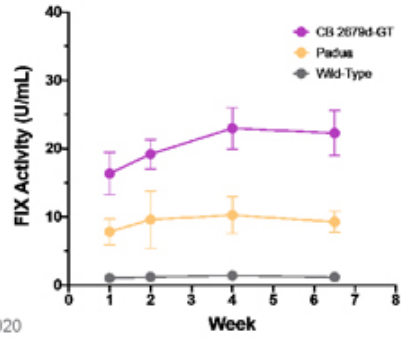
+ 4-5-fold reduction in bleeding time
+ Activity levels elevated throughout the study - **no nAbs**

Wholly-owned & issued patents covering gene therapy

The $8x10^{10}$ vg/kg in hemophilia B mice

FIX Transgene	AAV Capsid	Study Dose (vg/kg)	FIX Activity (U/mL)
CB 2679d-GT	**Novel Chimeric**	**$8.0x10^{10}$**	**20**
Padua	TAK-748*	$7.4x10^{11}$	20
Padua	TAK-748*	$7.4x10^{10}$	1

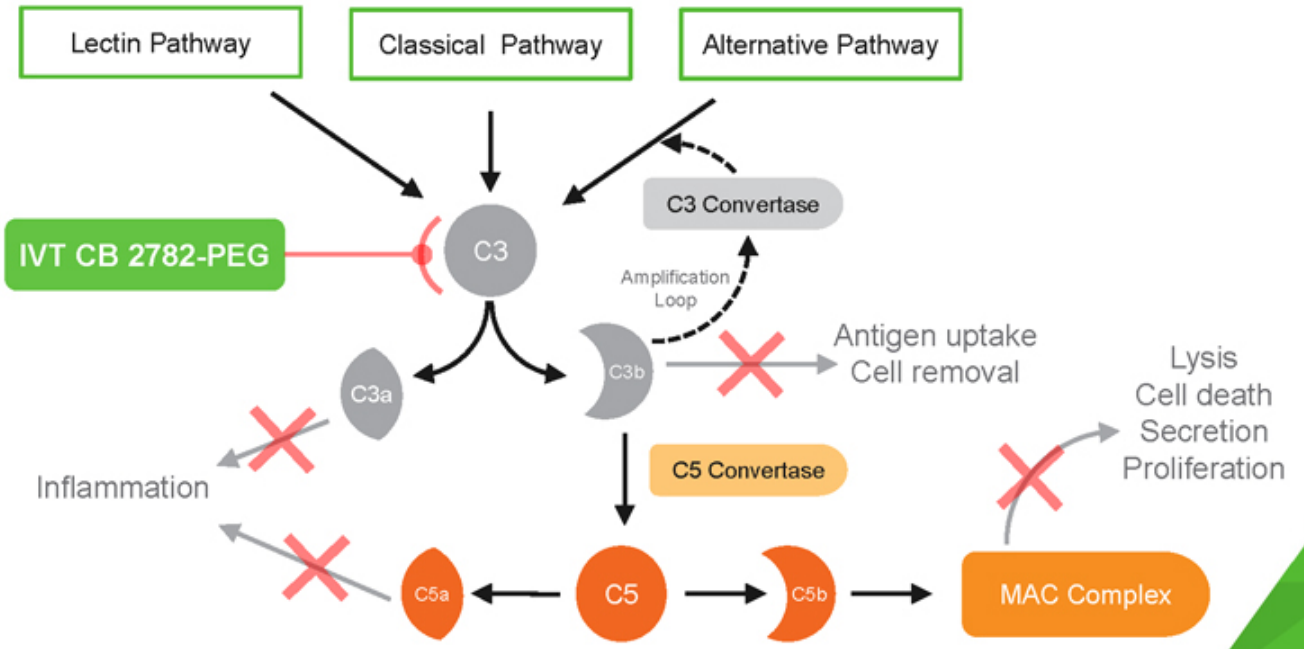
*Weiller *et al.* (2019) *Blood* Vol. 134, Supplement S1 P4633



Blouse *et al.* EAHAD 2020

Targeting C3 blocks the downstream complement cascade

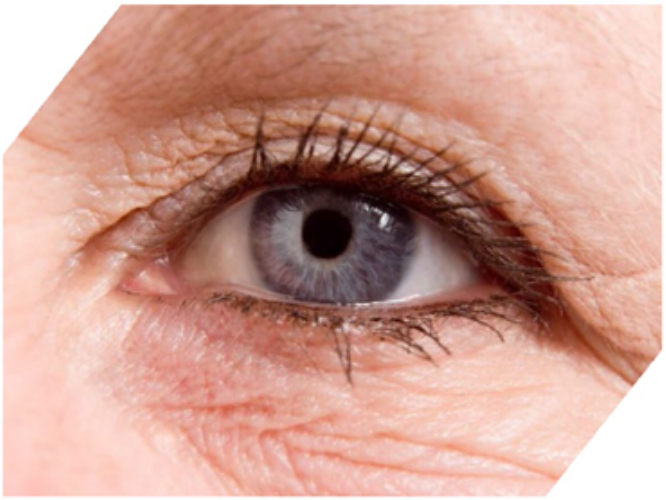
Nasdaq: CBIO



CB 2782-PEG anti-complement factor 3 (C3) protease

Nasdaq: CBIO

Geographic Atrophy in Dry AMD



- Geographic atrophy is an advanced stage of dry age-related macular degeneration that results in the irreversible loss of retina and leads to blindness
- Dry AMD affects a million people in the United States and over five million people worldwide
- Global market is estimated at >$5B with no approved drugs
- C3 is the only clinically validated target for the treatment of Dry AMD

Sources: National Eye Institute. Facts About Age-Related Macular Degeneration, Tufail 2015, The Eye Diseases Prevalence Research Group 2004, GlobalData

CB 2782-PEG long acting anti-C3 protease

Best-in-class anti-C3 profile for dry AMD

+ Generated from Catalyst's proprietary protease engineering platform
+ Potent, selective and long acting anti-C3 protease that degrades C3 into inactive fragments
+ Preclinical PK & PD data predict best-in-class human intravitreal dosing three or four times a year
+ Dry AMD is a $5B+ market opportunity with no approved drugs

Biogen Collaboration

+ Announced December 19, 2019
+ $15M upfront, up to $340M in milestones and tiered royalties up to low double digits
+ Catalyst to perform fully funded pre-clinical and manufacturing activities
+ Biogen responsible for IND-enabling activities, worldwide clinical development & commercialization

Biogen

Milestones

	2019	Q1	Q2	H2
MarzAA (FVIIa)	**P2 efficacy**	EoP2	ToB enabling PK/PD	Registration Trial
DalcA (FIX)	**Positive P2b Interim data**	P2b Update	Final P2b data	
CB 2679d-GT (FIX Gene Therapy)	**Preclinical efficacy**	NextGen Vector	NHP Efficacy	
CB 2782-PEG (dAMD)	**Partnership** Biogen			

Financial information

Selected data

Financial results	Q3 2019
Cash & Cash Equivalents	$85.0 M
Operating Expense (YTD)	$43.3 M
Net Loss (YTD)	($41.6M)
Net Loss per share (YTD)	($3.47)

Share data	
Common Stock Outstanding	12,029,992
Officer & Director ownership	7.0%
Fully Diluted Shares*	14,859,051

* Includes ~1M options available for issuance

Team

President & CEO
Nassim Usman, Ph.D.

26 years in biotech

SVP, Technical Operations
Andrew Hetherington, M.B.A.

20 years in biotech

Chief Medical Officer
Howard Levy, M.B.B.Ch., Ph.D., M.M.M.

18 years in hematology

VP, Translational Research
Grant Blouse, Ph.D.

12 years in biotech

VP, Business Development
Jeffrey Landau, M.B.A.

16 years in biotech

Summary

Nasdaq: CBIO

Disruptive approach to billion-dollar markets – protease engineering platform

- FVIIa: SQ MarzAA ~$2.2B market
  - + P2 efficacy & safety demonstrated
  - + P1/2 PK/PD supports ToB
  - + FDA EoP2 in early 2020, P3 expected in 2020
- FIX: SQ DalcA >$1.5B market
  - + Phase 2b efficacy & safety demonstrated
  - + Final Phase 2b data in 2Q 2020
- FIX Gene Therapy: CB 2679d-GT
  - + Proprietary preclinical gene therapy asset with superior activity *vs* current clinical constructs
- Anti-C3 dAMD: IVT CB 2782-PEG >$5B market
  - + Biogen collaboration
  - + $15M upfront, up to $340M in milestones and tiered royalties up to low double digits
- SQ systemic complement inhibitor program
  - + Large orphan disease opportunity
  - + Builds complement franchise
- Strong financial position

THANK YOU

Nasdaq: CBIO

catalystbiosciences.com

CATALYST BIOSCIENCES

Exhibit 99.2

Catalyst Biosciences Presents Positive Data from its Phase 2b Trial of Subcutaneous Dalcinonacog Alfa (DalcA) and Marzeptacog alfa (activated) (MarzAA) Programs at the 13th Annual EAHAD Congress

Enrollment in the DalcA trial is complete; results demonstrate DalcA provides Factor IX (FIX) activity exceeding the efficacy endpoint with no anti-drug antibodies

Company to host investor call and webcast on Friday, February 7 at 8:30 a.m. ET

SOUTH SAN FRANCISCO, Calif., Feb. 7, 2020 — Catalyst Biosciences, Inc. (NASDAQ: CBIO), today announced positive efficacy and safety data from its Phase 2b trial of DalcA, a next-generation subcutaneously (SQ) administered Factor IX (FIX) therapy being developed for the treatment of hemophilia B. The data were presented by Johnny Mahlangu, M.B.B.Ch., M.Med, F.C.Path, professor of haematology, faculty of health sciences, head of the School of Pathology at the University of Witwatersrand in Johannesburg, South Africa, and principal investigator in the clinical trial in an oral presentation at the 13th Annual Congress of the European Association for Haemophilia and Allied Disorders (EAHAD) in The Hague, Netherlands.

Data from the trial showed that 28 days of daily SQ dosing of DalcA achieved protective target FIX levels of >12%, with steady state FIX levels of up to 27% after 14 days with no bleeds, demonstrating effective prophylaxis and the potential for lower or less frequent dosing. One subject withdrew on day 7. No anti-drug antibodies were detected and no serious adverse events were reported. Three subjects reported injection site reactions (ISRs), the majority of which were mild in severity and resolved without sequelae.

The open-label Phase 2b study was designed to evaluate the ability of DalcA to maintain steady state protective FIX levels above 12% in six individuals with severe hemophilia B. Each subject received a single intravenous dose, followed by daily SQ doses of DalcA for 28 days. Pharmacokinetics, pharmacodynamics, safety and tolerability of daily SQ dosing and anti-drug antibody formation are being monitored.

“The DalcA Phase 2b trial data presented today at EAHAD clearly demonstrate the potential for DalcA to significantly change the treatment paradigm for those suffering from hemophilia B,” said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. “With the trial now fully enrolled and one final subject completing dosing, we will announce final data in the second quarter of this year.”

Dr. Usman continued, “We are very encouraged by the data presented at EAHAD from three of our programs and see 2020 as a pivotal year for our entire hemophilia franchise. In addition to the Phase 2b DalcA data, our SQ FVIIa marzeptacog alfa (activated) MarzAA candidate has demonstrated efficacy and safety in individuals with hemophilia A or B with inhibitors in a Phase 2 prophylaxis study, and this week we presented pharmacokinetic and pharmacodynamic data that support SQ MarzAA use in acute or on-demand settings. Our high-potency FIX gene therapy candidate, CB 2679d-GT is developing into a promising asset with encouraging pre-clinical data using a proprietary next-generation AAV capsid. Our entire team is committed to developing novel treatments in multiple rare bleeding disorders.”

In addition to the oral presentation on the Phase 2b DalcA data, Catalyst presented three posters at the EAHAD congress. Dr. Linda Neuman, vice president, clinical development, presented data from a Phase 1 study to evaluate the pharmacokinetics, pharmacodynamics, and safety of ascending doses of SQ MarzAA in adult subjects with hemophilia, which showed that SQ dosing reaches target levels to treat ongoing bleeding. Dr. Grant Blouse, vice president, translational research, presented data on SQ MarzAA

demonstrating that on-demand treatment in Hemophilia A mice treated after a tail clip injury was as efficient as intravenous NovoSeven at reducing bleeding. Dr. Blouse also presented a poster on Hemophilia B gene therapy in mice demonstrating that a novel chimeric AAV capsid combined with the Company's proprietary potency enhanced CB 2679d-GT FIX variant may reduce the vector dose required in gene therapy while maintaining high FIX levels.

A copy of the presentation materials can be accessed on the Events and Presentations section of the Catalyst website. Catalyst will host an investor call on Friday, February 7, at 8:30 a.m. ET.

Conference Call Details

The management team will host a conference call for investors on Friday, February 7 at 8:30 a.m. ET to discuss the DalcA and MarzAA data presented at EAHAD. Conference call, webcast and post-conference call replay details are as follows:

Domestic:	+1.877.425.9470
International:	+1.201.389.0878
Conference ID:	13698597
Webcast link:	http://public.viavid.com/index.php?id=137884

A webcast replay will be available for 30 days following the live event.

A copy of the presentation materials can be accessed on the Events and Presentations section of the Catalyst website.

About Catalyst Biosciences

Catalyst is a clinical-stage biopharmaceutical company focused on addressing unmet needs in rare diseases and systemic complement mediated disorders. Our protease engineering platform includes development programs in hemophilia and a research program on subcutaneous (SQ) systemic complement inhibitors. Our engineered coagulation factors are designed to overcome the significant limitations of current IV treatment options, facilitate prophylaxis, and ultimately deliver substantially better outcomes for patients using SQ dosing. Our lead asset, MarzAA has completed Phase 2 development having met its primary endpoint of significantly reducing the annualized bleed rate (ABR) in individuals with hemophilia A or B with inhibitors. Our second hemophilia asset, DalcA is in a Phase 2b clinical trial and is being developed for the treatment of hemophilia B. We also have a global license and collaboration agreement with Biogen for the development and commercialization of pegylated CB 2782 for the potential treatment of geographic atrophy associated dry age-related macular degeneration. For more information, please visit 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 the potential uses and benefits of DalcA to provide benefits and change the treatment paradigm for patients with hemophilia B and for MarzAA to treat patients with hemophilia A or B with inhibitors, the potential benefits of SQ dosing, statements about Catalyst's clinical trial status for DalcA, the potential for CB 2679d-GT to be a promising asset and the potential use of MarzAA as an on-demand therapy. 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, or MarzAA, including the generation of antibodies, which has been observed in patients previously treated with DalcA, the risk that costs required to develop or manufacture the Company's products will be higher than anticipated, competition and other risks described in the "Risk Factors" section of the Company's quarterly report filed with the Securities and Exchange Commission on November 7, 2019, 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:

Ana Kapor
Catalyst Biosciences, Inc.
investors@catbio.com