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): September 17, 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 September 17, 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.

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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Presentation slide deck.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: September 17, 2020

/s/ Clinton Musil

Clinton Musil
Chief Financial Officer

Exhibit 99.1

Nasdaq: CBIO

CATALYST BIOSCIENCES

Corporate Overview

17 September 2020

CatalystBiosciences.com

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. Forward-looking statements include statements about the potential benefits of products based on Catalyst's engineered protease platform; potential markets for and advantages of MarzAA and DalcA; plans in Q4 2020 to enroll a pivotal Phase 3 registration study of MarzAA , initiate a Phase 1/2 trial in FVII Deficiency, Glanzmann Thrombasthenia, and patients treated with Hemlibra and initiate a pivotal non-human primate study of CB 2679d-GT; the potential for MarzAA and DalcA to effectively and therapeutically treat hemophilia subcutaneously; potential markets for our anticomplement and gene therapy programs; potential payments from Biogen; plans to declare a development candidates in our systemic complement program in Q4 2020; the superiority of CB 2679d-GT over other gene therapy candidates; and the Company's collaboration with Biogen for the development and commercialization of pegylated CB 2782 for the potential treatment of geographic atrophy-associated dry age-related macular degeneration (AMD). 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 as a result of the novel coronavirus (COVID-19) outbreak and other factors, that trials 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 neutralizing 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, including as a result of delays in development and manufacturing resulting from COVID-19 and other factors, the risk that Biogen will terminate Catalyst's agreement, competition and other risks described in the "Risk Factors" section of the Company's quarterly report filed with the Securities and Exchange Commission on August 6, 2020, 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 – Protease medicines

Protease engineering platform

Late-stage asset

SQ Marzeptacog alfa (activated)
MarzAA (FVIIa)

Phase 3 in 2020

Hemophilia

SQ MarzAA (FVIIa)

SQ Dalcinonacog alfa – DalcA (FIX)

Factor IX Gene Therapy

Factor Xa

Complement

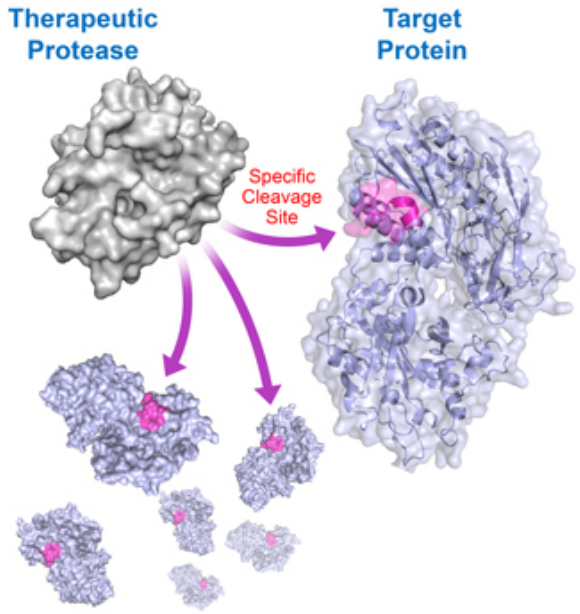
IVT Anti-C3 Dry AMD
CB 2782-PEG

Biogen

SQ Systemic Complement Inhibitors

Harnessing the catalytic power of proteases

One protease molecule activates or inactivates 1000s of target molecules



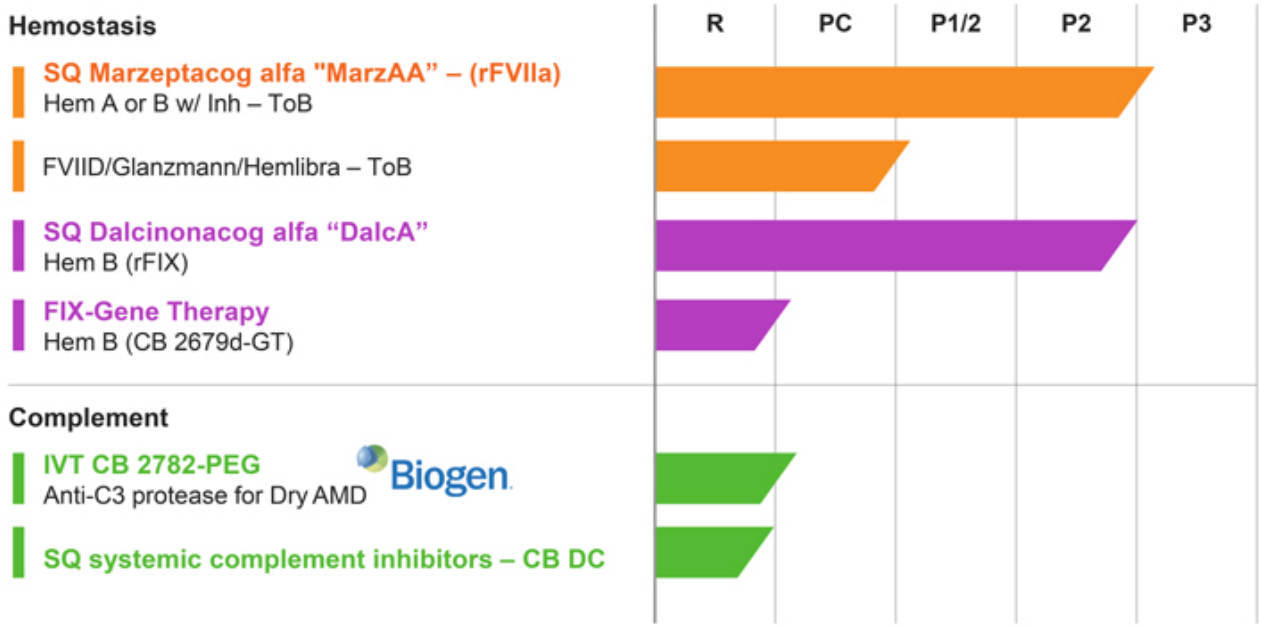
An adaptable protease platform

- Functionally enhanced natural proteases (FVIIa, FIX)
- Engineered novel protein degraders (Anti-C3)
- Extended half-life variants
- Increased potency
- Proven efficacy of clinical stage assets

Advantages

- Quick & simple SQ dosing for systemic use
- Less frequent intravitreal dosing in ophthalmology
- Low vector dose gene therapy constructs
- Ideal for high concentration drug targets or controlling amplification cascades

Pipeline



Investment highlights

Novel subcutaneous factors with orphan drug designation, MarzAA & DalcA – P2 efficacy in prophylaxis studies complete

Anti-C3 Dry AMD with Biogen

SQ systemic complement regulator research program

Multibillion-dollar market opportunities

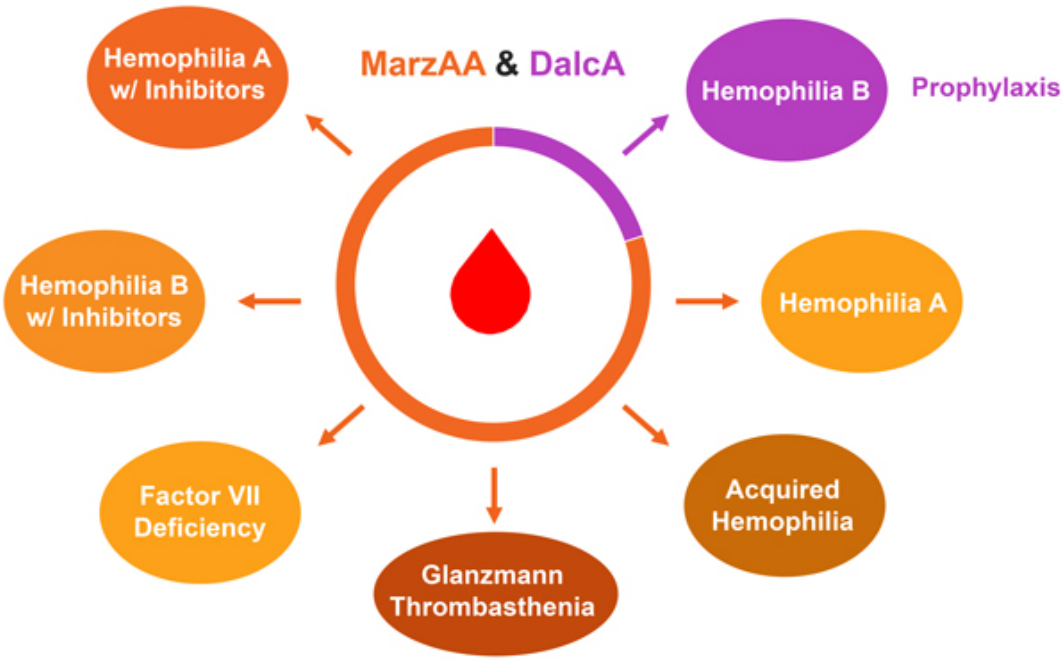
Experienced team

Strong balance sheet, $117.4 M cash – Q2

177 worldwide patents
CBIO retains full ownership of all compounds

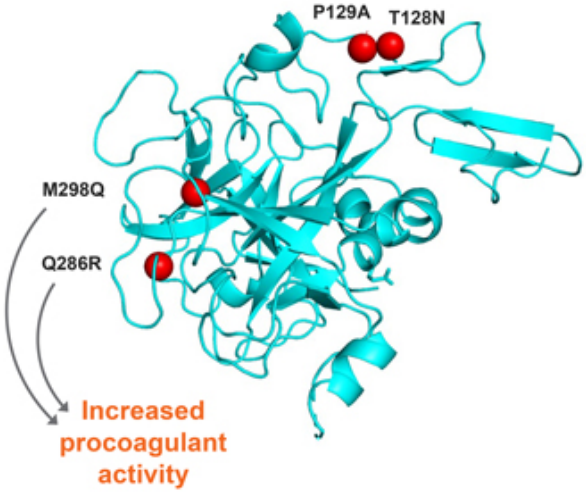
Addressing unmet needs in rare bleeding disorders

SQ treatment of episodic bleeding and prophylaxis – $4B+ market



Marzeptacog alfa (activated): MarzAA rFVIIa

Addresses a clear unmet need in hemophilia & other bleeding disorders



Four amino acid substitutions

+ Multiple advantages over NovoSeven RT
+ 9-fold higher activity *vs* NovoSeven RT
+ Potency allows for SQ dosing

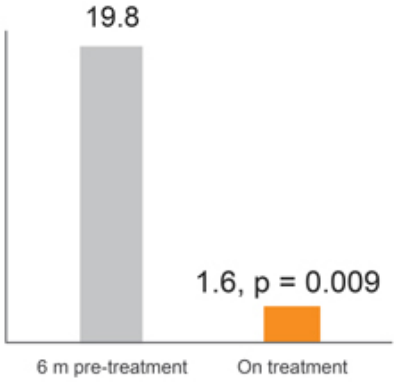
Only SQ bypass agent for on demand treatment

+ Small volume SQ administration
+ Improved bioavailability
+ Prolonged half-life

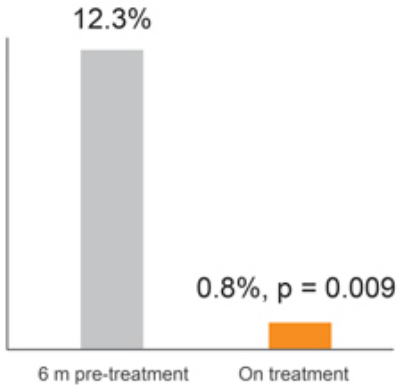
Orphan Drug Designation in US and EU

MarzAA Phase 2 demonstrates efficacy with daily prophylaxis

Annualized bleed rate
n = 9



Proportion of days with bleeding
n = 9

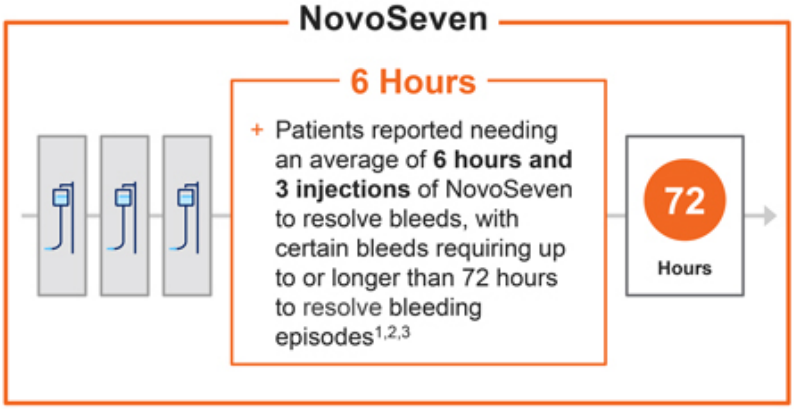


- Greater than 90% reduction in all bleeding – Median ABR = 0
- 7 of 9 subjects had no bleeding at final dose level
- Safe & well tolerated, ~1% ISR (6/517 doses) & no ADA

Mahlangu *et al.* EAHAD 2020

Current bypass agents require multiple IVs over the course of hours

Patients identify a need for an easy to administer treatment to stop bleeds quickly



"I have trouble securing a vein for IV administration due to the fact that my veins are very scarred from years of IV injections. My veins are prone to collapse."

- Hemophilia Patient

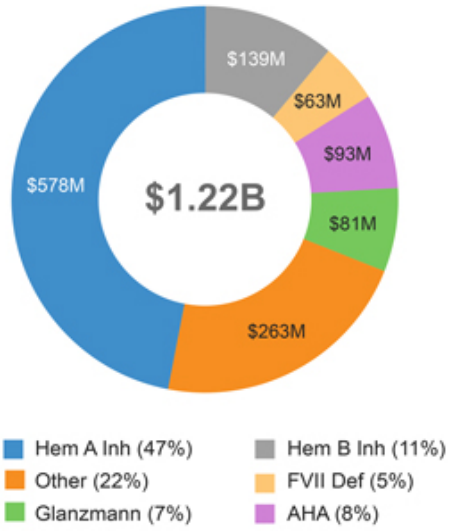
"Wish we could do [treatment of a bleed] via something outside of IV, we would love the convenience of a subcutaneous administration."

- Hemophilia Patient

Source: [1]NovoSeven PI Rev 7/2020; [2]Adivo Associates market research; [3]Catalyst Biosciences market research. Data on file

SQ treatment of a bleed is a large commercial opportunity

Global NovoSeven sales breakdown by indication (2019)

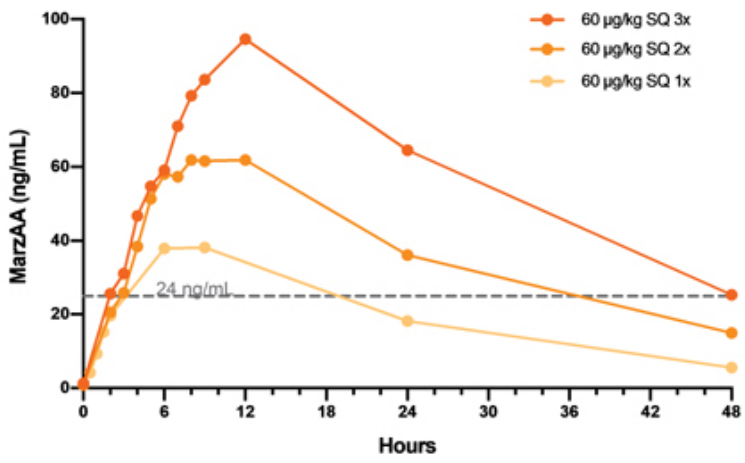


Source: Adivo Associates market research; Catalyst Biosciences market research. Data on file

SQ MarzAA has a superior profile

- Faster & easier to administer *vs* N7 dosed every 2 hours IV
- MarzAA half-life ~8x longer than N7
- 9-fold higher activity *vs* N7
- Potential to reduce rebleeding
- Stops bleeding in multiple preclinical models
- Can be combined with Hemlibra *in vitro* without increased thrombogenicity
- Potential for prophylaxis
- Ideal for pediatrics and patients with venous access issues

MAA-102: PK MarzAA levels support SQ treatment of a bleed

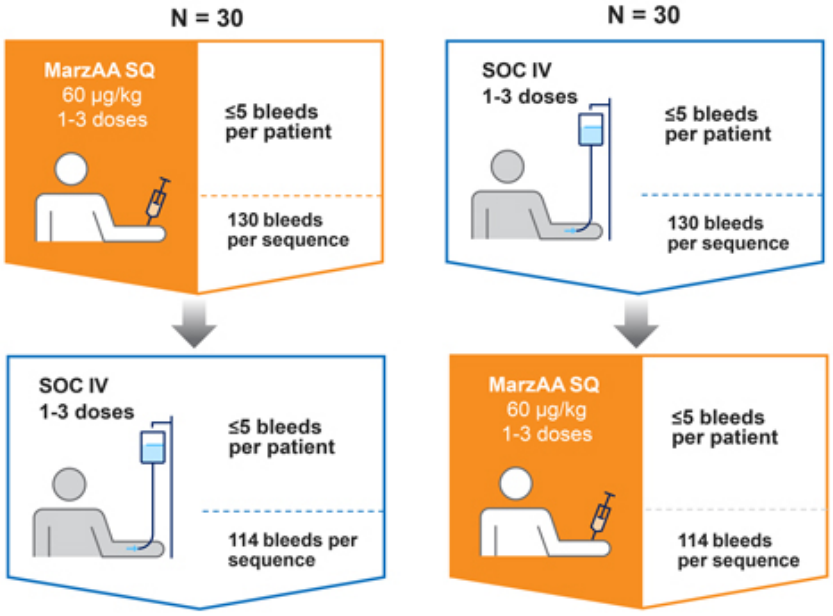


- Target of 24-120 ng/mL to treat a bleed is based on continuous infusion levels of NovoSeven for surgery
- Target levels are rapidly achieved
- 25% and 50% of C_{max} at 1 and 2 hours, respectively
- Dose-proportional increases in C_{max} and AUC
- Target levels can be maintained for 18 hours with a single SQ dose of 60 µg/kg
- Multiple dosing cohorts completed
  - 60 µg/kg every 3 hours; twice and thrice
- No ADA

Neuman *et al.* ISTH 2020

Crimson 1 Phase 3 study: Treatment of episodic bleeding

Hemophilia A or B with inhibitors



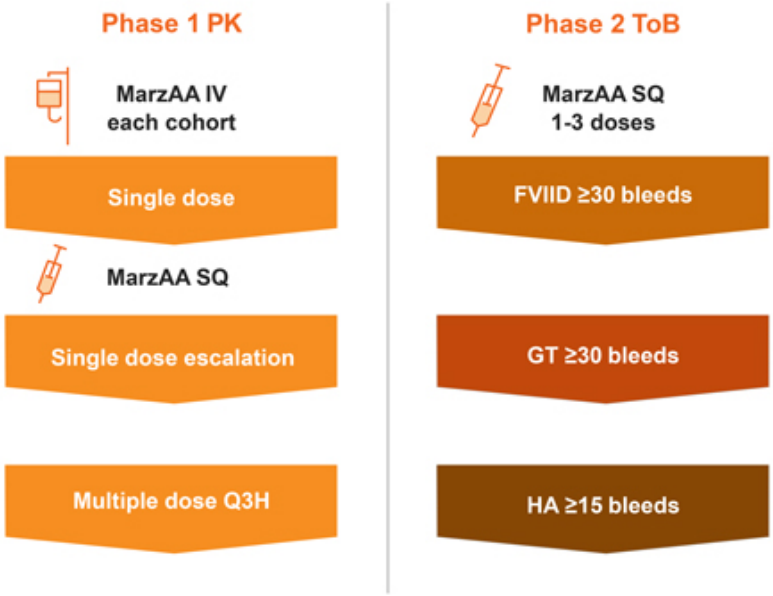
- **Primary endpoint**
  Non-inferior hemostatic efficacy: standard 4-point scale
- **Secondary endpoints**
  Time to bleed resolution; number of doses; rescue meds
- **Safety**
  Adverse events, anti-drug antibodies (ADA); thrombosis

Statistics

+ **SOC estimate 85%**
  Excellent/good treatment of bleeds
+ Non-inferiority margin of **12%**
+ **2.5%** significance, one-sided
+ **90%** power

MAA-202 Phase 1/2 study design

FVII deficiency, Glanzmann thrombasthenia and HA on Hemlibra: N = 8 each



- **Phase 1**

  Primary endpoints:
  Pharmacokinetics

  Secondary endpoints:
  Pharmacodynamics

- **Phase 2 ToB**

  Primary endpoints:
  Hemostatic efficacy at 24 hours

  Secondary endpoints:
  Effective hemostasis at successive timepoints; doses needed; rescue meds

  Safety:
  Adverse events and ADA

MarzAA clinical development plan for treatment of bleeds

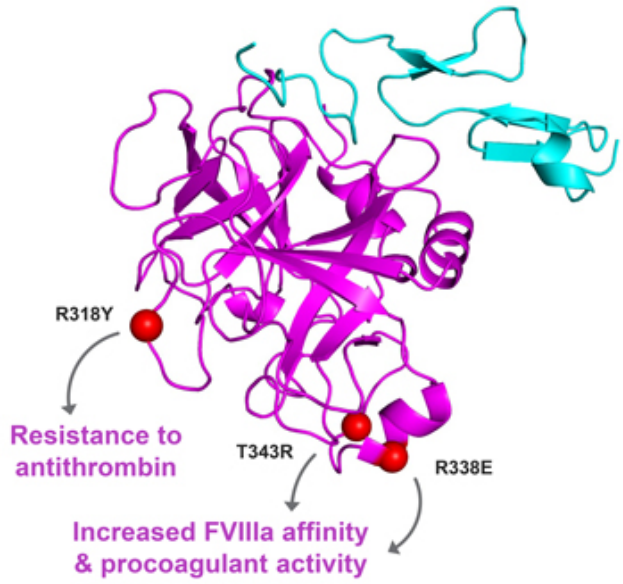
Large commercial opportunity across multiple rare bleeding disorders

- Initiate P3 Crimson 1 study in Q4 2020
- HA/HB with inhibitors

- Initiate P1/2 study MAA 202 in Q4 2020
- FVII deficiency, Glanzmann thrombasthenia, Hemlibra breakthrough bleeds

- Data expected in 2021 & 2022

Dalcinonacog alfa: novel FIX replacement for SQ delivery



Three amino acid substitutions

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

Differentiated from marketed IV FIXs

+ Small volume SQ administration
+ Enhanced pharmacokinetics with prolonged half-life
+ Excellent extravascular distribution
+ Potential to maintain continuous protective levels

Orphan drug designation in US & EU

Dalcinonacog alfa Phase 2b SQ clinical trial

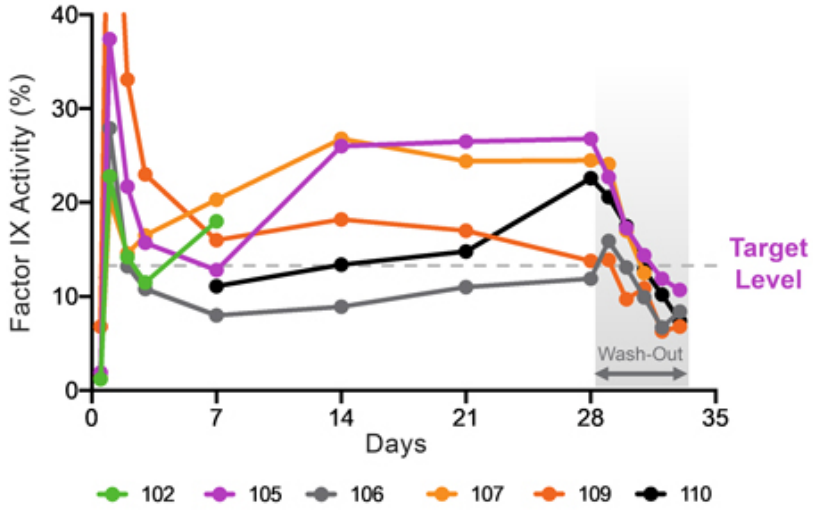
Trial completed

Endpoint achieved with steady state FIX activity levels >12%

- Primary endpoint: **Steady state FIX activity** level above 12% with daily dosing
- Secondary endpoints: **safety including weekly ADA testing**, pharmacokinetics, pharmacodynamics, bleeding events
- 6 severe Hemophilia B subjects dosed
- Rare propeptide mutation excluded
- HLA profile associated with nAb risk was excluded

DalcA P2b demonstrated proof of safety and efficacy

Target levels >12% achieved with 100 IU/kg dosing for 28 days



+ Dosed 6 severe HB subjects
  - Subject 102 withdrew on Day 7
+ **Steady state FIX levels up to 27%** achieved after 14 days
+ **No breakthrough bleeds**
+ **No neutralizing ADAs**
+ Consistent PK profiles
+ Terminal half-life is 2.5 - 5.1 days

Dalcinonacog alfa

Potential to provide effective SQ prophylaxis for individuals with Hemophilia B

- Phase 2b trial complete
- Protective therapeutic FIX activity levels achieved
- No bleeding events during treatment indicates effective prophylaxis
- No SAEs, systemic hypersensitivity, nAb
- Mild to moderate ISR primarily with initial injections – transient & self-limiting
- Long half-life – potential for lower dose/reduced dosing frequency

Catalyst's CB 2679d - gene therapy

Limitations of 1st generation GTs create an opportunity

AAV serotype

- High vector doses needed to achieve stable expression
- Preexisting neutralizing antibodies to the capsids limit efficacy & eligible patients
- Variable tissue tropism can limit effectiveness

Durability

+ FIX transgenes encode the Padua high-activity FIX variant
- Gene therapies have yet to demonstrate durable and clinically meaningful FIX expression 5 years post-infusion
- FIX activity has decreased over time

CB 2679d-GT for hemophilia B

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

Stanford University License & sponsored research agreement

CB 2679d-GT has a superior profile *vs.* Padua in preclinical studies

- Stable high activity levels with a vector dose reduced 10-fold in a mouse hemophilia B mode
- 4 to 5-fold reduction in bleeding time when compared to the Padua transgene in mice
- Potential for an improved efficacy & safety

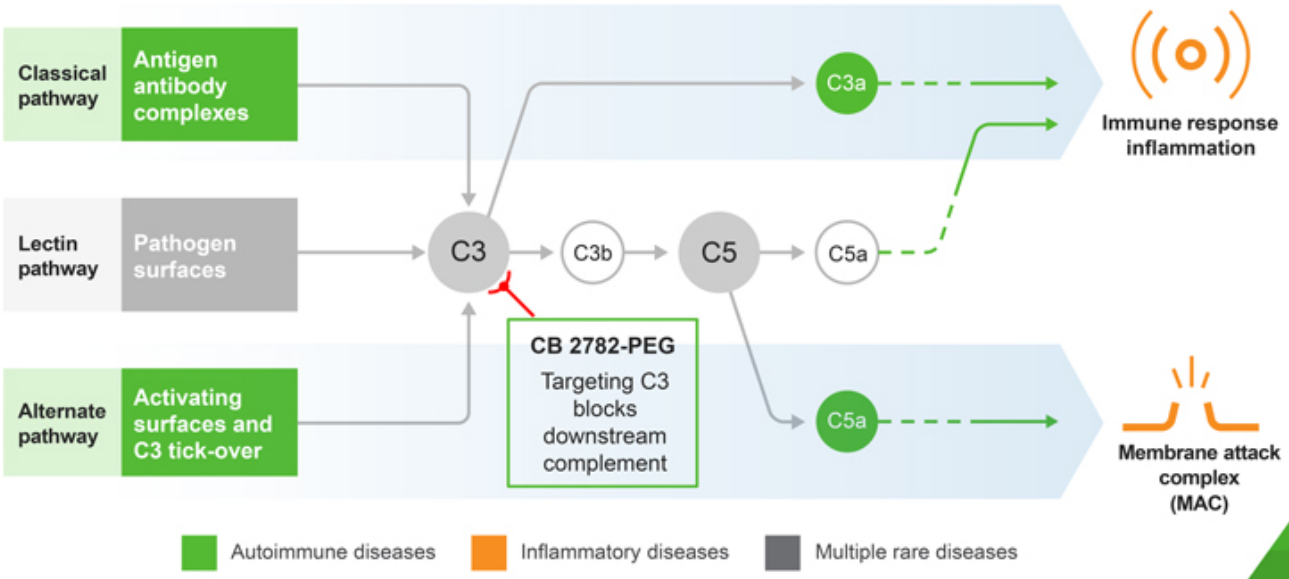
Achieved high initial FIX levels in NHPs

- Presented at World Federation of Hemophilia Virtual Summit 2020 (June 19, 2020)
- Additional vector optimization & dose ranging studies ongoing

Wholly-owned & issued patents covering gene therapy

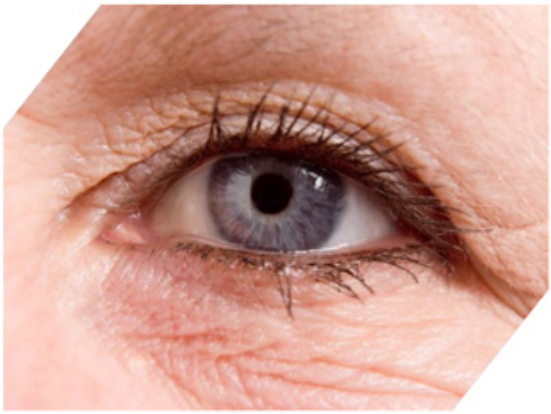
Targeting complement – a pathway regulated by proteases

Dysregulated complement activity is associated with a broad range of disorders and a logical fit for our protease platform



CB 2782-PEG: Complement factor 3 (C3) cleaving protease

Geographic atrophy in dry AMD can result in blindness



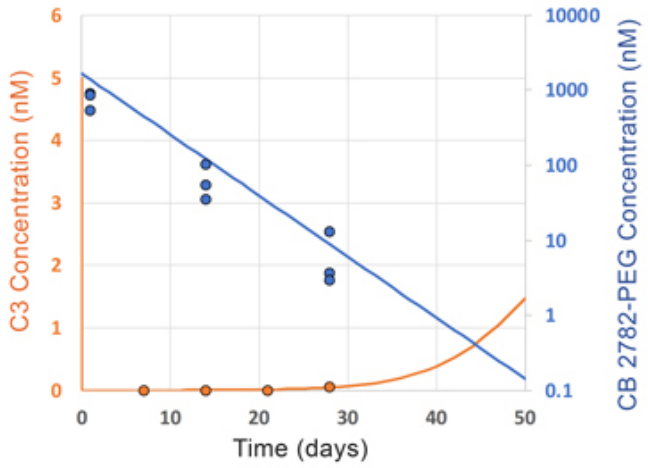
- Geographic atrophy is an advanced stage of dry age-related macular degeneration (dAMD)
- Dry AMD affects ~1M people in the US and over 5M worldwide
- Global market estimated at >$5B
- C3 is the only clinically (randomized P2) validated target for the treatment of dAMD
- No currently approved therapy

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

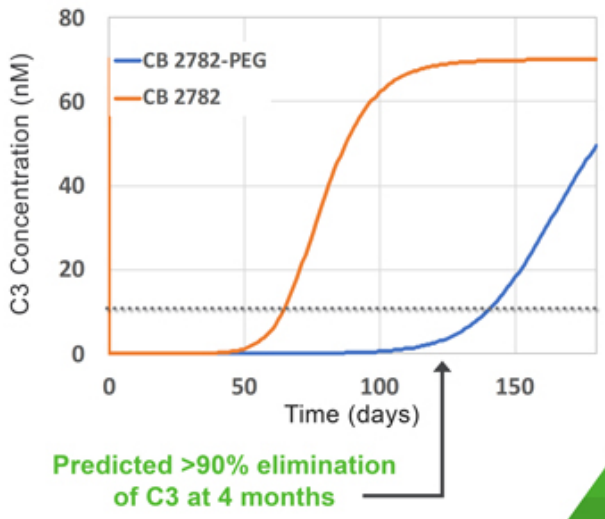
CB 2782-PEG long acting anti-C3 protease

Best-in-class anti-C3 profile for dry AMD with dosing every 3 to 4 months

Non-Human Primates



Human Modeling



Predicted >90% elimination of C3 at 4 months

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 NHP PK & PD data* predict **best-in-class** human intravitreal dosing three or four times a year

Biogen collaboration

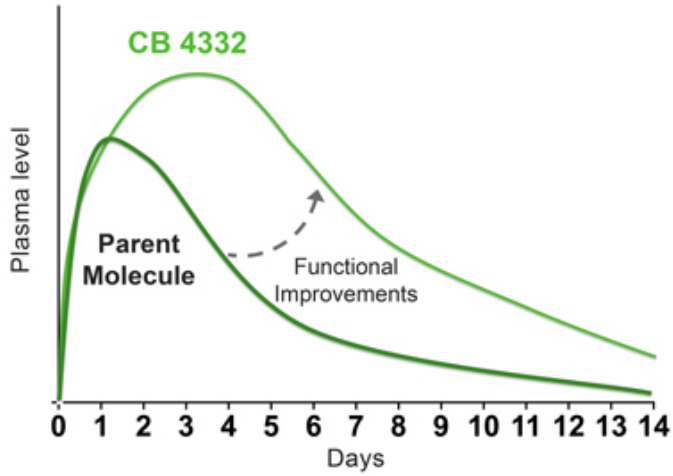
Biogen

+ 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

*Furfine *et al.* ARVO 2019

CB 4332 SQ long-acting systemic complement regulator

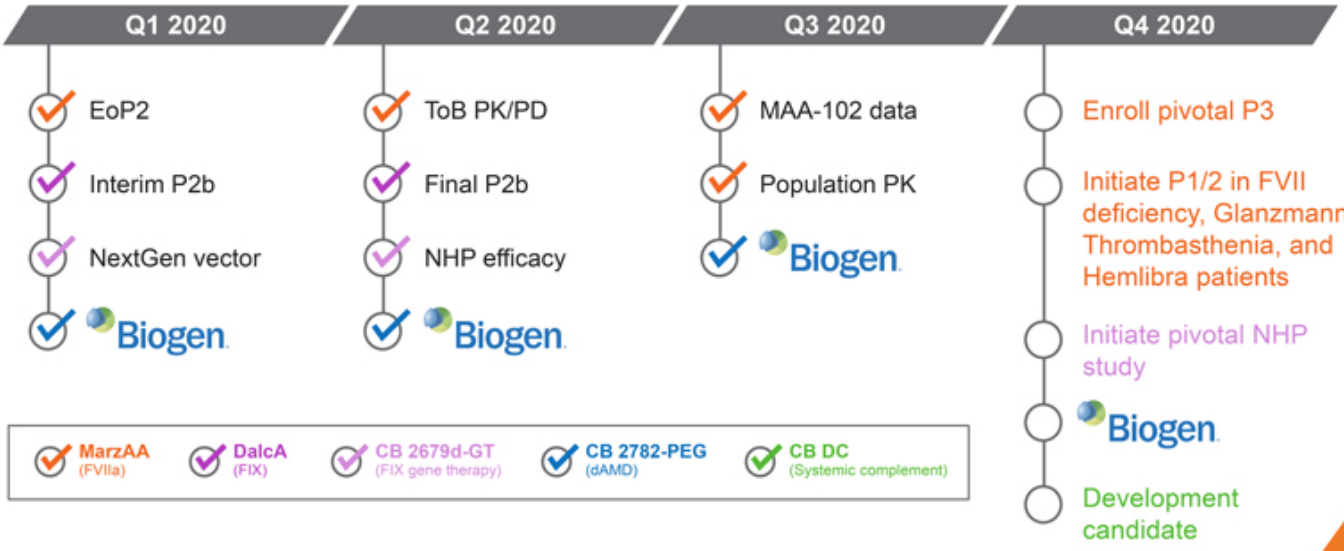
Non-human primate PK supports weekly SQ dosing in humans



Expanding the complement portfolio

+ Leverages Catalyst's proprietary **protease engineering platform**
+ Designed for **SQ administration & improved bioavailability**
+ **Simple & efficient** production process
+ Program update in Q4

Milestones – 2020



Team

Nassim Usman, Ph.D.
President & CEO

28 years in biotech

Grant Blouse, Ph.D.
SVP Translational Research

13 years in biotech

Clinton Musil, M.B.A
Chief Financial Officer

16 years in biotech & investing/banking

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

18 years in biotech

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

20 years in hematology

Anju Chatterji, Ph.D.
SVP Biologics Development & Manufacturing

19 years in biotech

Summary

Disruptive approach to billion-dollar markets – protease engineering platform

FVIIa: SQ MarzAA ~$2.2B market

+ P1 PK/PD & preclinical data supports ToB
+ P2 efficacy & safety demonstrated
+ P3 patient enrollment in Q4 2020

FIX: SQ DalcA >$1.8B market

+ Phase 2b efficacy & safety demonstrated
+ Potential for less frequent dosing

FIX Gene Therapy: CB 2679d-GT

+ Proprietary preclinical gene therapy asset with superior activity *vs* current clinical constructs with lower doses

Anti-C3 dAMD: IVT CB 2782-PEG >$5B market

+ Biogen collaboration
+ $15M upfront, up to $340M in milestones, up to low double digits tiered royalties

SQ systemic complement inhibitor program

+ Large $B+ rare-disease opportunity
+ Multiple indications & applications
+ 1st development candidate in Q4 2020

Well capitalized

+ Cash runway into 2022

THANK YOU

Nasdaq: CBIO

CatalystBiosciences.com

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