

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): November 17, 2020

CATALYST BIOSCIENCES, INC.  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation)

000-51173  
(Commission  
File Number)

56-2020050  
(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 November 17, 2020, Catalyst Biosciences, Inc. (the "Company") posted an update to its corporate presentation (the "Presentation") on its website, [ir.catalystbiosciences.com/presentations-events](http://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

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Presentation slide deck.</a>
104	Cover Page Interactive Data File (formatted as Inline XBRL).

**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: November 17, 2020

/s/ Clinton Musil  
Clinton Musil  
Chief Financial Officer

# CATALYST BIOSCIENCES

Corporate Overview  
17 November 2020

[CatalystBiosciences.com](https://CatalystBiosciences.com)

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# 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; 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 candidate 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 to differ materially, including, but not limited to, the risk that trials may be delayed as a result of the novel coronavirus outbreak and other factors, that trials may not have the desired outcomes, that additional human trials will not be required from earlier trials, that potential adverse effects may be observed from testing or use of DalcA or MarzAA, including the presence of neutralizing antibodies, which has been observed in patients treated with DalcA, the risk that costs required to develop and commercialize the Company's products will be higher than anticipated as a result of delays in development and manufacturing, the risk that COVID-19 and other factors, the risk that Biogen may not enter into Catalyst's agreement, competition and other risks discussed in the "Risk Factors" section of the Company's quarterly reports, the risk of regulatory action by the Securities and Exchange Commission on November 19, 2019, and other filings with the Securities and Exchange Commission. The Company does not assume any obligation to update 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

### Compleme

IVT Anti-C3 Dry  
CB 2782-PE



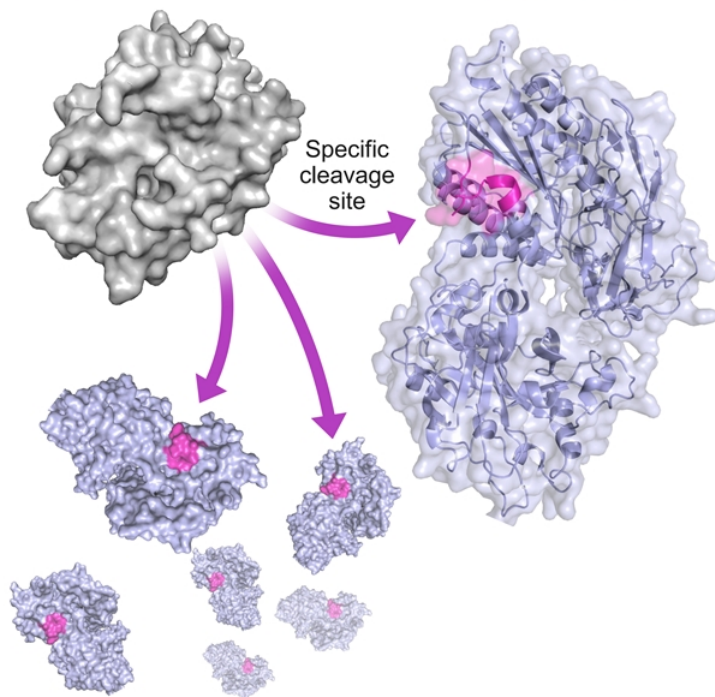
SQ Systemic  
Complement  
Inhibitors

# Harnessing the catalytic power of proteases

One protease molecule regulates 1000s of target molecules

Therapeutic protease

Target protein



## An adaptable protease platform

- ✓ Demonstrated efficacy of clinical
- ✓ Functionally enhanced natural protease
- ✓ Engineered novel protein degrader
- ✓ Ideal for high concentration drug target amplification cascades
- ✓ Potential to address novel targets
- ✓ Increased potency and extended half-life

# Pipeline

## Hemostasis

**SQ Marzeptacog alfa (activated) "MarzAA"**  
Hem A or B with inhibitors – ToB

FVIIID/Glanzmann/Hemlibra – ToB

**SQ Dalcinonacog alfa "Dalca"**  
Hem B (rFIX)

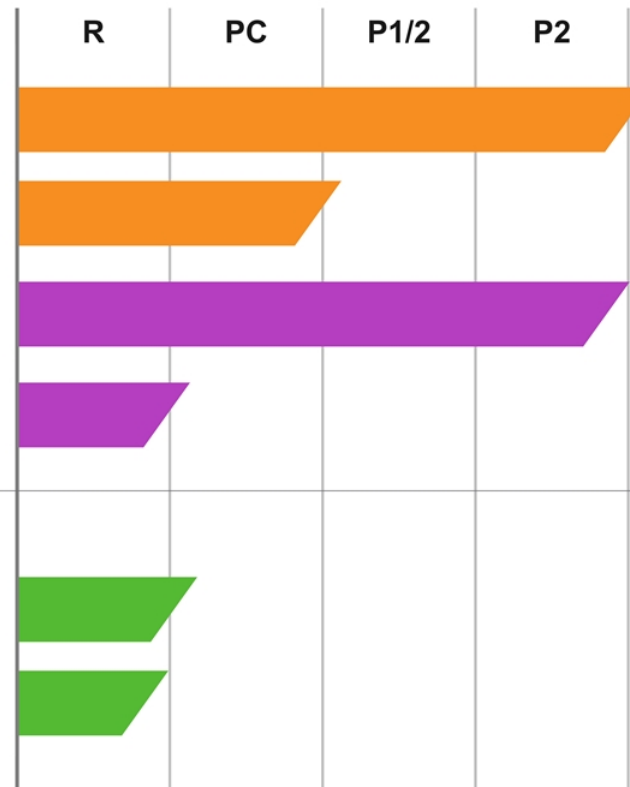
**FIX-Gene Therapy**  
Hem B (CB 2679d-GT)

## Complement

**IVT CB 2782-PEG**  
Anti-C3 protease for Dry AMD



**SQ systemic complement inhibitors – CB DC**





# Investment highlights



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



Anti-C3 Dry AMD  
SQ systemic complement regulator research



Multibillion-dollar market opportunities



Experienced team



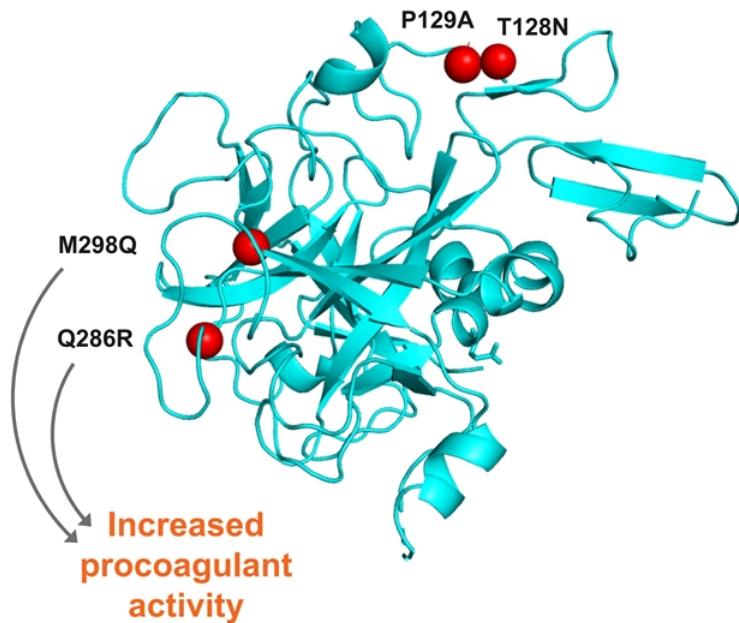
Strong balance sheet, \$104M cash – Q3



178 worldwide patents  
CBIO retains full rights of all compounds

# Marzeptacog alfa (activated): MarzAA rFVIIa

Addresses a clear unmet need in hemophilia & other bleeding disorder



## 9-fold higher activity vs NovoSev

- + Potency allows for SQ dosing that pro
- + Simple, small volume SQ administrati

## Preclinical efficacy of SQ on-den

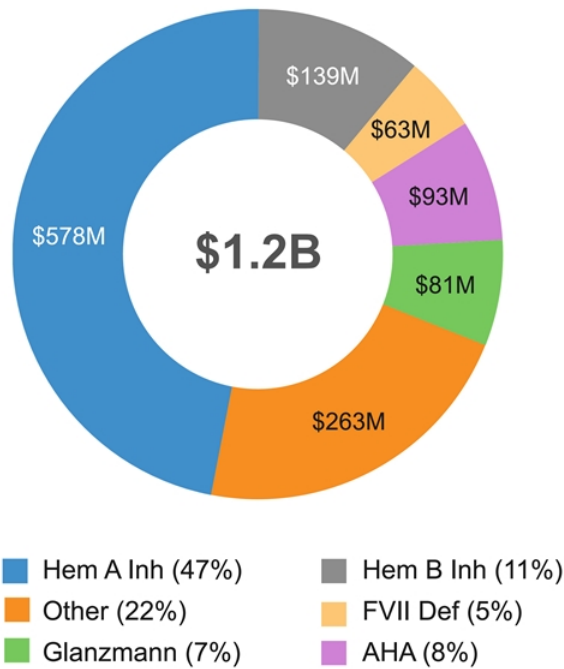
- + HA mouse after tail cut; HA dog; HA r

## P2/3 prophylaxis efficacy & safet with inhibitors

- + 46 patients treated including: single d doses/day, & daily SQ up to 97 days

# SQ MarzAA is a large commercial opportunity

## Global NovoSeven sales breakdown by indication (2019)



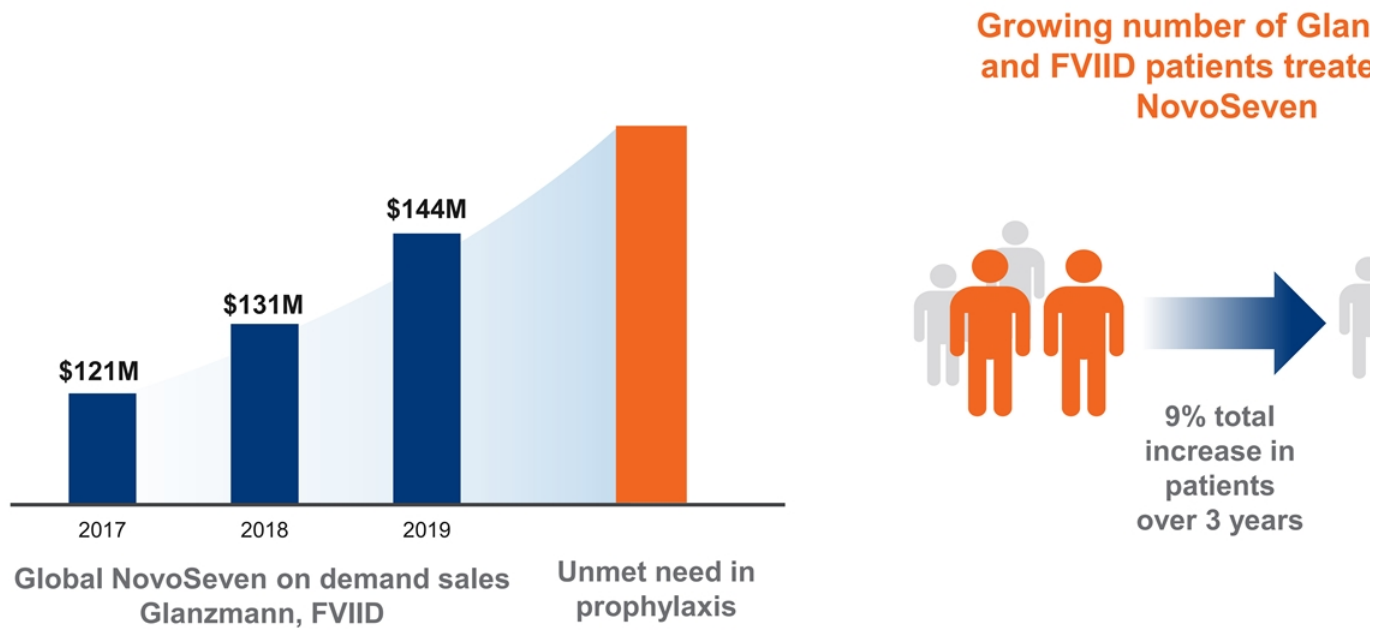
## SQ MarzAA has a superior profile

- ✓ Faster & easier to administer vs N7 every 2 hours IV until hemostasis
- ✓ MarzAA SQ 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 thrombotic risk
- ✓ Ideal for pediatrics and patients with IV access issues
- ✓ Prophylaxis efficacy demonstrated

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

© Catalyst Biosciences

# MarzAA could be the first prophylaxis for Glanzmann & FV

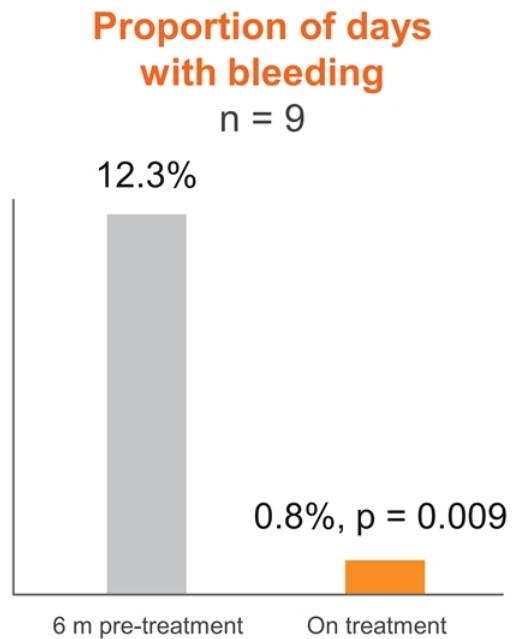
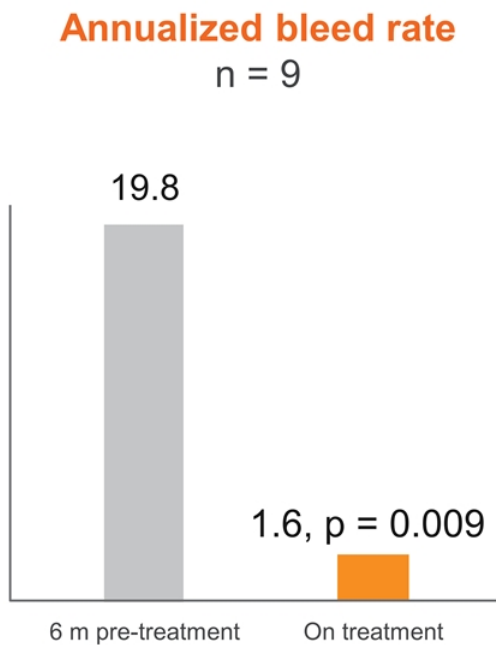


Source: Catalyst Biosciences, Adivo Associates Market Research, Data on file. \*Note: Treated patients may be counted multiple times as patients may have multiple bleeding events per year needing factor treatment

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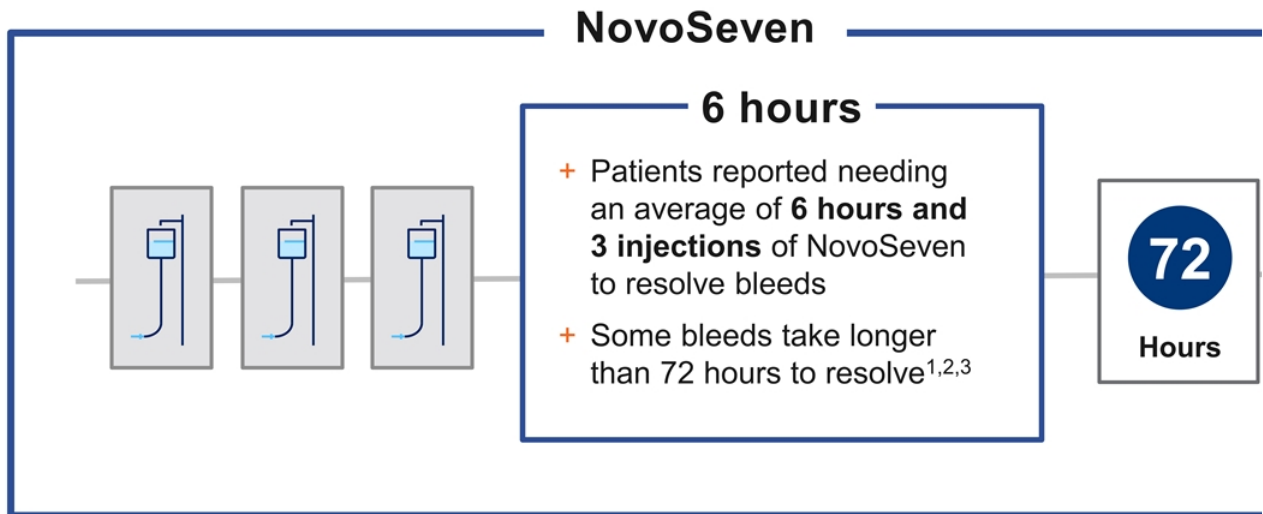
# MarzAA is efficacious with daily prophylaxis

## Phase 2: Daily SQ dosing for 44 – 97 days



- + Greater than all bleeding
- + 2 subjects had bleeding from 30 to 6
- + Safe & well tolerated (6/517 doses)

# Current bypass agents require multiple IVs over the course of

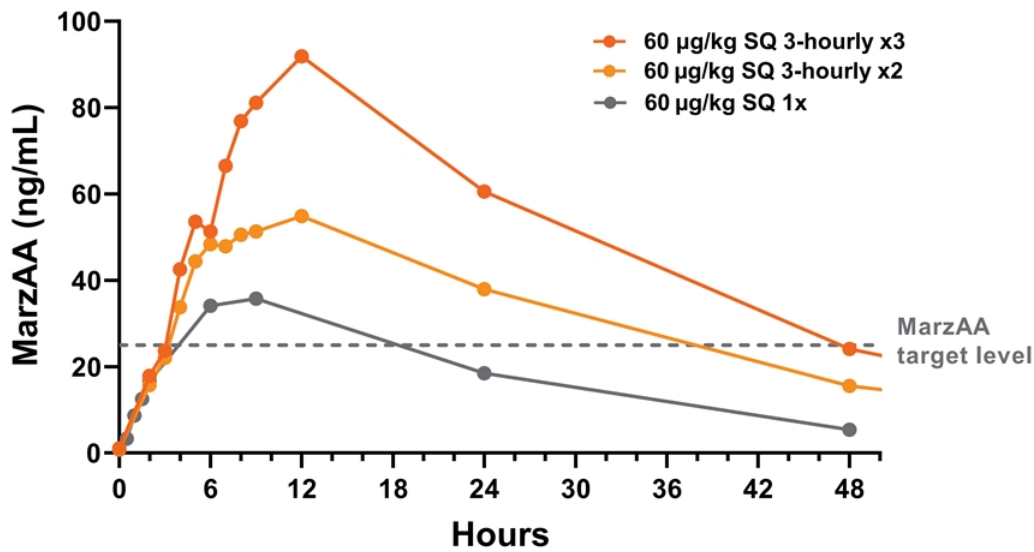


Source: <sup>1</sup>NovoSeven PI Rev 7/2020; <sup>2</sup>Adivo Associates market research; <sup>3</sup>Catalyst Biosciences market research. Data on file

© Catalyst Biosciences

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

8 subjects at each dose level

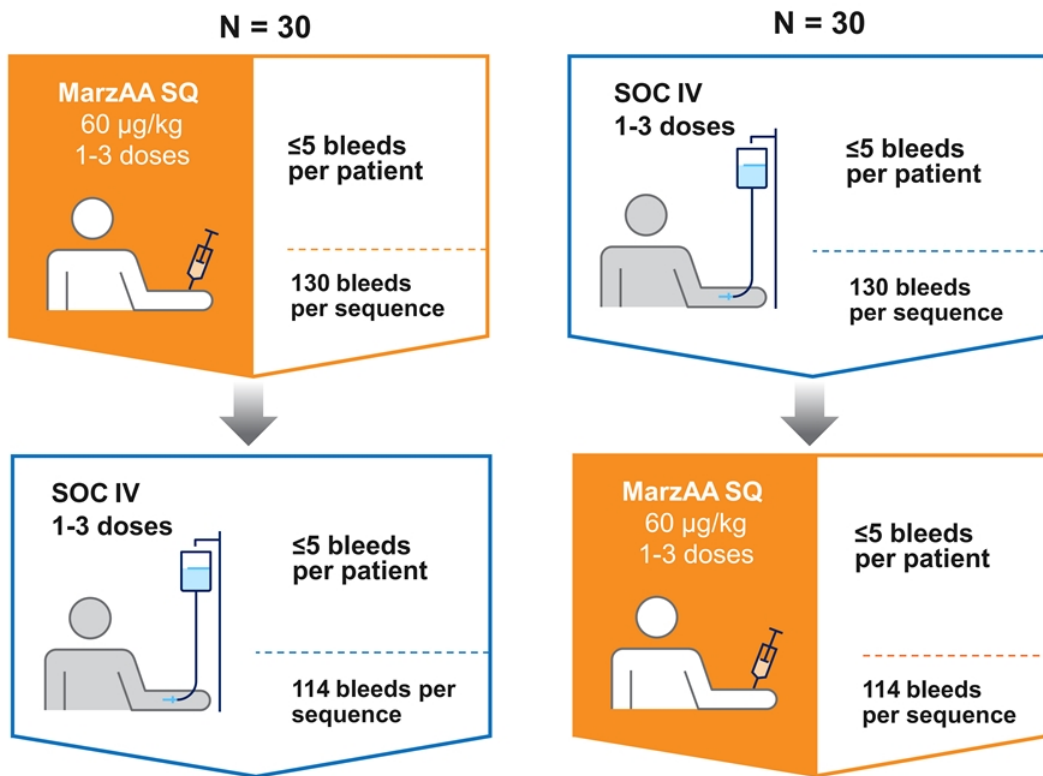


- + Target of 24-120 ng bleed is based on c infusion levels of N hemostasis during s
- + Target levels are ra
- + Target levels can be 18 hours with a sing 60 µg/kg
- + No ADA

Neuman *et al.* ISTH 2020

© Catalyst Biosciences

# Crimson 1 Phase 3 study: Treatment of episodic bleeding Hemophilia A or B with inhibitors, ABR $\geq 8$



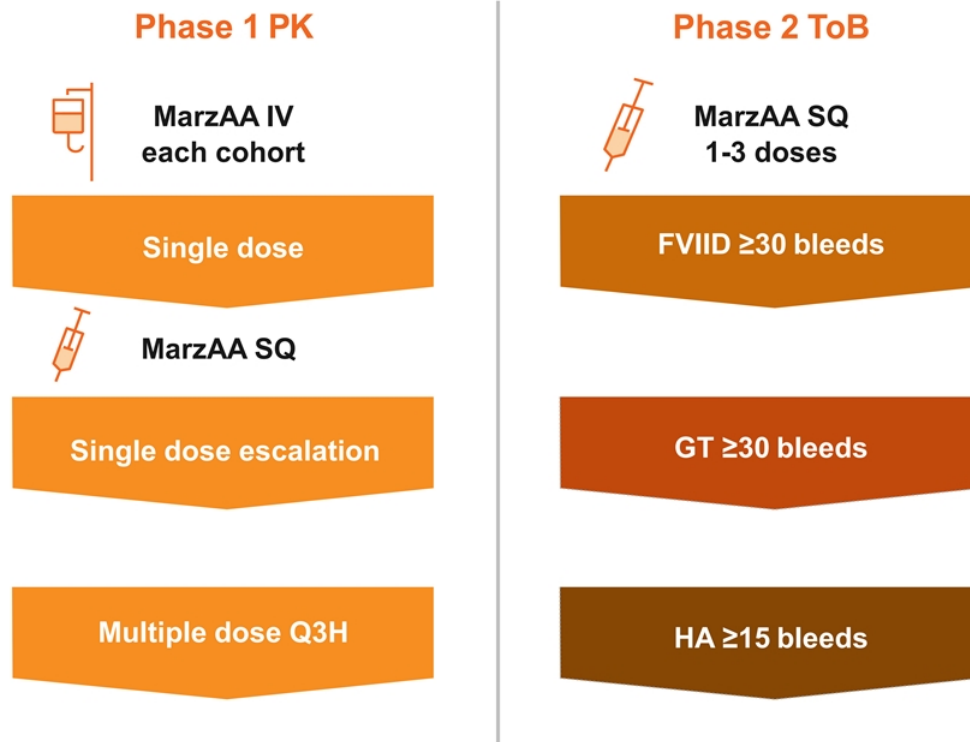
- **Primary endpoint**  
Non-inferior hemophilia standard 4-point
- **Secondary endpoint**  
Time to bleed re number of doses
- **Safety**  
Adverse events, antibodies (ADA)

- Statistics**
- + **SOC estimate**  
Excellent/good bleeds
  - + Non-inferiority
  - + **2.5%** significance
  - + **90%** power



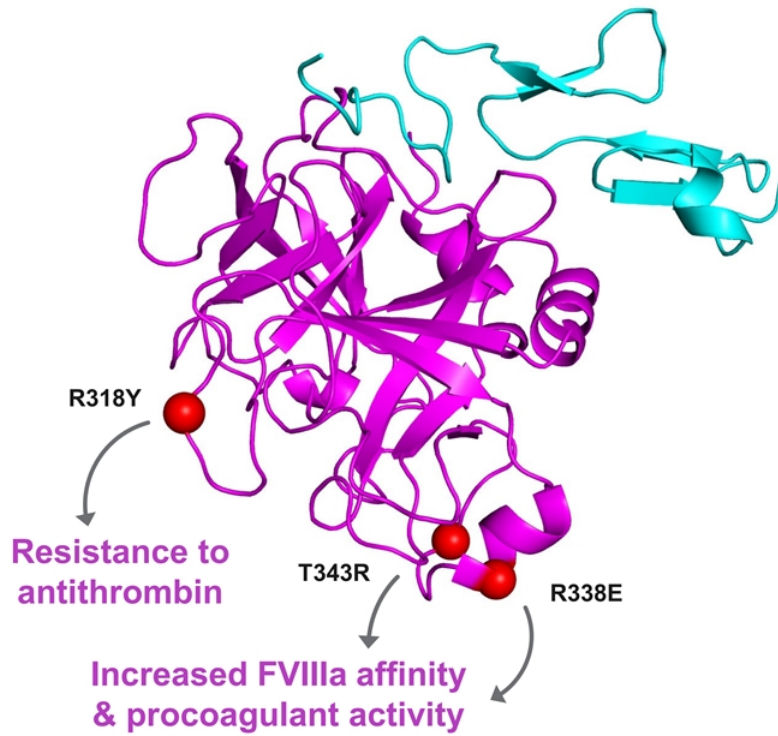
# MAA-202 Phase 1/2 study design

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



- **Phase 1**  
**Primary endpoint:** Pharmacokinetics  
**Secondary endpoint:** Pharmacodynamics
- **Phase 2 ToB**  
**Primary endpoint:** Hemostatic efficacy  
**Secondary endpoint:** Effective hemostasis timepoints; doses n rescue meds  
**Safety:** Adverse events and

# Dalcinonacog alfa: novel FIX replacement for SQ delivery



## Three amino acid substitutions

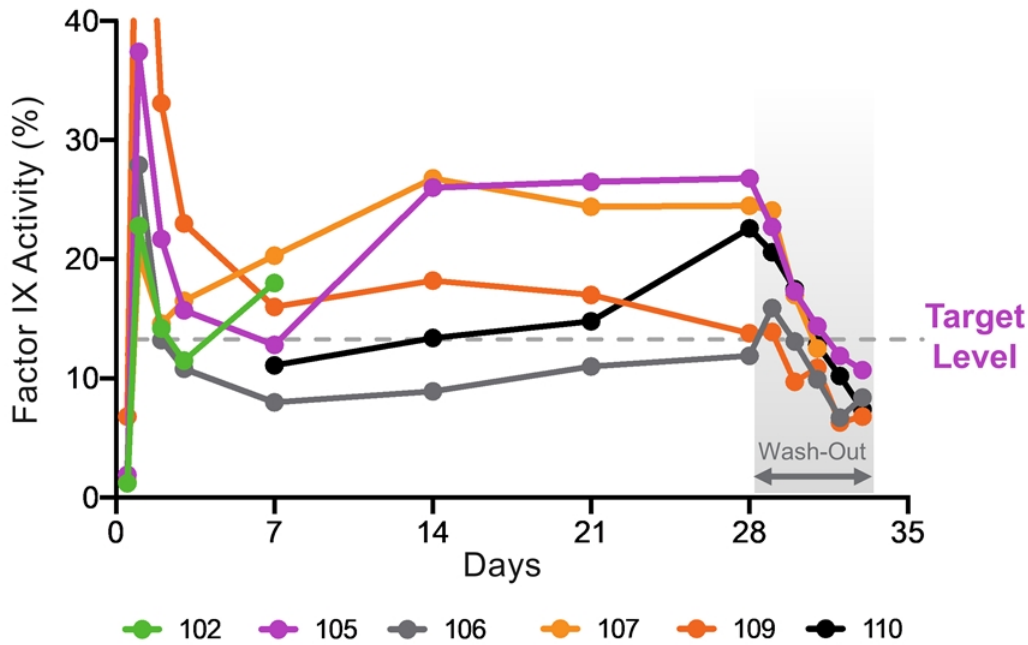
+ 22-fold increased potency vs Benel

## Differentiated from marketed I'

- + Small volume SQ administration
- + Enhanced pharmacokinetics with p
- + Excellent extravascular distribution
- + Potential to maintain continuous pr

# DalcA P2b demonstrated efficacy & safety

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



- + Dosed 6 severe
- + Subject 102 with
- + Steady state FI
- + 27% achieved a
- + No breakthrough
- + No neutralizing
- + Mild to moderate
- + self-limiting
- + Terminal half-life
- + 2.5 - 5.1 days

# Catalyst's CB 2679d gene therapy for hemophilia B



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

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

**Stanford University** License & sponsored research agreement

## ✓ CB 2679d-GT has a superior Padua in preclinical studies

- + Stable high activity levels with low bleed in mouse model
- + 4 to 5-fold reduction in bleed compared to the Padua
- + Potential for improved efficacy with a reduced dose

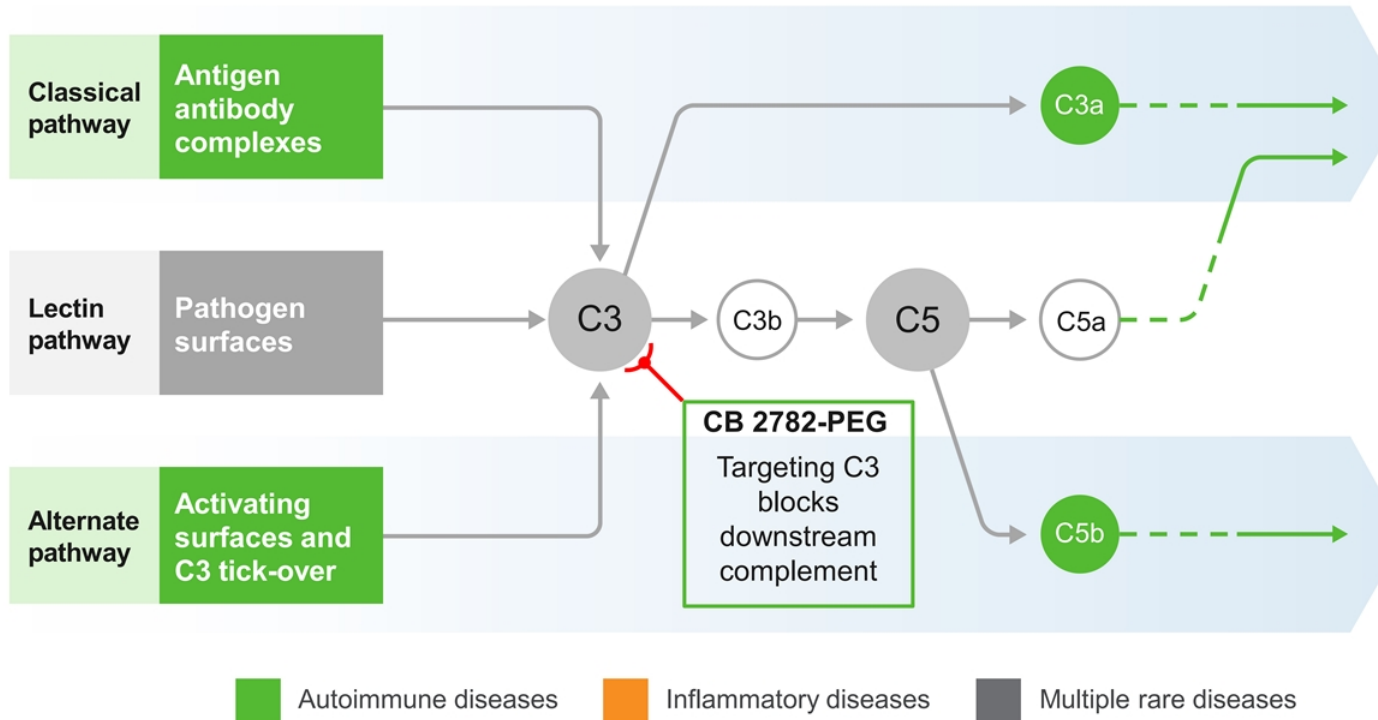
## ✓ Achieved high initial FIX activity in NHP

- + Presented at World Federation of Hematology Virtual Summit 2020
- + Additional vector optimization studies ongoing

## ✓ Wholly-owned & issued patent covering gene therapy

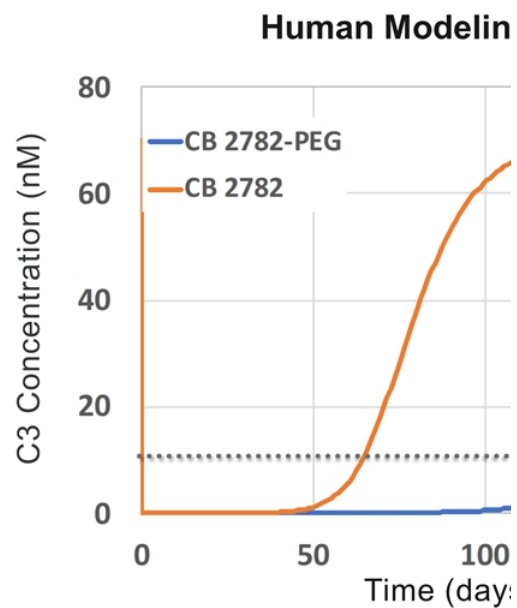
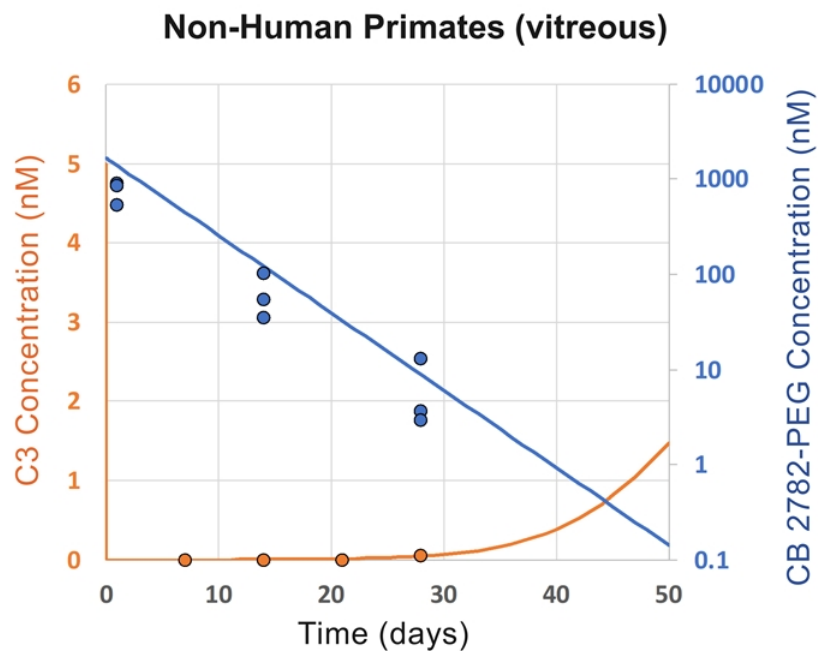
# Targeting complement – a pathway regulated by proteases

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



# CB 2782-PEG long acting anti-C3 protease

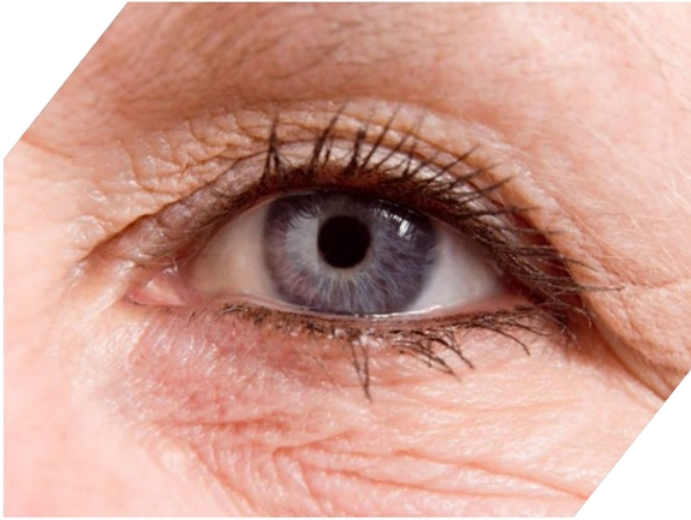
Best-in-class anti-C3 profile for dry AMD with dosing every 3 to 4 months



Predicted >90% elimination of C3 at 4 months

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

## Geographic atrophy in dry AMD can result in blindness



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

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

# CB 2782-PEG long acting anti-C3 protease

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

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- + 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

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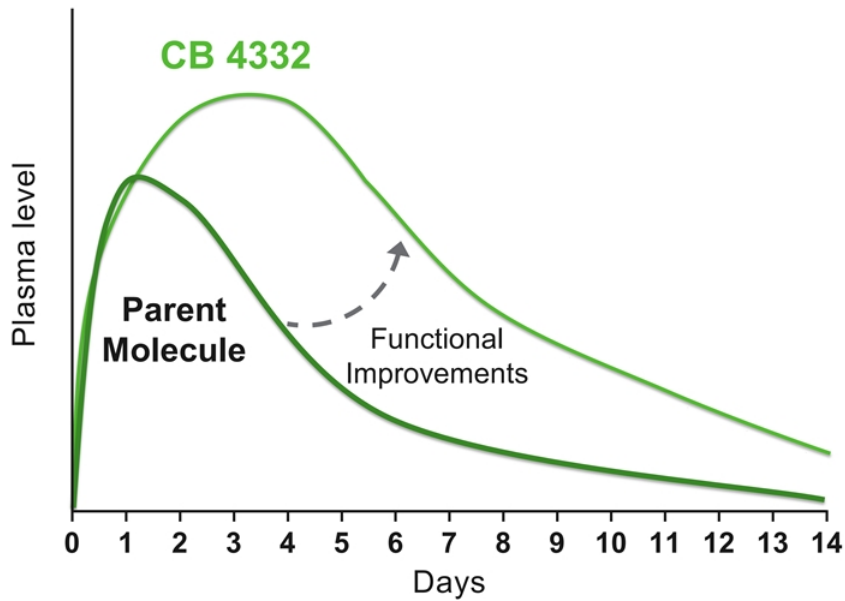
- + Announced December 2019
- + \$15M upfront, up to \$340M in milestone **tiered royalties up to low double digits**
- + Catalyst to perform fully funded pre-clinical and manufacturing activities
- + Biogen responsible for IND-enabling studies, worldwide clinical development & commercialization

\*Furfine *et al.* ARVO 2019



# CB 4332 SQ long-acting systemic complement regulator

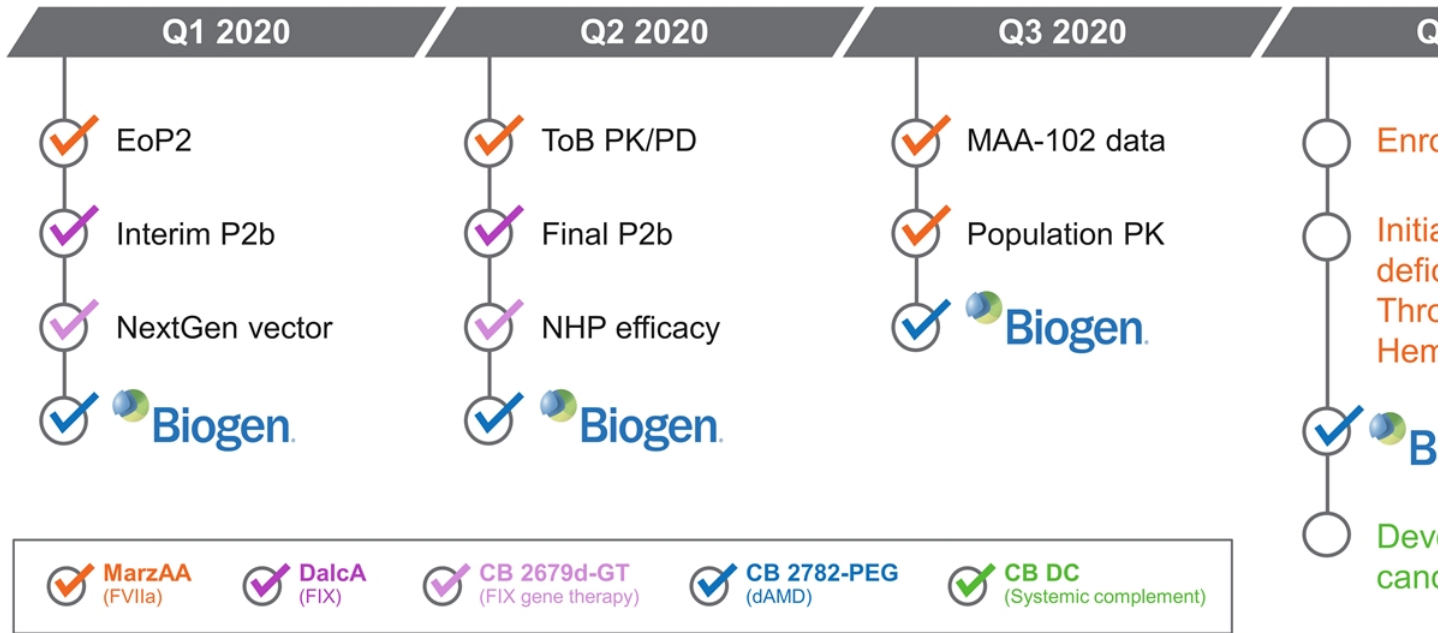
Non-human primate PK supports weekly SQ dosing in humans



## Expanding the complement

- + Leverages Catalyst's proprietary **engineering platform**
- + Designed for **SQ administration** **improved bioavailability**
- + **Simple & efficient** production
- + 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 & Manufactur



19 years in biotech

# Summary

## Disruptive approach to billion-dollar markets – protease engineering p

### ✓ 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 and lower dose vs current clinical constructs

### ✓ Anti-C3 dAMD: IVT CB 2782-PI

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

### ✓ SQ systemic complement inhi

- + Large \$B+ rare-disease opportunity
- + Multiple indications & applications
- + 1<sup>st</sup> development candidate in Q4 2020

### ✓ Well capitalized

- + Cash runway into 2022

# THANK YOU

Nasdaq: CBIO  
CatalystBiosciences.com

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