

**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): June 18, 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 June 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). The Presentation was also presented by the Company on June 18, 2020 at the Raymond James Health Innovation Conference. 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>

**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: June 18, 2020

/s/ Nassim Usman

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Nassim Usman, Ph.D.

President and Chief Executive Officer

# CATALYST BIOSCIENCES

Corporate Overview  
18 June 2020



# 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, treatment of bleeding, Factor VII deficiency, Glanzmann's Thrombasthenia 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, the use of engineered proteases to treat diseases, including dAMD, by mediating the complement cascade, clinical trial results, plans for a registrational trial for MarZAA and a Phase 1/2 trial in Factor VII deficiency, Glanzmann's Thrombasthenia and treatment of bleeding in Hemlibra subjects in Q4 2020, plans to declare development candidates for CB 2679d-GT and in the complement program in Q4 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 to differ materially, including, but not limited to, the risk that clinical studies may be delayed as a result of the COVID-19 pandemic or other factors, that trials may not have satisfactory results, that potential adverse effects may arise from the testing of MarZAA or DalcA, including the generation of antibodies, which were observed in patients treated with DalcA, that clinical trials may take longer than anticipated to be completed, that costs to develop or manufacture the Company's products may be higher than anticipated, that Biogen will discontinue development of MarZAA, PEG, competition and other factors that affect our ability to enter into collaborations on commercially reasonable terms as described in the "Risk Factors" section of the Company's most recent report on Form 10-K filed with the Securities and Exchange Commission on February 20, 2020, and the Company's most recent report on Form 10-Q filed on May 11, 2020, and in the Company's most recent report on Form 10-K filed with the Securities and Exchange Commission. The Company does not assume any obligation to update any forward-looking statements except as required by law.

Essential Medicines – Superior Outcomes

**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

**Complem**

IVT Anti-C3 Dr  
CB 2782-P



SQ Systemic  
Complement  
Inhibitor

Protease Engineering Platform

# Pipeline

## Hemostasis

### SQ Marzeptacog alfa "MarzAA" – (rFVIIa)

Hemophilia A or B w Inhibitors – ToB

FVIID/Glanzmann/Hemlibra – ToB

### SQ Dalcinonacog alfa "DalcA"

Hemophilia B (rFIX)

### FIX-Gene Therapy

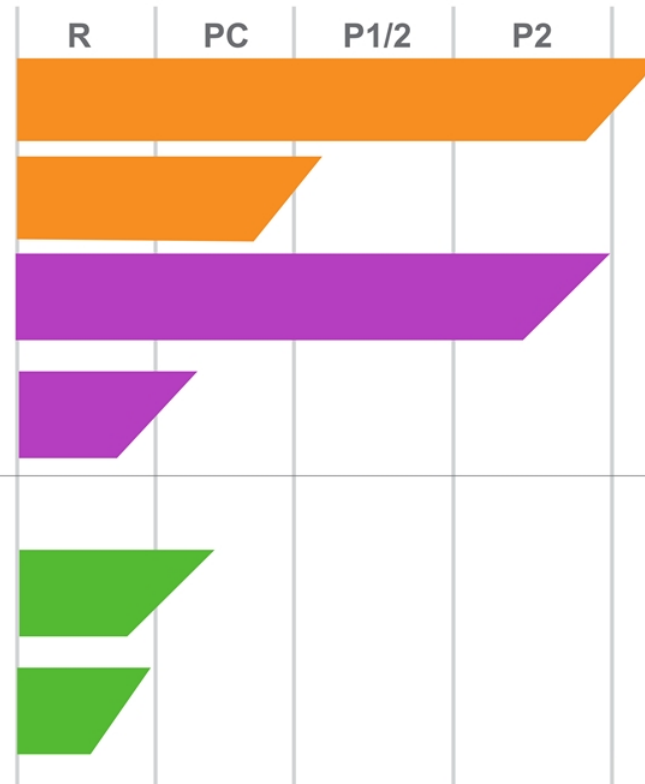
Hemophilia B (CB 2679d-GT)

## Complement

### IVT CB 2782-PEG

anti-C3 protease for Dry AMD

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 con  
regulator research



Multibillion-dollar market opportunities



Experienced team



Strong balance sheet,  
\$104.5 M cash – Q1

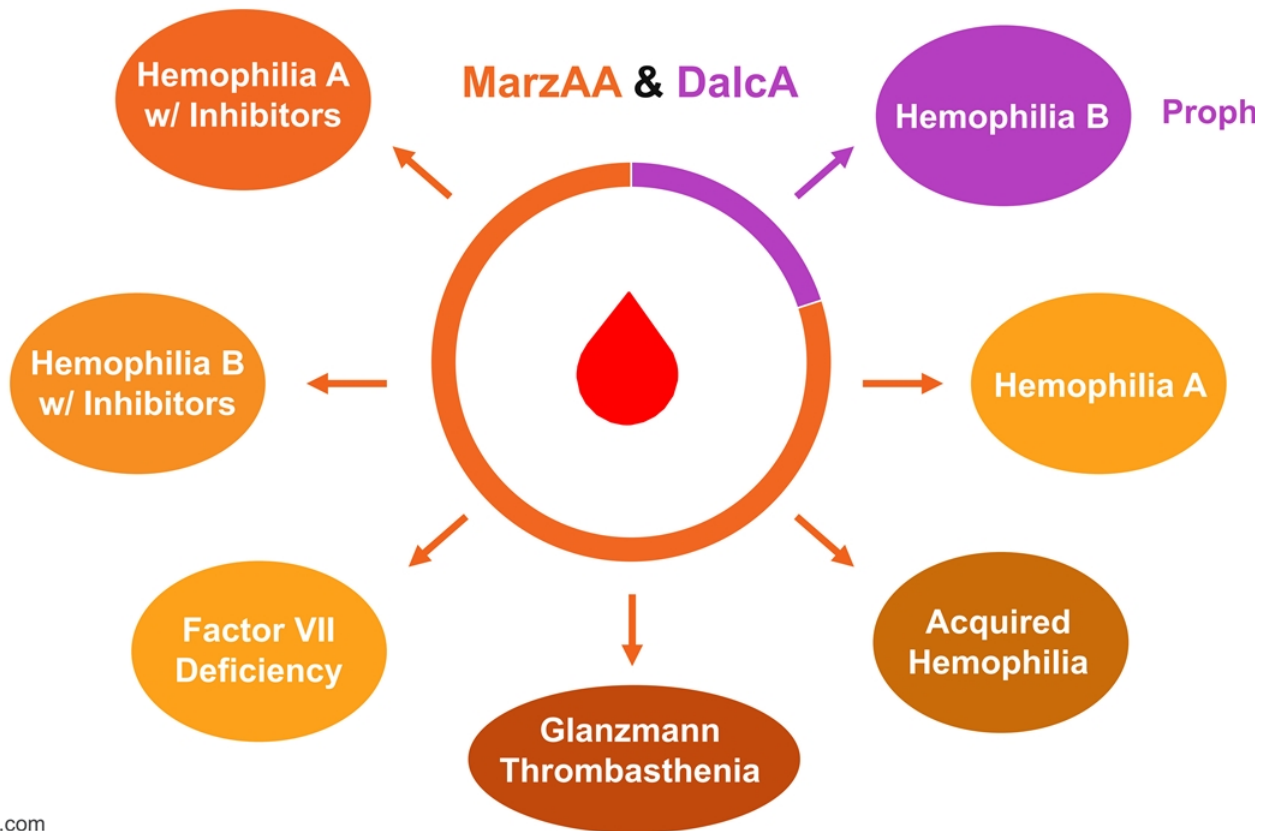


177 worldwide patents  
CBIO retains full  
of all compounds



# Addressing unmet needs in orphan bleeding disorders

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



# The Catalyst Biosciences subcutaneous solution

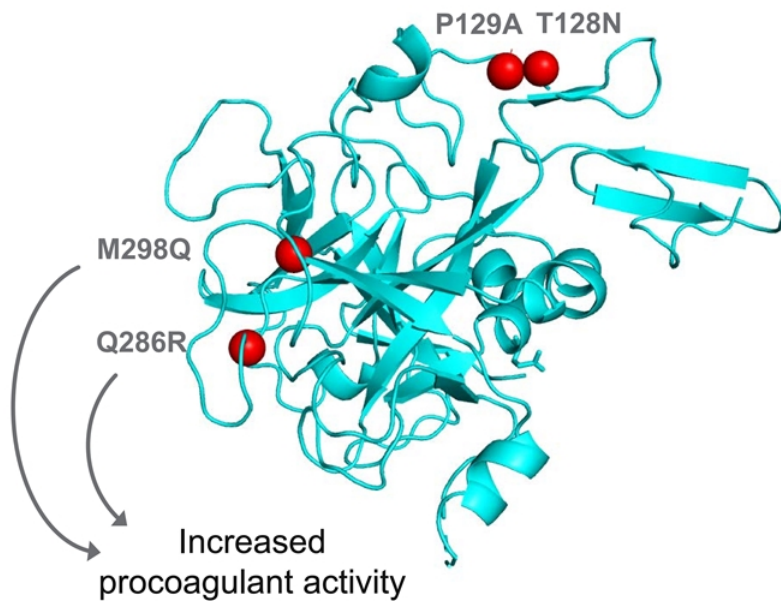


## Our highly potent ca

- + Quick & simple self-administration
- + SQ dosing is the future for other rare hematologic complement-mediated diseases
- + Significantly increases survival
- + Much higher & more stable levels for prophylaxis
- + Enables SQ treatment of relapsed and refractory disease
- + Ideal for children and elderly patients

# Marzeptacog alfa (activated): MarzAA rFVIIa

Addresses a clear unmet need in hemophilia & other bleeding disorders



## Four amino acid substitutions

- + Multiple advantages over NovoS
- + 9-fold higher activity vs NovoSev
- + Potency allows for SQ dosing

## Only SQ bypass agent for on demand

- + Simple, small volume SQ admini
- + Improved bioavailability & pron

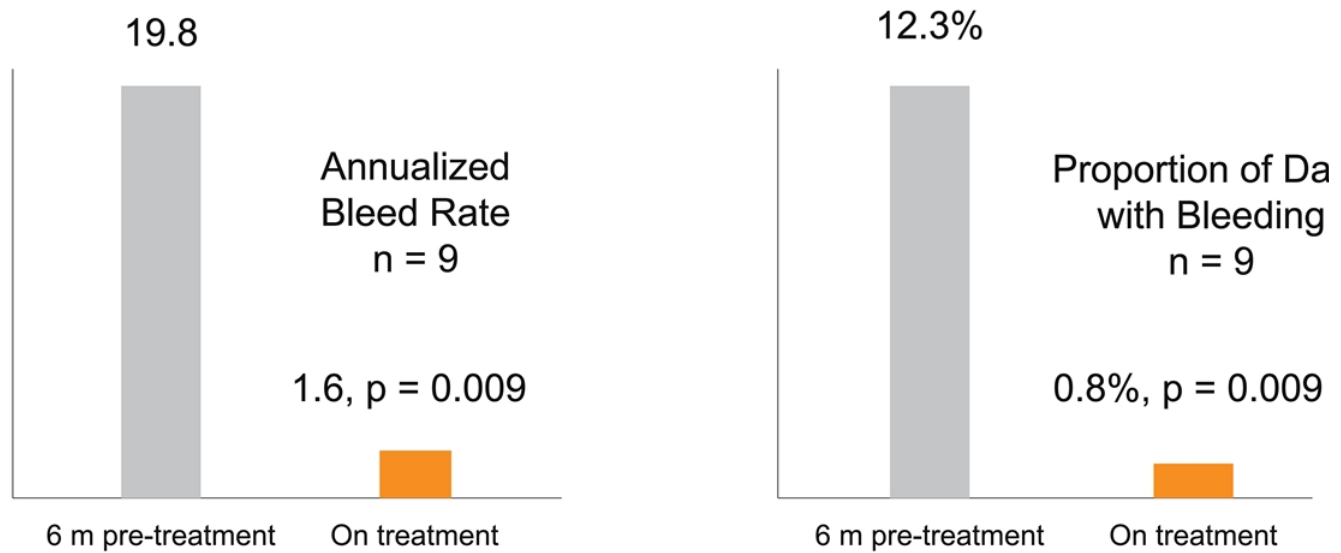
## Orphan Drug Designation in US and

# MarzAA Phase 2 demonstrates efficacy in prophylaxis

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



# In a world of SQ prophylaxis

## Patients & KOLs want SQ treatment of a bleed

Individuals on Hemlibra® have breakthrough bleeds

NovoSeven® is safe but is administered IV

FEIBA should not be used with Hemlibra and is given IV

### MarzAA has optimal pro

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- ✓ Fast & easy to administer
- ✓ Achieves therapeutic level
- ✓ Stops bleeding in multiple preclinical models
- ✓ Can be combined with Hemlibra *in vitro* without increased thrombogenicity

CRIMSON-1 Registration Study – A Global Clinical Trial

Phase 1 & 2 trials demonstrated the clinical impact of SQ MarzAA

- MAA-102 rapidly achieved target activity levels
- MAA-201 demonstrated efficacy in prophylaxis, safe & well tolerated with no ADA
- Clinically support P3 SQ MarzAA treatment of episodic bleeding

Open label trial evaluating the safety & efficacy of SQ MarzAA in episodic bleeding

- Primary endpoint: Hemostatic efficacy using a standard 4-point assessment scale
- ~230 bleeding episodes to be treated in ~75 HA/HB individuals with inhibitors
- Anticipate first patient enrolled by end of 2020

Opportunity in multiple bleeding disorders

- ✓ Hemophilia A or B with inhibitors
- ✓ Hemlibra breakthrough bleeds
- ✓ Factor VII deficiency
- ✓ Glanzmann thrombasthenia
- Acquired hemophilia

# MarzAA development plan in 2020

**Phase 3 HA/HB w Inhibitors – ToB**

**Phase 1/2 study in FVIID, Glanzmann & Hemlibra ToB**

Large commercial opportunity across multiple rare bleeding disorders

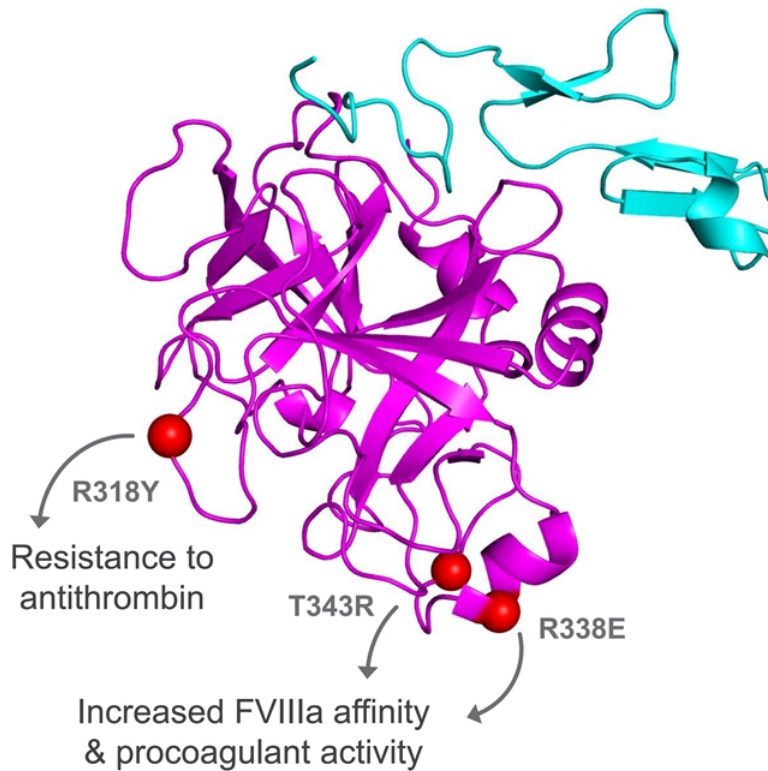
Phase 1 PK/PD data support on demand as well as prophylactic treatment of bleeding

Phase 2 demonstrated clinical efficacy & tolerability for prophylaxis indications

Efficacy demonstrated for SQ on demand treatment of bleeding in pre-clinical model

MarzAA can be safely combined with Hemlibra in human plasma *in vitro*

# 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 Bene

## Differentiated from marketed IV FIX

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

## Orphan Drug Designation in US & E



# Dalcinonacog alfa phase 2b SQ clinical trial

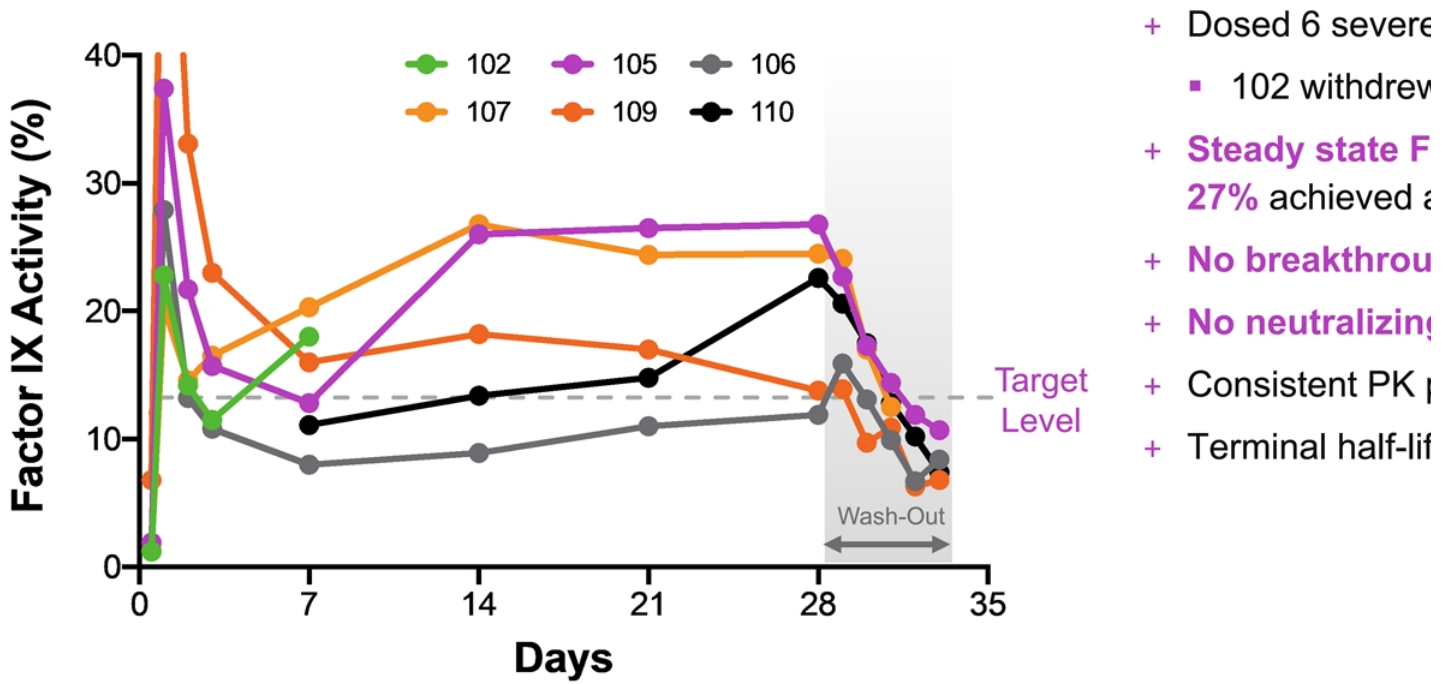
## Trial completed



- + 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
- + Rare propeptide mutation excluded
- + HLA profile associated with non-responders excluded

# DalcA P2b efficacy & safety demonstrated

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



# Dalcinonacog alfa

## Potential to provide effective SQ prophylaxis for individuals with Hem

Phase 2b trial complete

Excellent protective therapeutic FIX activity levels achieved

No bleeding events during treatment demonstrates effective prophylaxis

No SAEs, systemic hypersensitivity, nAb to DalcA or wild-type FIX

Mild to moderate ISR primarily with initial injections – transient & self-limiting

Long half-life – demonstrates potential to lower dose / reduce dosing frequency

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

## 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 nAb**
- + 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



FIX Transgene	AAV Capsid	Study (vg/l)
CB 2679d-GT	Novel Chimeric	8.0x1
Padua	TAK-748*	7.4x1
Padua	TAK-748*	7.4x1

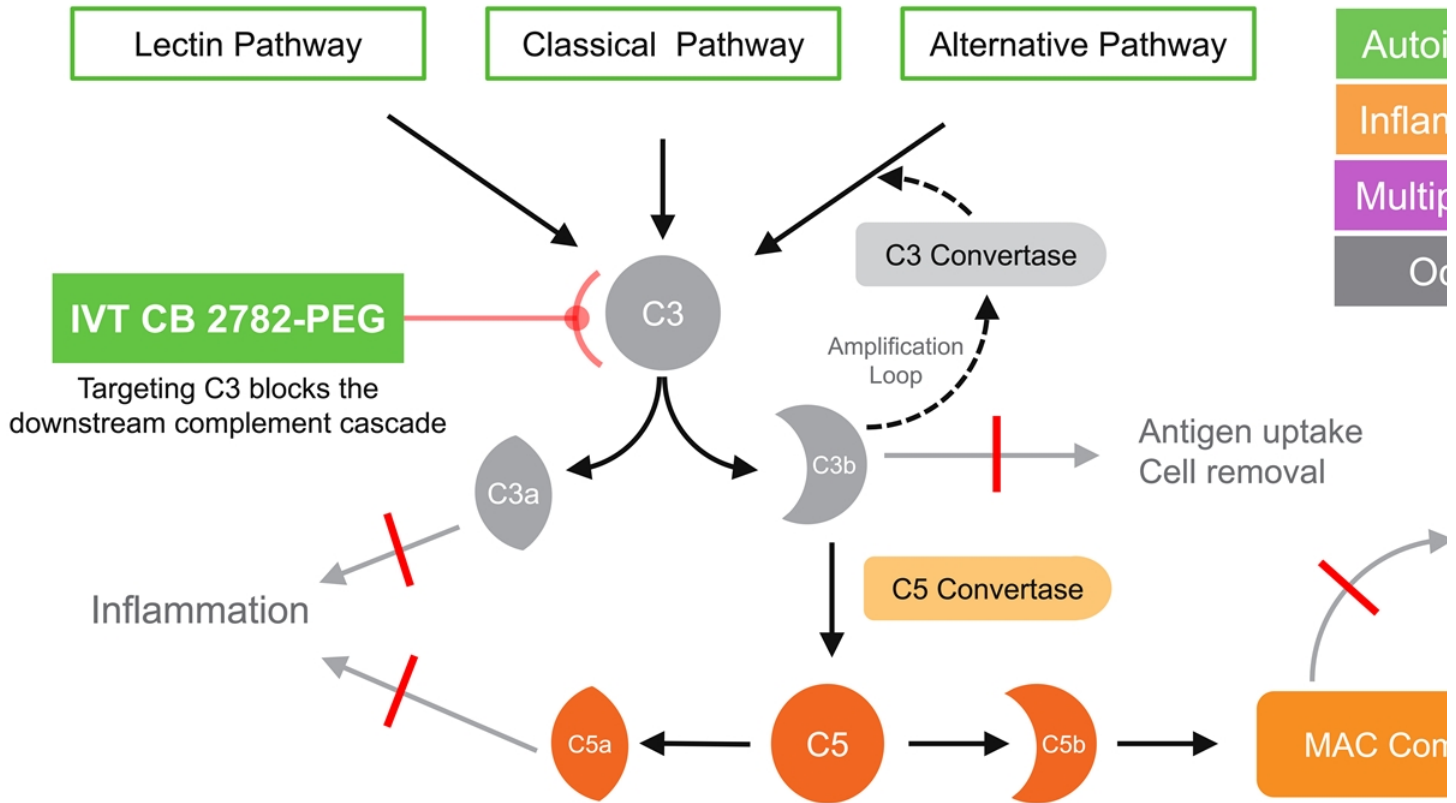
\*Weiller *et al.* (2019) *Blood* Vol. 134, Sup

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

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

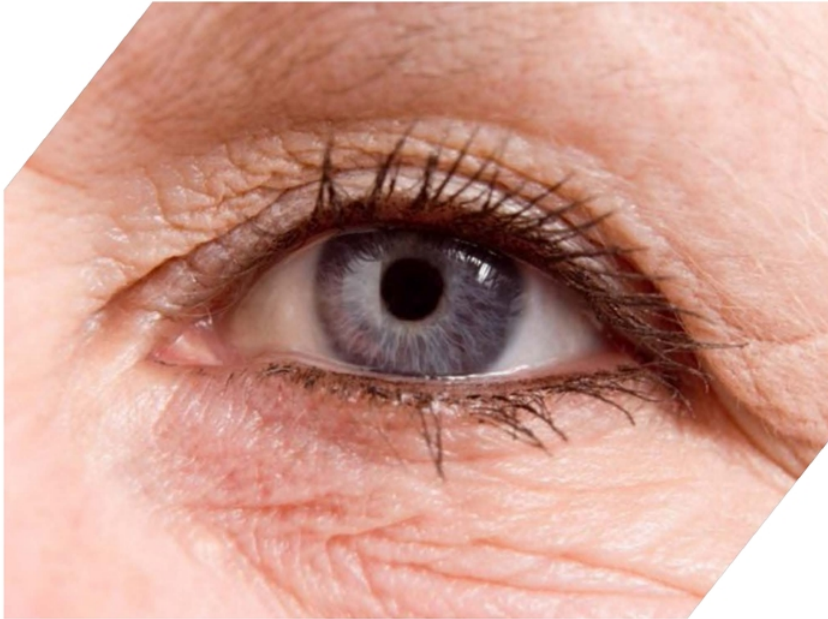
## Wholly-owned & issued patents covering gene therapy

# Complement cascade is regulated by proteases



# 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
- + Dry AMD affects ~1M people over 5M worldwide
- + Global market estimated at > \$10B
- + C3 is the only clinically (randomized) validated target for the treatment of AMD
- + No currently approved drugs

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

# 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

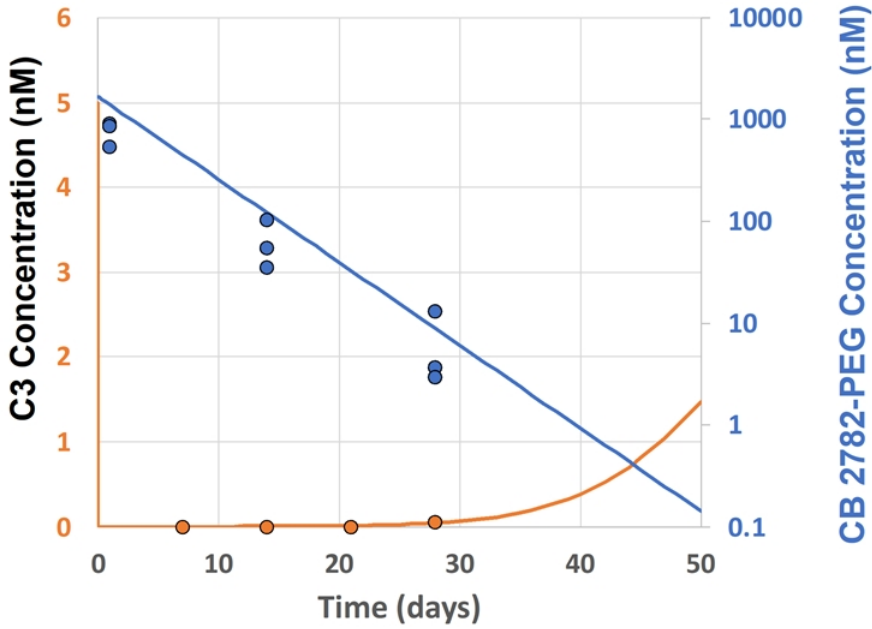
- + Announced December 19, 2017
- + \$15M upfront, up to \$340M in **and tiered royalties up to low c**
- + Catalyst to perform fully funded R&D and manufacturing activities
- + Biogen responsible for IND-enabling studies, worldwide clinical development and commercialization



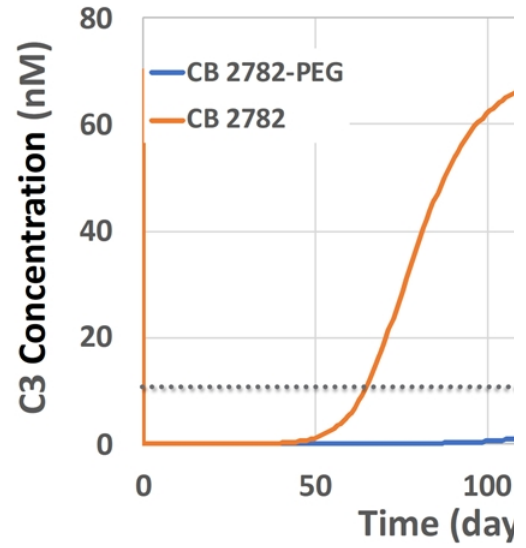
# CB 2782-PEG long acting anti-C3 protease

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

### Non-Human Primates



### Human Modelin

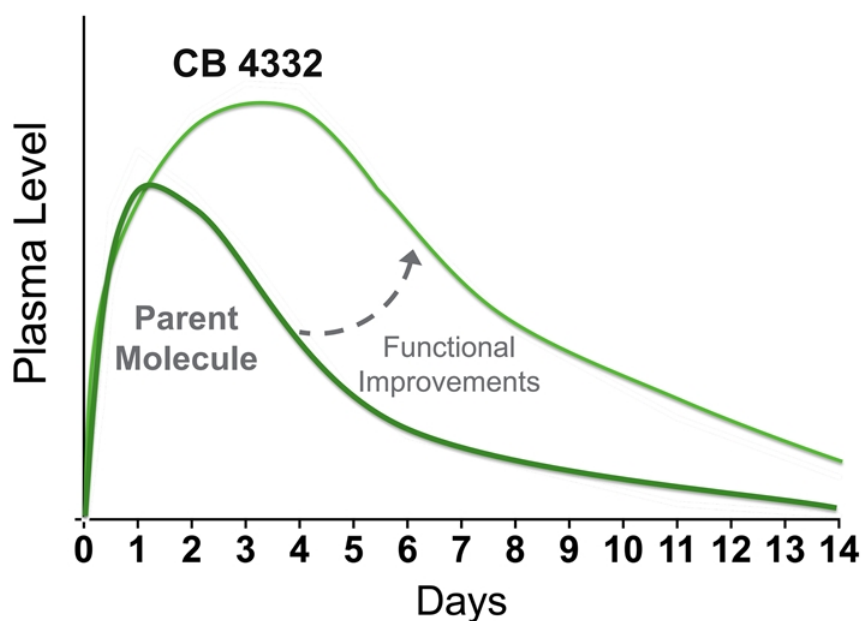


Predicted >90% elimination of C3 at 4 months



# 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** product

# Milestones – 2020

	Q1	Q2	Q3	
<b>MarzAA</b> (FVIIa)	<b>EoP2</b> 	<b>ToB PK/PD</b> 	<ul style="list-style-type: none"> <li>• MAA-102 data</li> <li>• Population PK</li> </ul>	<ul style="list-style-type: none"> <li>• Initiate p</li> <li>• Initiate F Deficien</li> <li>• Thromb</li> <li>• Hemlibra</li> </ul>
<b>DalcA</b> (FIX)	<b>Interim P2b</b> 	<b>Final P2b</b> 		
<b>CB 2679d-GT</b> (FIX Gene Therapy)	<b>NextGen Vector</b> 	<ul style="list-style-type: none"> <li>• NHP Efficacy</li> </ul>		<ul style="list-style-type: none"> <li>• Develop Candida</li> </ul>
<b>CB 2782-PEG</b> (dAMD)				
<b>CB DC</b> (Systemic complement)				<ul style="list-style-type: none"> <li>• Develop Candida</li> </ul>

## Team

Nasdaq: CBIO

**President & CEO**  
**Nassim Usman, Ph.D.**



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



**Chief Financial Officer**  
**Clinton Musil, M.B.A.**



**SVP, Translational Research**  
**Grant Blouse, Ph.D.**



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



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



catalystbiosciences



# 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
- ✓ **Anti-C3 dAMD: IVT CB 2782-**
  - + Biogen collaboration
  - + \$15M upfront, up to \$340M in low double digits tiered royalty
- ✓ **SQ systemic complement inhibitors**
  - + Large \$B+ rare-disease opportunity
  - + Multiple indications & applications
  - + 1<sup>st</sup> Development Candidate in Phase 1
- ✓ **Well capitalized**
  - + Cash runway into 2022

**THANK YOU**

Nasdaq: CBIO

[catalystbiosciences.com](http://catalystbiosciences.com)

CBIO

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

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

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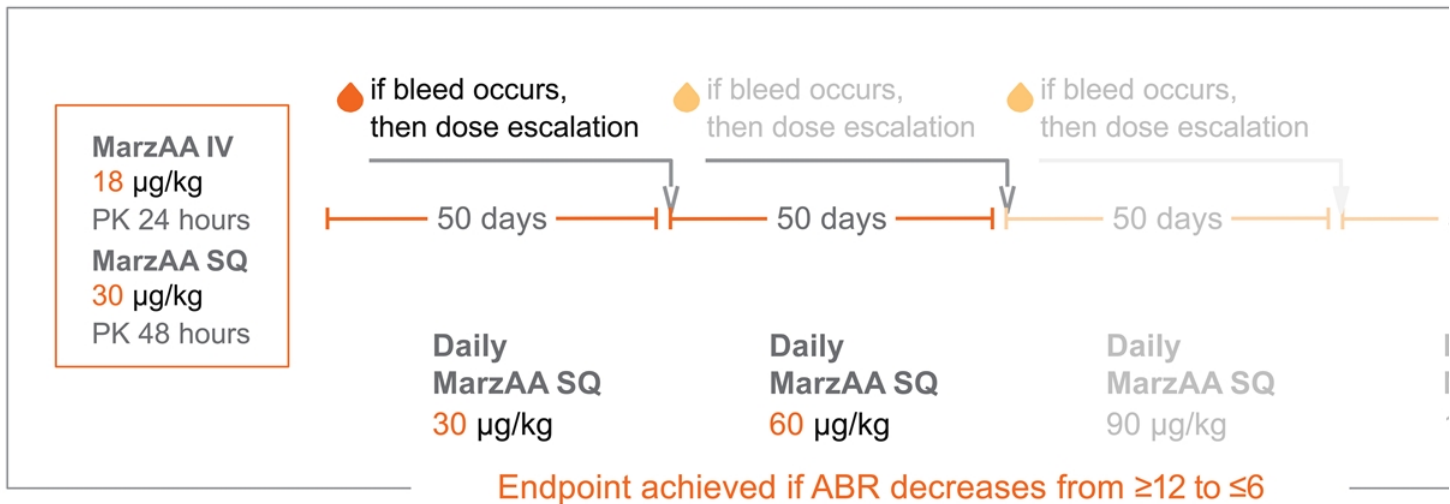
IV NovoSeven (\$1.2B 2019 sales) validates rFVIIa in multiple rare bleeding disorders

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

**SQ MarzAA has a superior profile over NovoSeven – over 100 clinicians and patients surveyed**

- + Physicians & patients overwhelmingly prefer SQ MarzAA over IV NovoSeven
- + **SQ MarzAA** can create & expand episodic bleed & prophylaxis markets

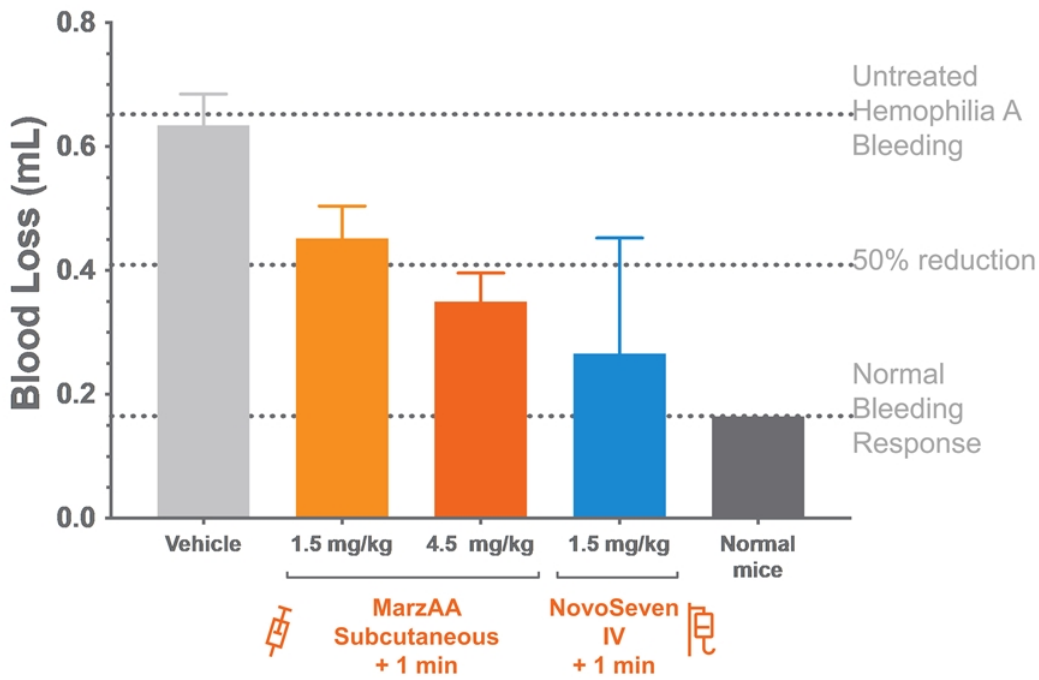
# MarzAA phase 2/3 SQ clinical trial MAA-201



- + Patients with documented annual bleeding rate (ABR)  $>12$
- + Open label SQ study with individual dose escalation if needed in Hemophilia A or B with inhibitors
- + Primary endpoint: reduction in annualized bleed rate **at final dose level**
- + Secondary endpoints: safety and tolerability, inhibitor formation

# SQ MarzAA reduces bleeding when dosed *After* the Injury

## Acute mouse injury model with dosing *after* the injury

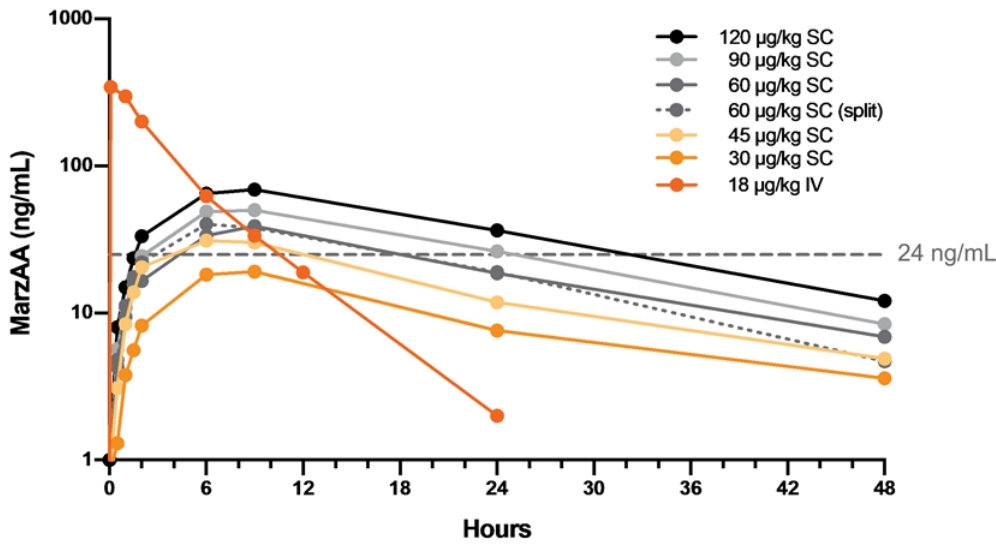


## Reduced bleeding

- + Hemophilic mice bleed **more** than normal mice
- + **SQ treatment** of MarzAA after traumatic bleeding has significantly **reduces** stops the bleed
- + The effect is **dose dependent**
- + Reduction in blood loss is **comparable** with IV NovoSeven



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



- + Target of 24-120 ng/mL to be based on continuous infusion of NovoSeven for surgery
- + Target levels are rapidly achieved
- + 25% and 50% of  $C_{max}$  at 1 and 6 hours respectively
- + Dose-proportional increase in AUC
- + Target levels can be maintained with a single SQ dose of 60 µg/kg
- + No ADA
- + Multiple dosing cohorts completed
  - 60 µg/kg 3-hourly; two

Neuman, 2020

catalystbiosciences.com