

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): January 8, 2020

CATALYST BIOSCIENCES, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

000-51173
(Commission
File Number)

56-2020050
(I.R.S. 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 (see General Instruction A.2. below):

- 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

Catalyst Biosciences, Inc. (the "Company") is furnishing this Current Report on Form 8-K in connection with an update to its corporate presentation (the "Presentation"). This information may be amended or updated at any time and from time to time through another Current Report on Form 8-K, a later company filing or other means. A copy of the Presentation is furnished herewith as Exhibit 99.1 and is incorporated into this Item 7.01 by reference. By furnishing this Current Report on Form 8-K and furnishing the Presentation, the Company makes no admission as to the materiality of any information in this Current Report on Form 8-K, including without limitation the Presentation.

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	Presentation slide deck dated January 8, 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: January 8, 2020

By: /s/ Nassim Usman
Nassim Usman, Ph.D.
President and Chief Executive Officer

CATALYST BIOSCIENCES

Corporate Overview
8 January 2020

Essential Medicines – Superior

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

Protease Engineering Pl

Pipeline

Hemostasis

SQ Marzeptacog alfa (activated) "MarzAA"

Hemophilia & bleeding disorders (rFVIIa)

SQ Dalcinonacog alfa "DalcA"

Hemophilia B (rFIX)

FIX-Gene Therapy

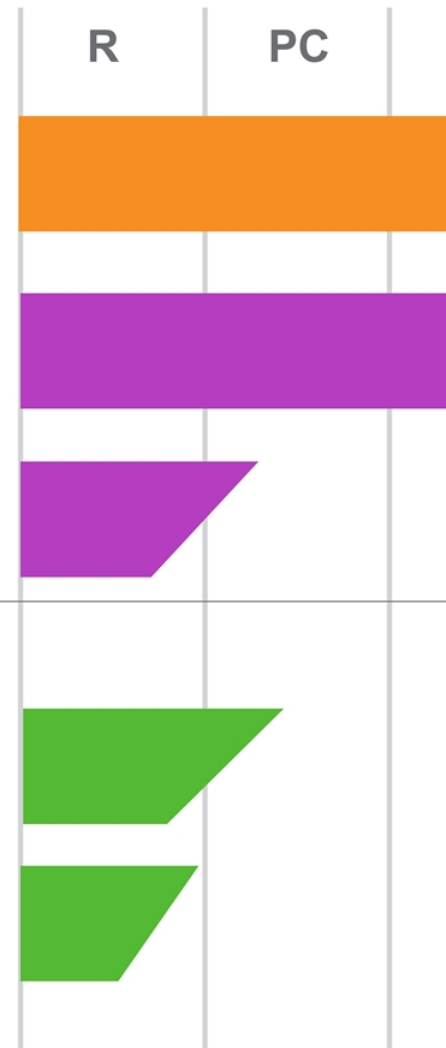
Hemophilia B (CB 2679d-GT)

Complement

IVT CB 2782-PEG

anti-C3 protease for Dry AMD

SQ Systemic complement inhibitors



Investment highlights



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



Anti-C3 collaboration with Biogen

SQ systemic complement inhibitors research program

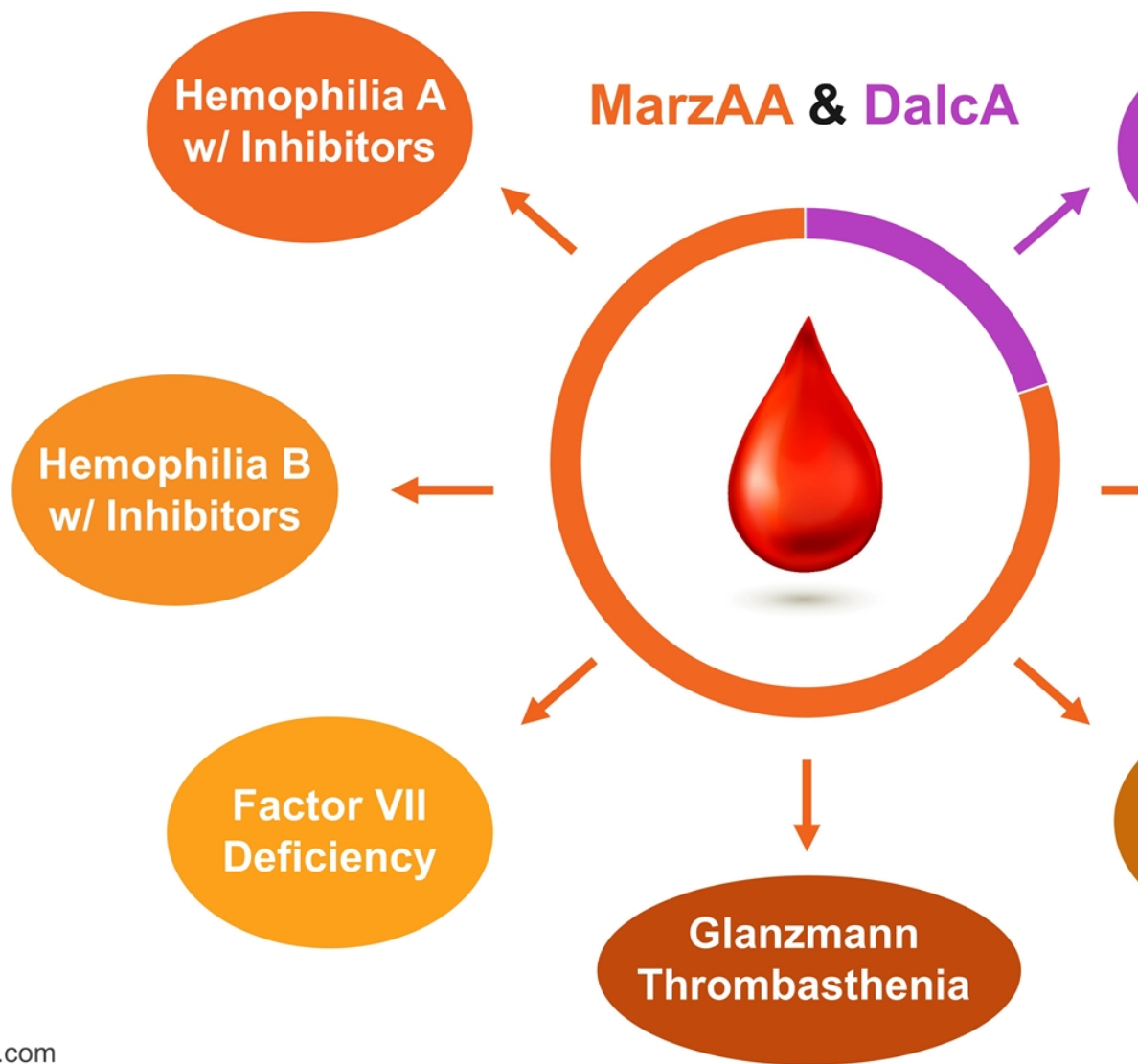


~134 worldwide patents – CBIO retains full ownership of all compounds



Addressing unmet needs in orphan bleeding

SQ treatment of bleeds and prophylaxis – \$3.7B market



The Catalyst Biosciences subcutaneous so



Our

+ C
ir

+ S
a

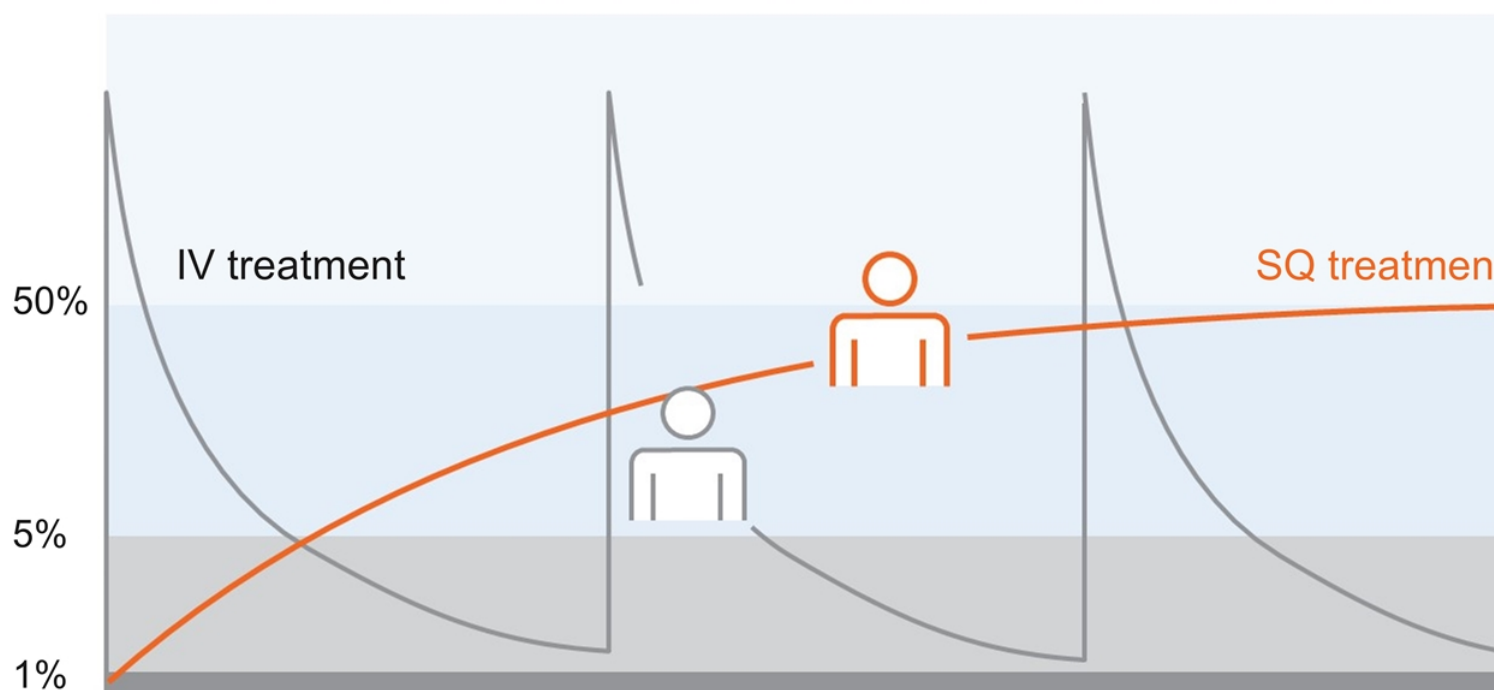
+ Ic

+ M
le

+ E

The new standard in hemophilia prophylaxis

Patients in high mild range are protected from spontaneous



- + 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 – The only bypass agent for **both** SQ and SQ treatment of bleeds

Attractive commercial profile targeting an existing

SQ MarzAA has a superior profile to IV NovoSeven –

- + All physicians surveyed indicated a preference for SQ MarzAA
- + SQ MarzAA can create & expand multiple prophylaxis markets

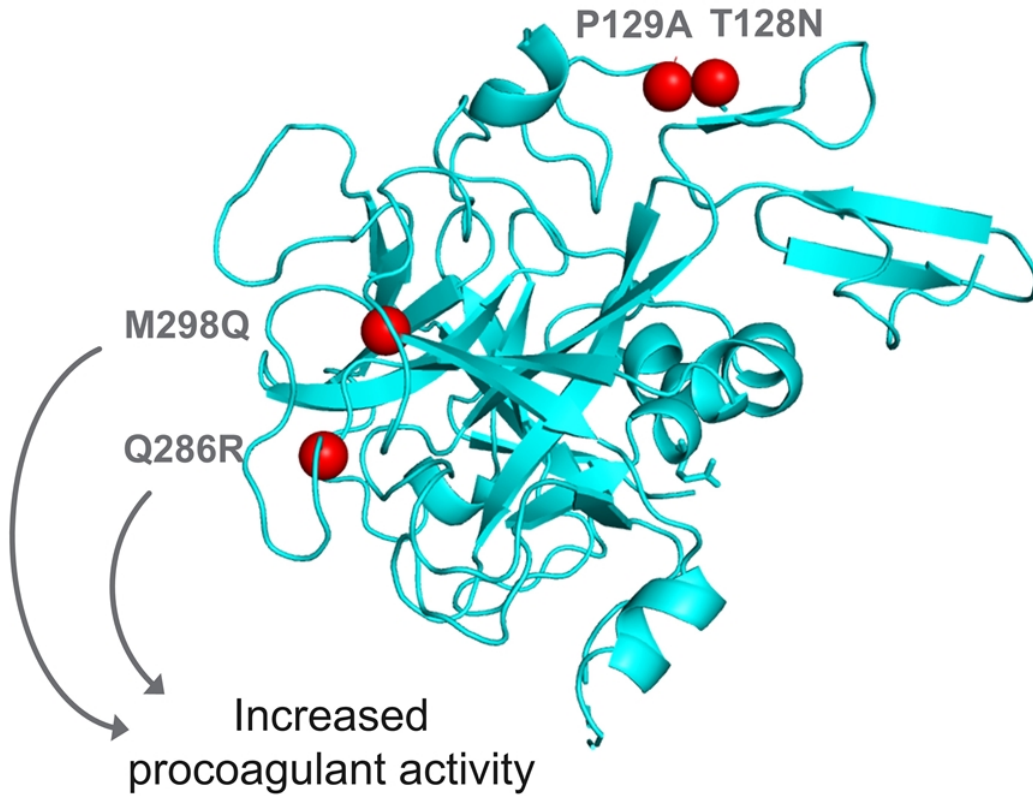
IV NovoSeven
(\$1.2B 2018 sales)
The most broadly used
bypass agent

**NovoSeven valid
bleeding disorder**

- + Hemophilia A or B
- + Severe Factor V deficiency
- + Glanzmann Thrombasthenia
- + Acquired Hemophilia

Marzeptacog alfa (activated): MarzAA rFVII

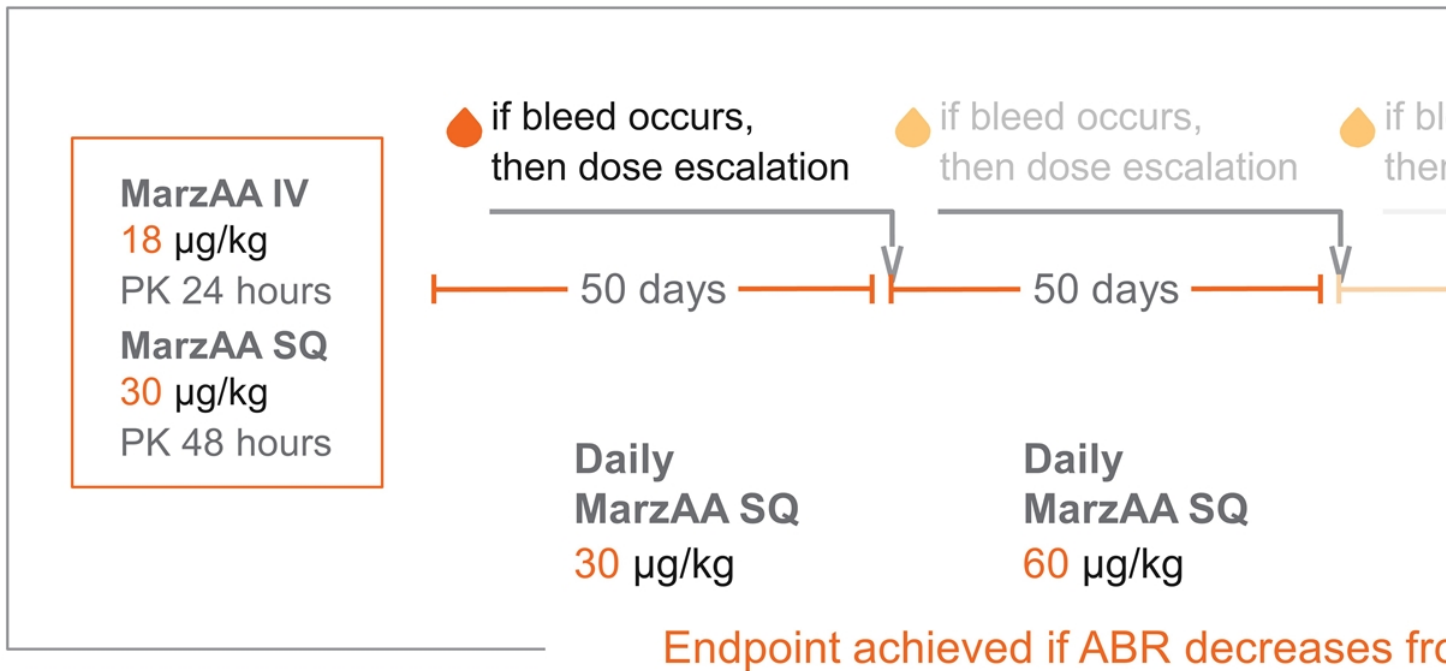
SQ prophylaxis and SQ treatment of a bleed are clear unmet needs in bleeding disorders



- + Four mutations
- + 9-fold increase in activity
- + Allow for SQ treatment
- + Half-life extension

Orphan Drug Designation

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: bleed rate at follow-up
- + Secondary endpoints: tolerability, inhibition

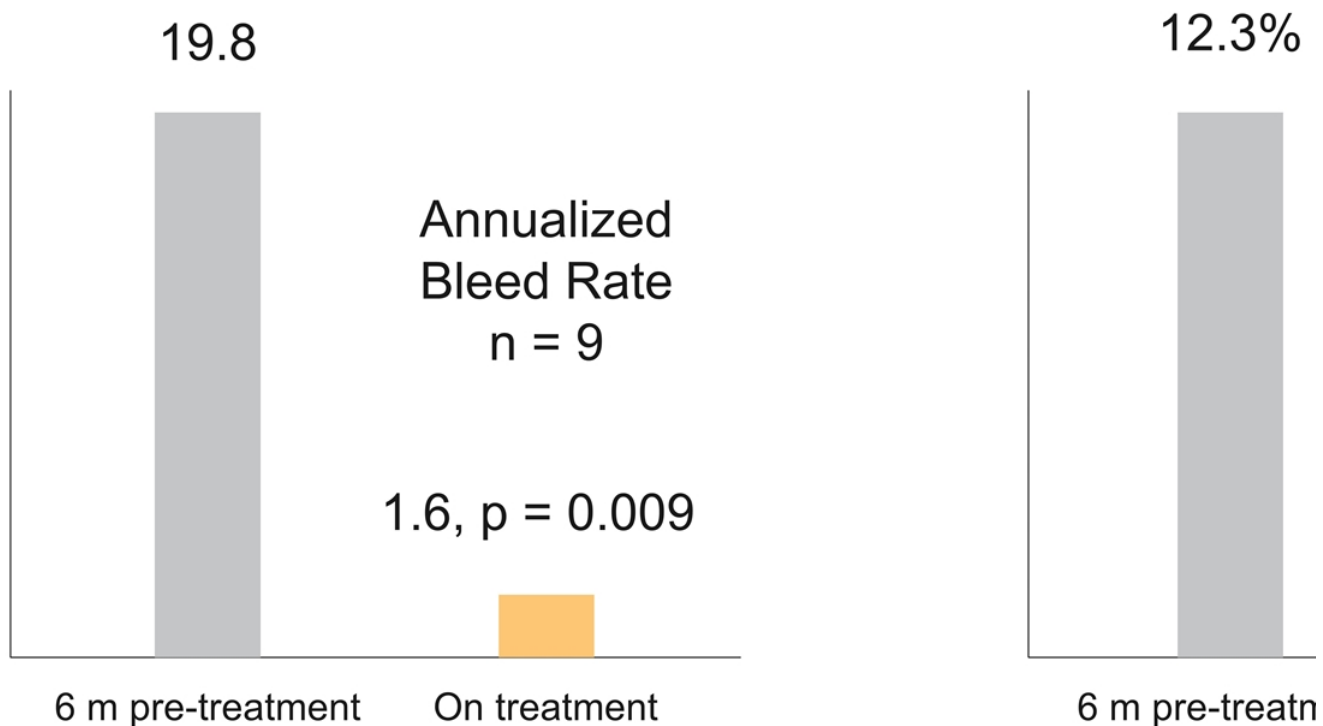
MarzAA Phase 2 demonstrates clinical efficacy

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

Mean Annualized Bleeding Rates (ABR) significantly **reduced**

Mean Proportion of Days with Bleeding (PDB) significantly **reduced**

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



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



SQ Mar

- ✓ Fast
- ✓ Stops
precli
- ✓ Can b
Heml

Blouse et al

Marzeptacog alfa (activated)

Phase 3 studies to initiate in 2020

Large commercial opportunity across multiple rare bleeding dis

Demonstrated P2 Clinical efficacy & tolerability for prophylaxis

Demonstrated preclinical PoC for SQ treatment of a bleed

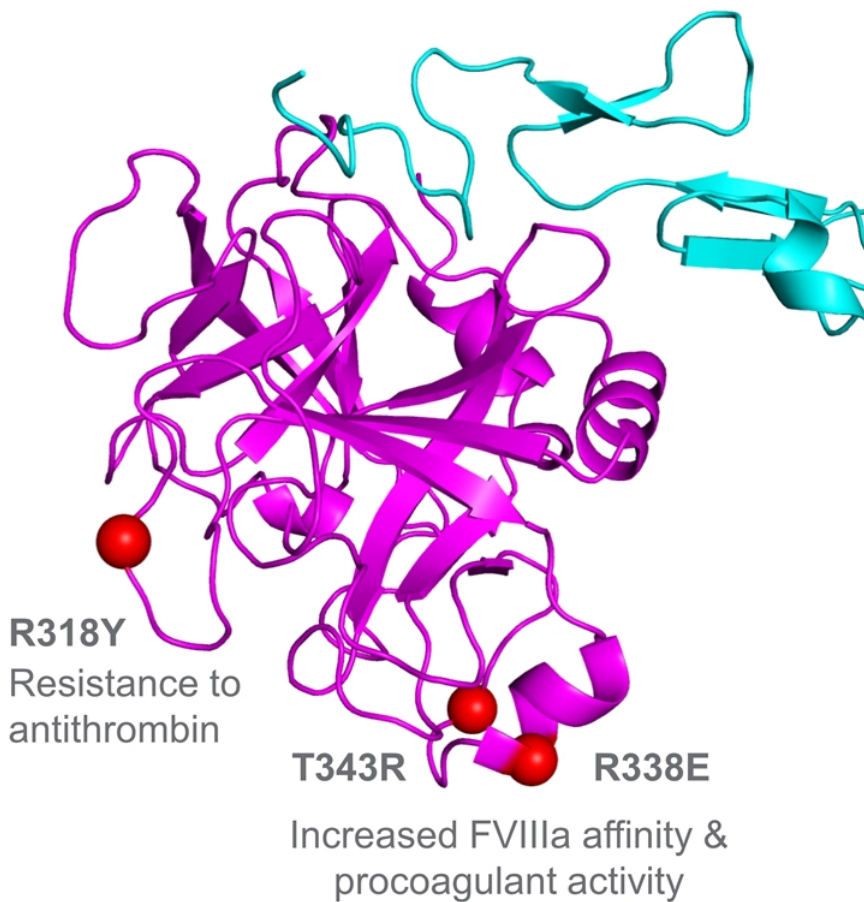
MarzAA combined with Hemlibra has comparable thrombin gen

Initiated SQ dose escalation PK study to support treatment of a

P3 guidance from EMA & MHRA received – FDA EoP2 meeting

Dalcinonacog alfa: DalcA rFIX

SQ prophylaxis is an unmet need in hemophilia B



Phase 1/2 co

- + 22-fold mor
- + **FIX activity**
- Observed 2 that were n
 - Returned issues
- + Extensive *i* low immunc

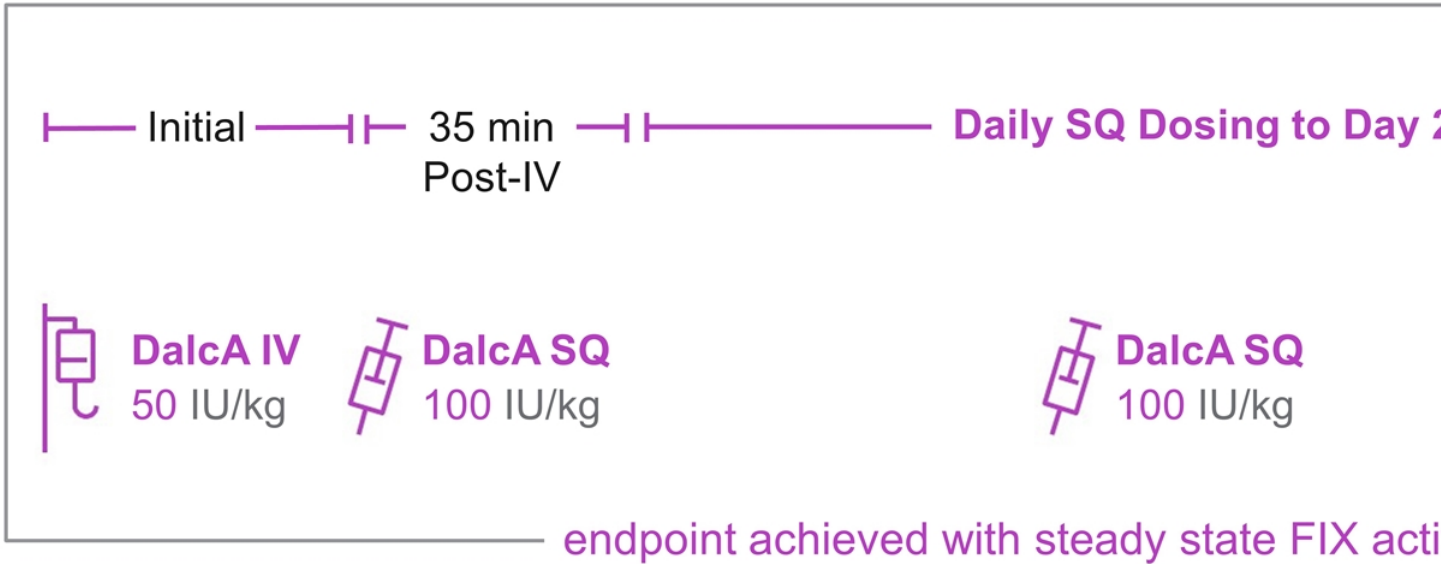
Phase 2b stu

- + No ADAs t

Orphan Dru

Dalcinonacog alfa phase 2b SQ clinical trial

DLZ – 201 ongoing



- + Target enrollment: 6 patients
- + Rare genotype and HLA signature from P1/2 excluded
- + Primary endpoint: FIX activity level above 100 IU/kg
- + Secondary endpoints: neutralizing antibody titer, pharmacokinetics

Dalcinonacog alfa – DalcA

Phase 2b update

All study participants identified – study is ongoing

2 subjects have successfully completed 28 days of dosing

FIX activity levels exceeded the trial efficacy endpoint

Final data in 1H 2020

FIX gene therapy: CB 2679d-GT

AAV gene therapy for hemophilia B

Superior preclinical efficacy of CB 2679d-GT vs Padua

- + Activity levels elevated throughout the study, no nAbs
- + **3-fold superior FIX activity**
- + **4-5-fold reduction in bleeding time**

Optimizing next generation vector construct

- + AAV license and sponsored research agreement with Stanford University School of Medicine
- + Higher activity levels
- + Lower vector dose
- + Improved efficacy & safety

Wholly-owned & issued patents covering gene therapy

Bleeding Time (min)

8

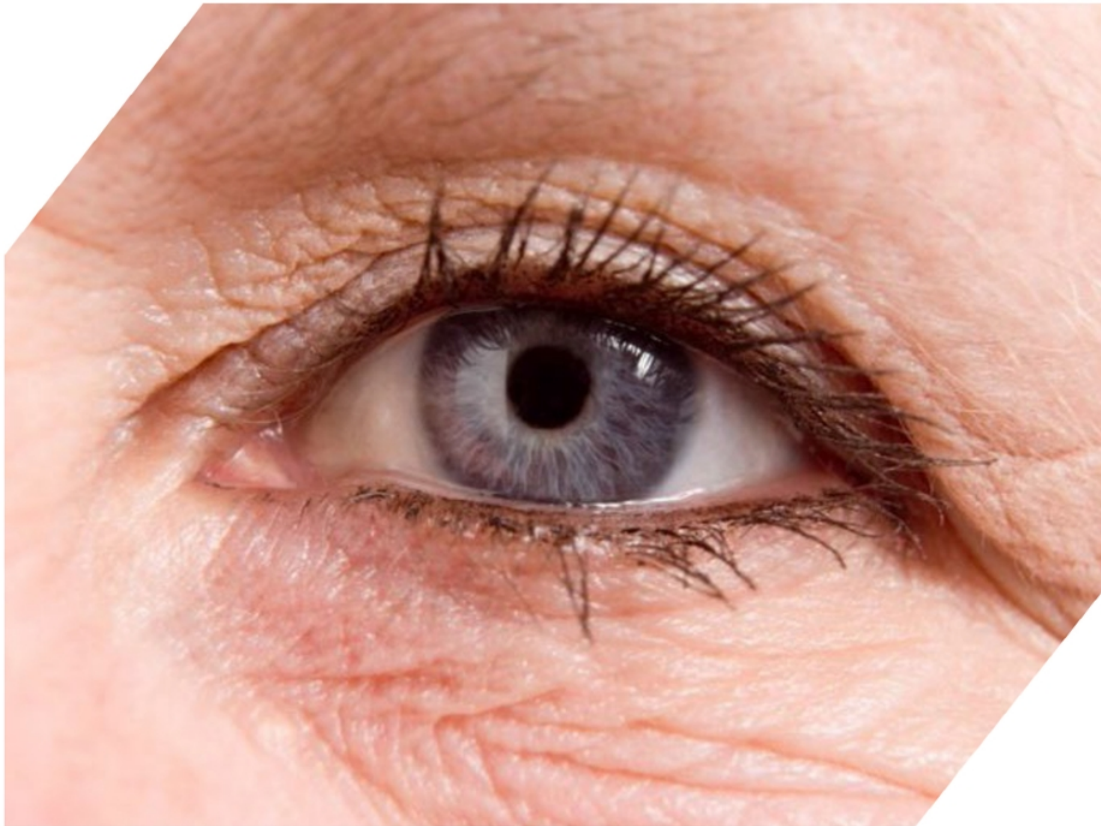
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CB 2782-PEG anti-complement factor 3 (C3)

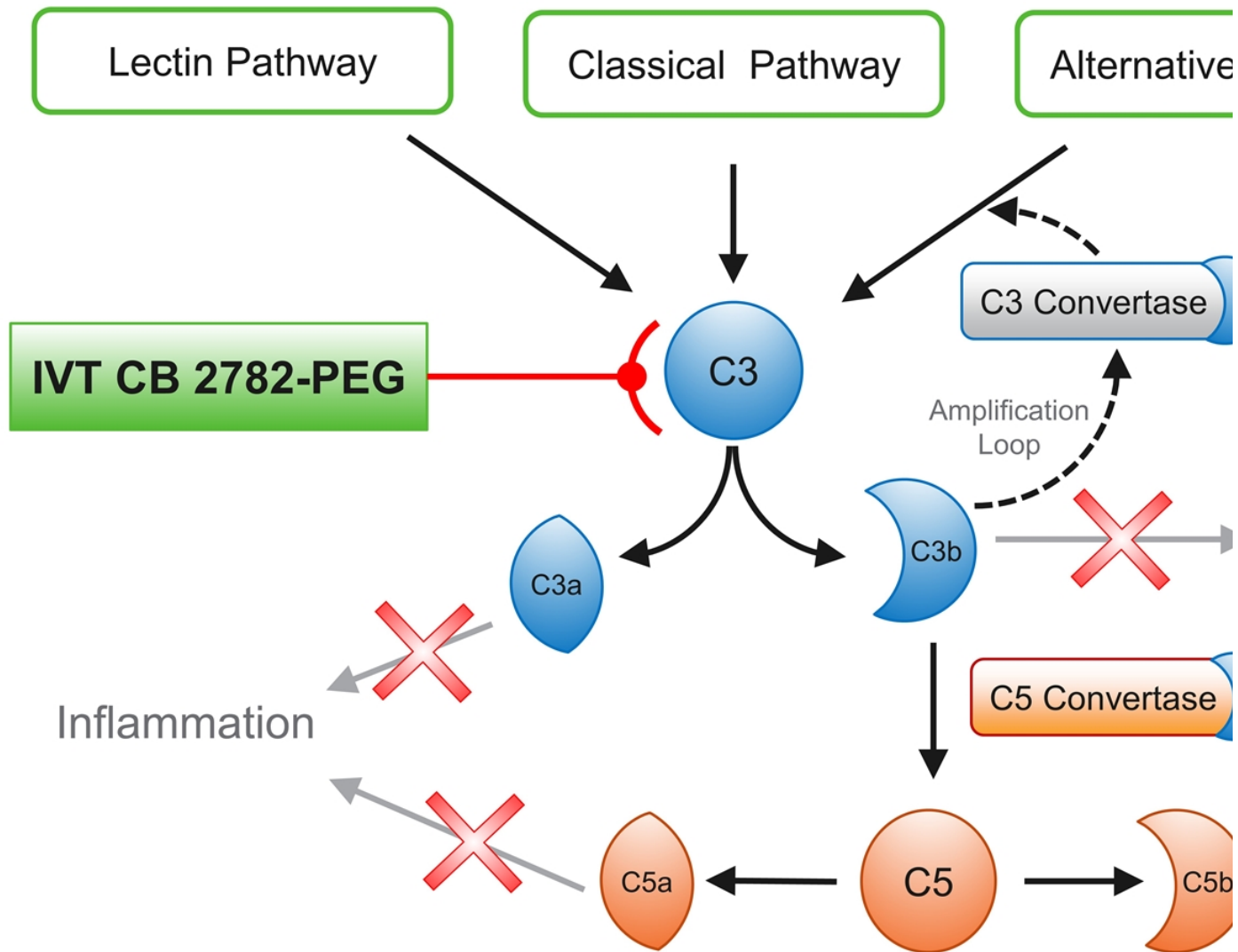
Geographic Atrophy in Dry AMD



- + Geographic atrophy in dry age-related macular degeneration (AMD) results in irreversible vision loss and leads to blindness.
- + Dry AMD is the leading cause of vision loss in the United States.
- + Global prevalence of dry AMD is approximately 10%.
- + C3 is the most promising treatment for geographic atrophy.

Sources: National Eye Institute. Facts About Age-Related Macular Degeneration, Tufail 2015, The Eye Diseases

Targeting C3 blocks the downstream comp



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 Co

- + Announc
- + \$15M up and tier
- + Catalyst and man
- + Biogen r activities commerc

Milestones

	2019	Q1	
MarzAA (FVIIa)	P2 efficacy 	EoP2	ToB F
DalcA (FIX)	Positive P2b Interim data 	P2b Update	Final
CB 2679d-GT (FIX Gene Therapy)	Preclinical efficacy 	NextGen Vector	NHF
CB 2782-PEG (dAMD)	Partnership  		

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 Operat

Andrew Hetherington, M.I.



Chief Medical Officer

Howard Levy, M.B.B.Ch., Ph.D., M.M.M.



18 years
in hematology

VP, Translational Rese

Grant Blouse, Ph.D.



VP, Business Development

Jeffrey Landau, M.B.A.



16 years
in biotech

catalystbiosciences

Summary

Disruptive approach to billion-dollar markets – protease en



FVIIa: SQ MarzAA ~\$2.2B market

+ P2 efficacy & safety demonstrated

+ FDA EoP2 in early 2020, P3 expected in 2020



Anti-C

+ Biog

+ \$15M
tiered



FIX: SQ DalcA >\$1.5B market

+ Interim Phase 2b efficacy demonstrated

+ Final Phase 2b data in 1H 2020



SQ sy

+ Lar

+ Bui



FIX Gene Therapy: CB 2679d-GT

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



Strong

THANK YOU

Nasdaq: CBIO

catalystbiosciences.com