# 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): January 26, 2021**

# 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 January 26, 2021, 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 (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: January 26, 2021

/s/ Clinton Musil
Clinton Musil
Chief Financial Officer

# CATALYST BIOSCIENCES

**Corporate Overview**

26 January 2021

CatalystBiosciences.com

# Forward looking statements

Certain information contained in this presentation and statements made orally during this presentation include forward-looking statements that involve substantial risks and uncertainties. All statements included in this presentation, other than statements of historical facts, are forward-looking statements. Forward-looking statements include, without limitation, statements about the product candidates of Catalyst Biosciences, Inc. (the “Company”) and the benefits of its protease engineering platform, potential markets for and advantages of MarzAA and DalcA;  plans to enroll a pivotal Phase 3 registration study of MarzAA; the initiation of a Phase 1/2 trial in patients with FVII Deficiency, Glanzmann Thrombasthenia, and patients treated with Hemlibra; MarzAA as possibly the first prophylactic for FVII Deficiency and Glanzmann Thrombasthenia; the potential for MarzAA and DalcA to effectively and therapeutically treat hemophilia subcutaneously; projected complement market opportunity, solution to fundamental shortcomings in current treatment options, plans to enroll the CB 4332 observational trial in the Company’s complement program in mid-2021, and ongoing updates related to CB 4322 and the C4b degrader.

Actual results c
expectations ar
statements. Va
events to differ
and studies ma
that trials may
replicate the re
develop or mar
anticipated, inc
manufacturing
Biogen will tern
other risks desc
Company’s Ann
and Exchange
Report on Form
other filings wit
presentation re
presentation ar
update any forv

CATALYST BIOSCIENCES

# The Protease Medicines Company

## Harnessing the catalytic power of protea

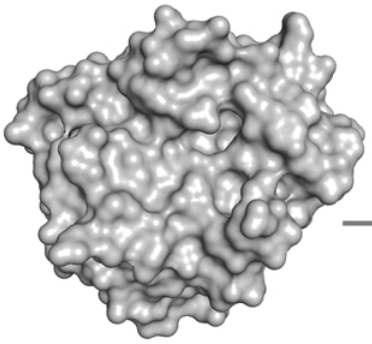
- Late-stage asset in Phase 3
- Robust complement portfolio
- Clinical-stage hemophilia assets
- Novel differentiated protease medicines

# Catalyst's protease platform generates dif

## Unique expertise in protease biology enables design of op

### Discovery platform

Protease scaffold



Structure guided design

Molecular evolution

Engineered regulation

Pharmacokinetic improvement

+

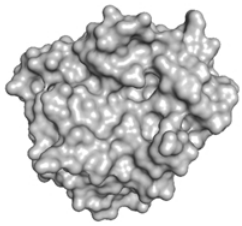
+

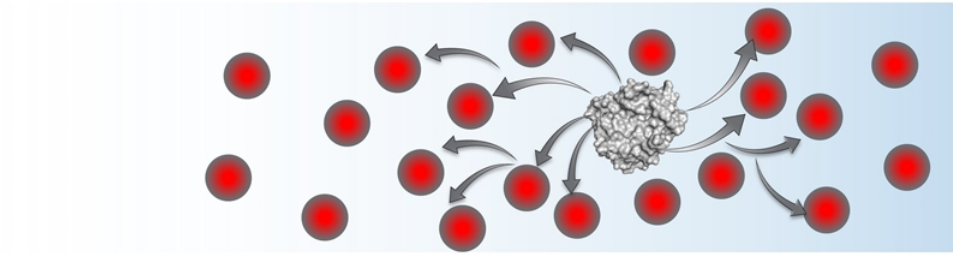
+

# Proteases are ideal for high abundancy ta

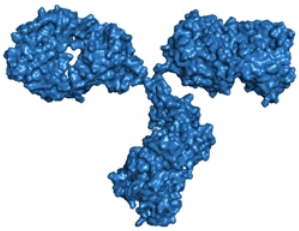
## A better way to regulate biological processes compared w

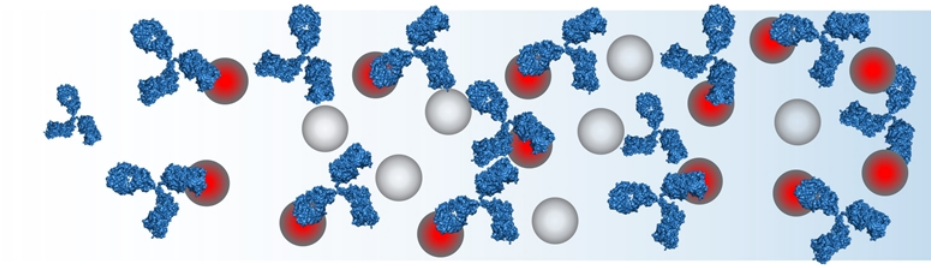
Proteases



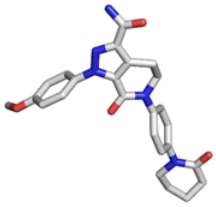


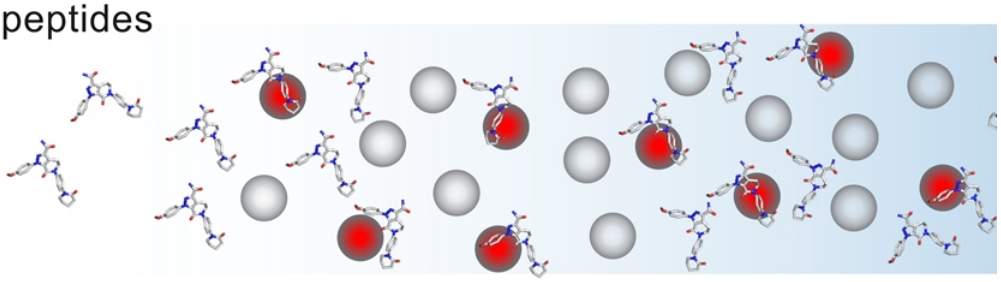
Antibodies



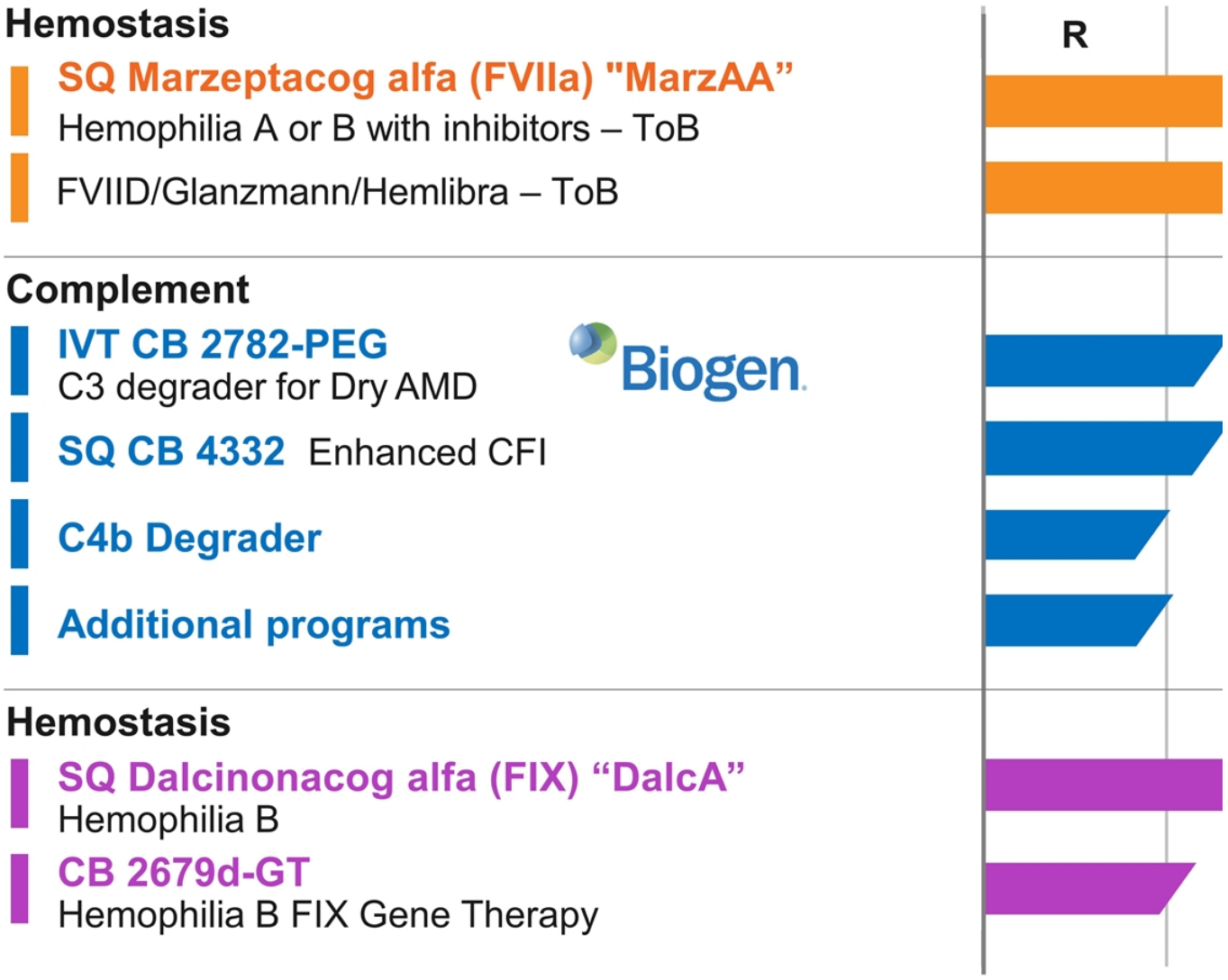


Small molecules / peptides





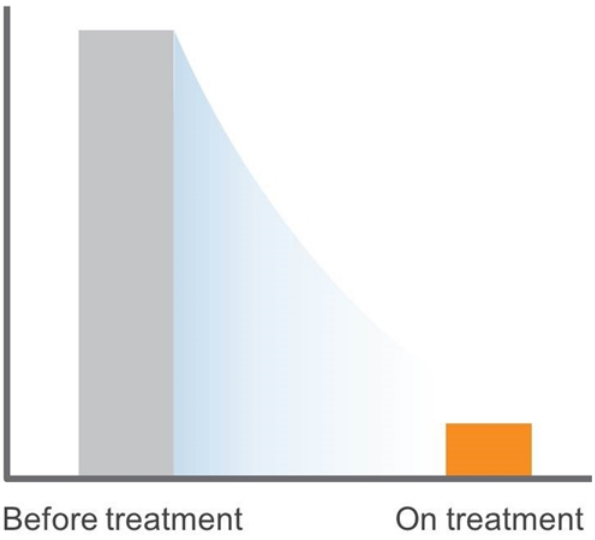
# Pipeline



# Clinical & partnering success of the CBIO

## Marzeptacog alfa

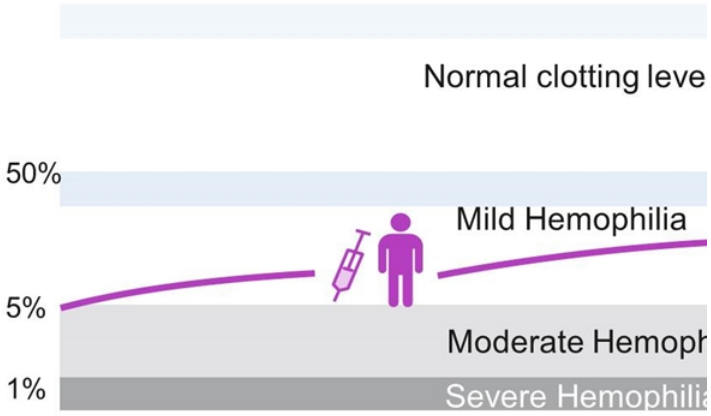
90% reduction
in annualized bleed rate




Engineered
rFVIIa protease

## Dalcinonacog alfa

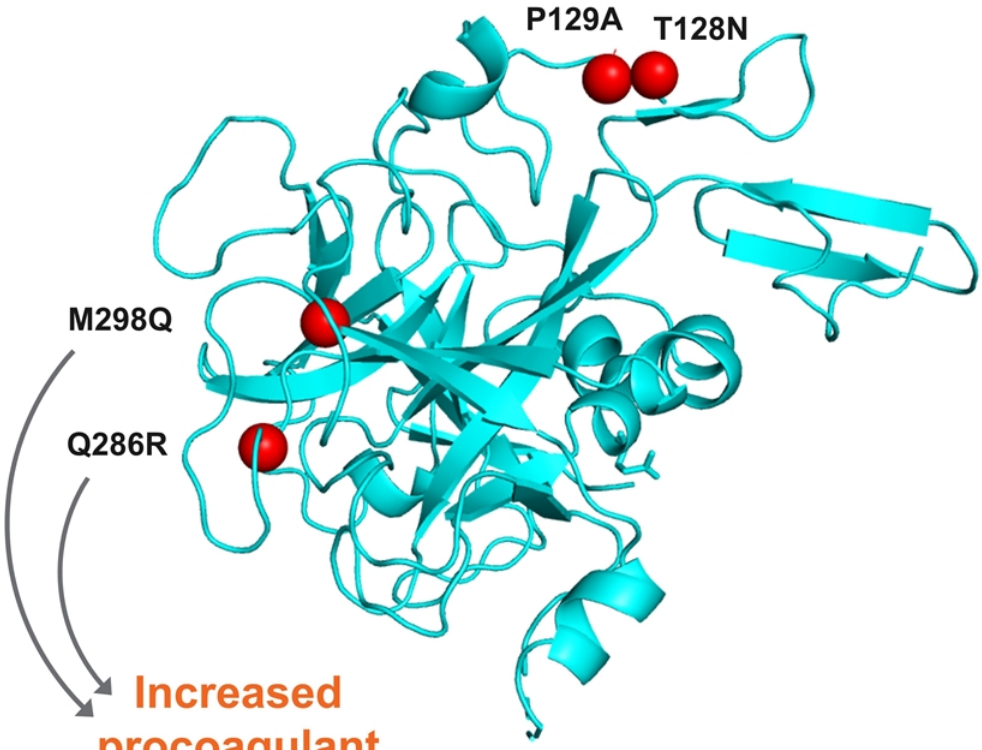
Achieved sustained
& high target levels of FIX




Engineered
rFIX protease

# Marzeptacog alfa (activated) – MarzAA: SC

## Addresses a clear unmet need in hemophilia & othe




### 9-fold higher a

+ Potency allows
+ Simple, small v

### Preclinical effi

+ HA mouse afte

### P2/3 prophylax HB with inhibi

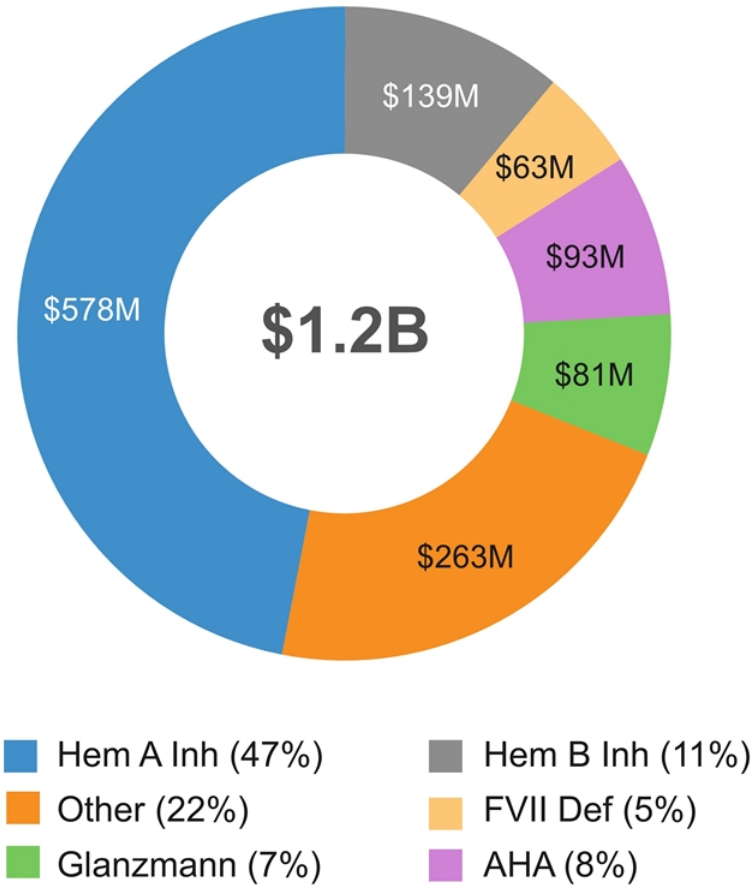
+ 46 patients trea
  3 SQ doses/da

### FDA Fast Trac episodic bleed

+ Granted on 2 D

# SQ MarzAA is a large commercial opportu

## Global NovoSeven sales breakdown by indication (2019)

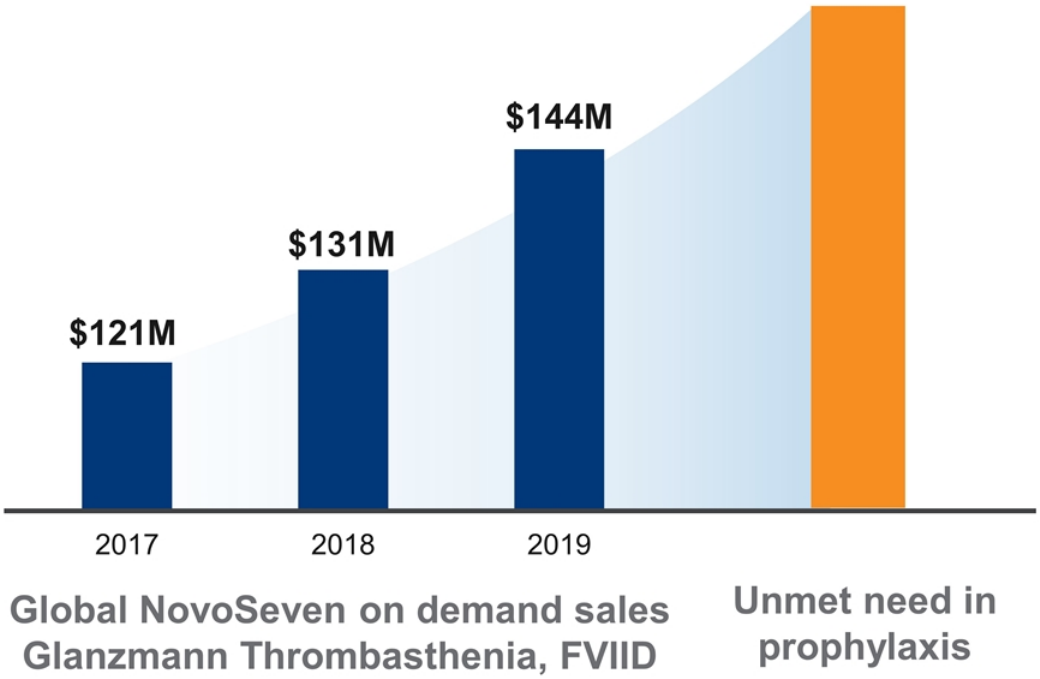



## SQ MarzA

- Faster & every 2
- MarzAA
- Potentia
- Can be *in vitro*
- Ideal fo access
- Prophyl

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

# MarzAA could be the first prophylactic for




Source: Catalyst Biosciences, Adivo Associates Market Research, Data on file. *Note: Treated patients may be counted multipl
events per year needing factor treatment

# Unmet need in treatment of a bleed

## NovoSeven

+ Patients reported needing an average of **6 hours and 3 infusions** of NovoSeven to resolve bleeds
+ Some bleeds take longer than 72 hours to resolve[1,2,3]

**Current bypass agents require multiple infusions over the course of hours**

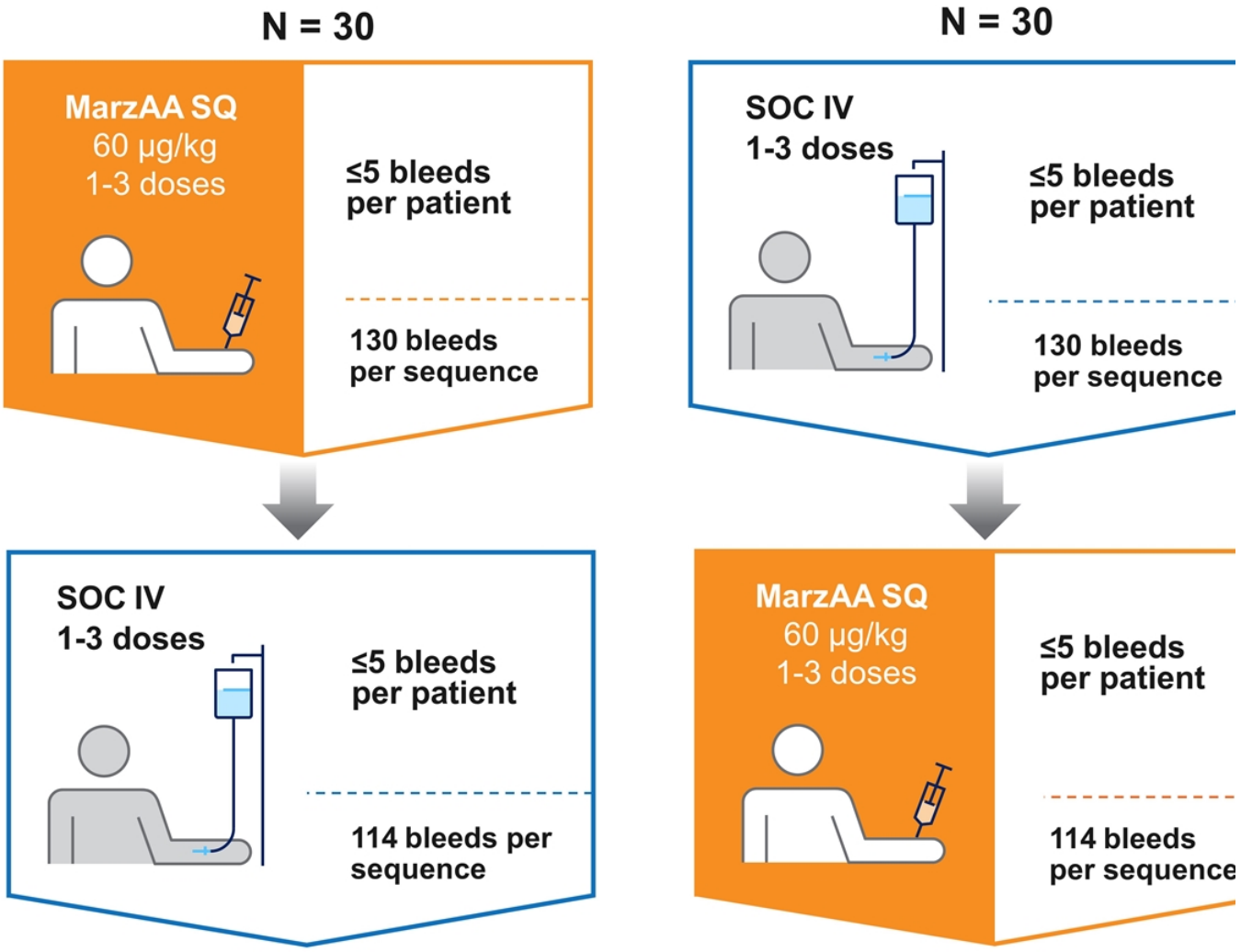
+ MA
  sup
+ Tar
+ Tar
  18
  60

Clini

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

# Crimson 1 Phase 3 study: Treatment of ep

## Hemophilia A or B with inhibitors, ABR ≥ 8



# MAA-202 Phase 1/2 study design

## FVII deficiency, Glanzmann Thrombasthenia and HA

### Phase 1 PK

MarzAA IV
each cohort

Single dose

MarzAA SQ

Single dose escalation

Multiple dose Q3H

### Phase 2 ToB

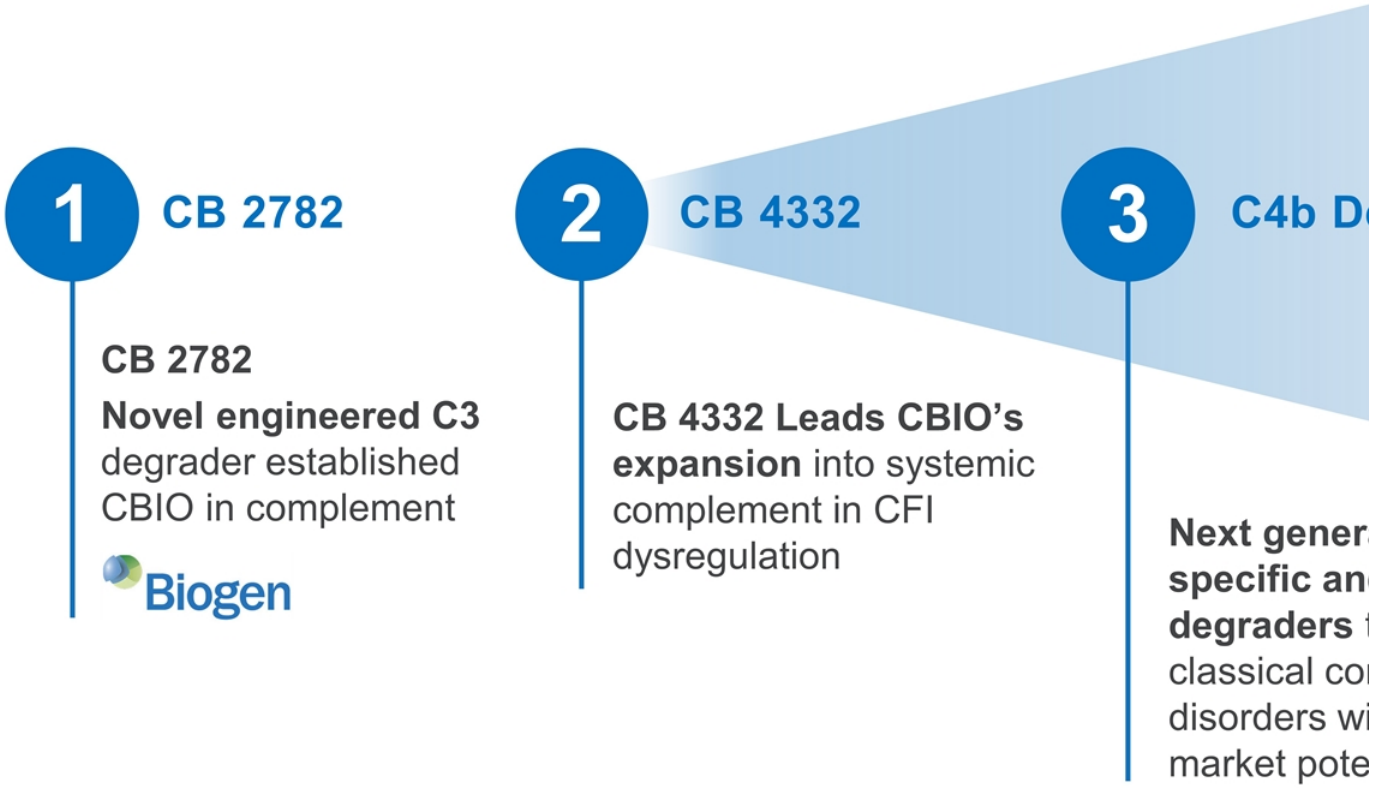
MarzAA SQ
1-3 doses

FVIID ≥30 bleeds

GT ≥30 bleeds

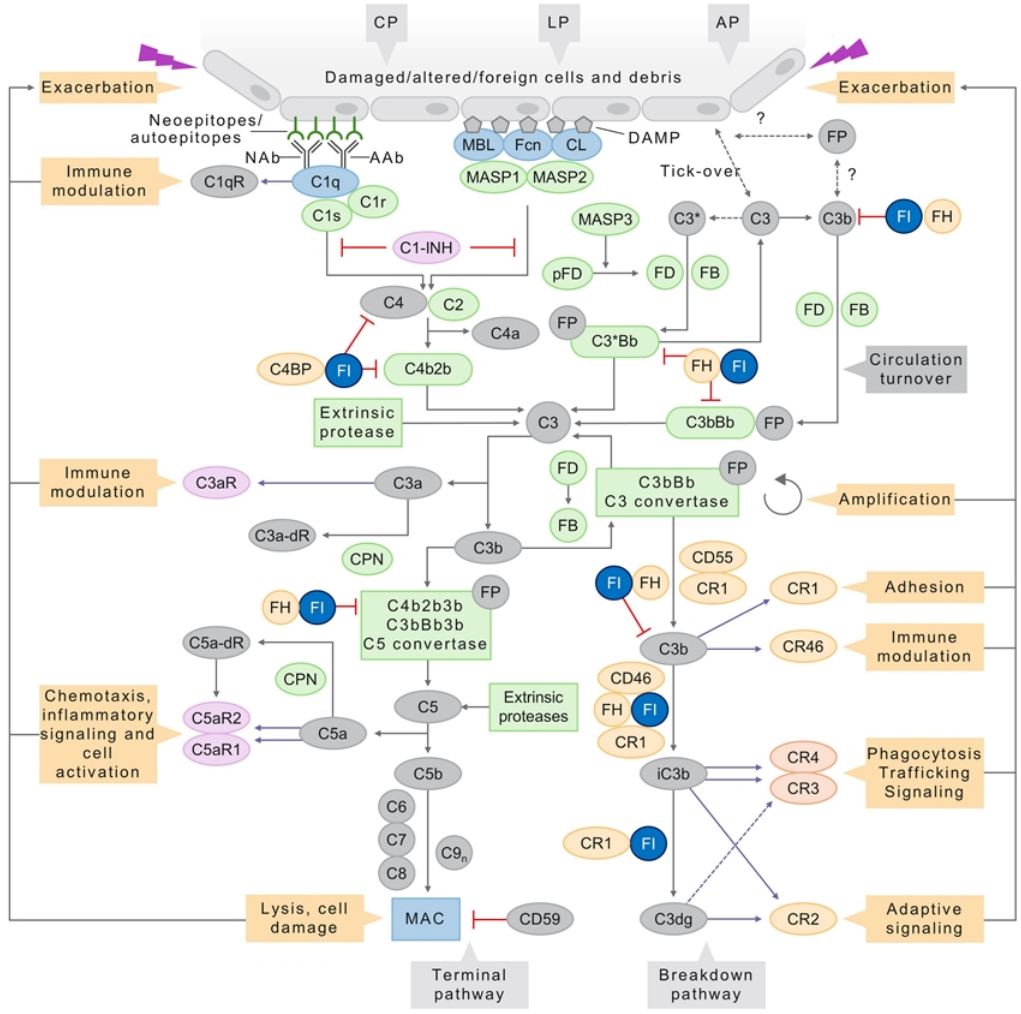
HA ≥15 bleeds

# CBIO's complement pipeline



# Complement is a perfect fit to develop pro

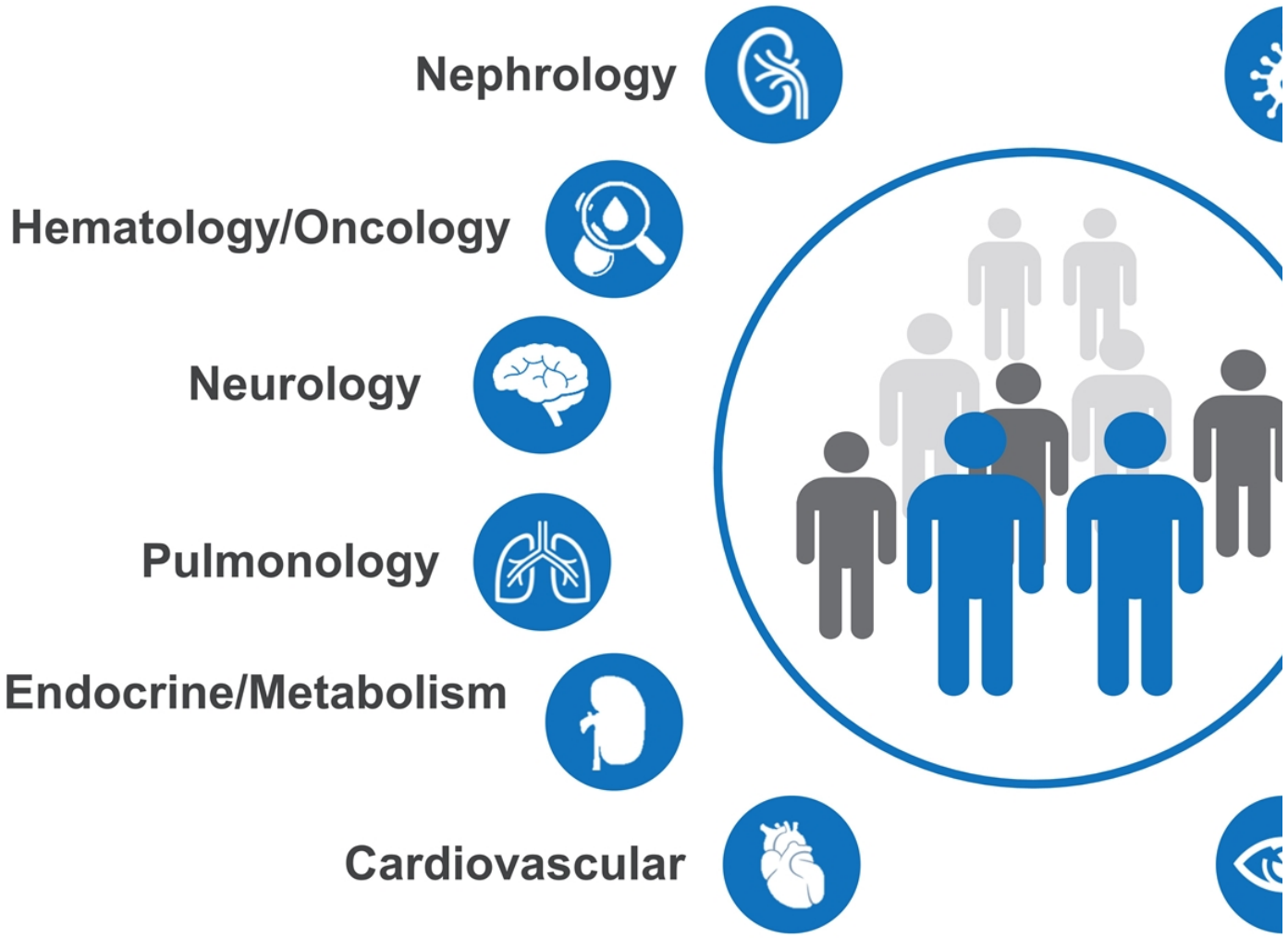
## The complement pathway is driven by a protease ca




Reference: Figure adapted from Mastellos *et al.*, Clinical promise of next-generation complement therapeutics. Nat

# Complement plays a critical role in many

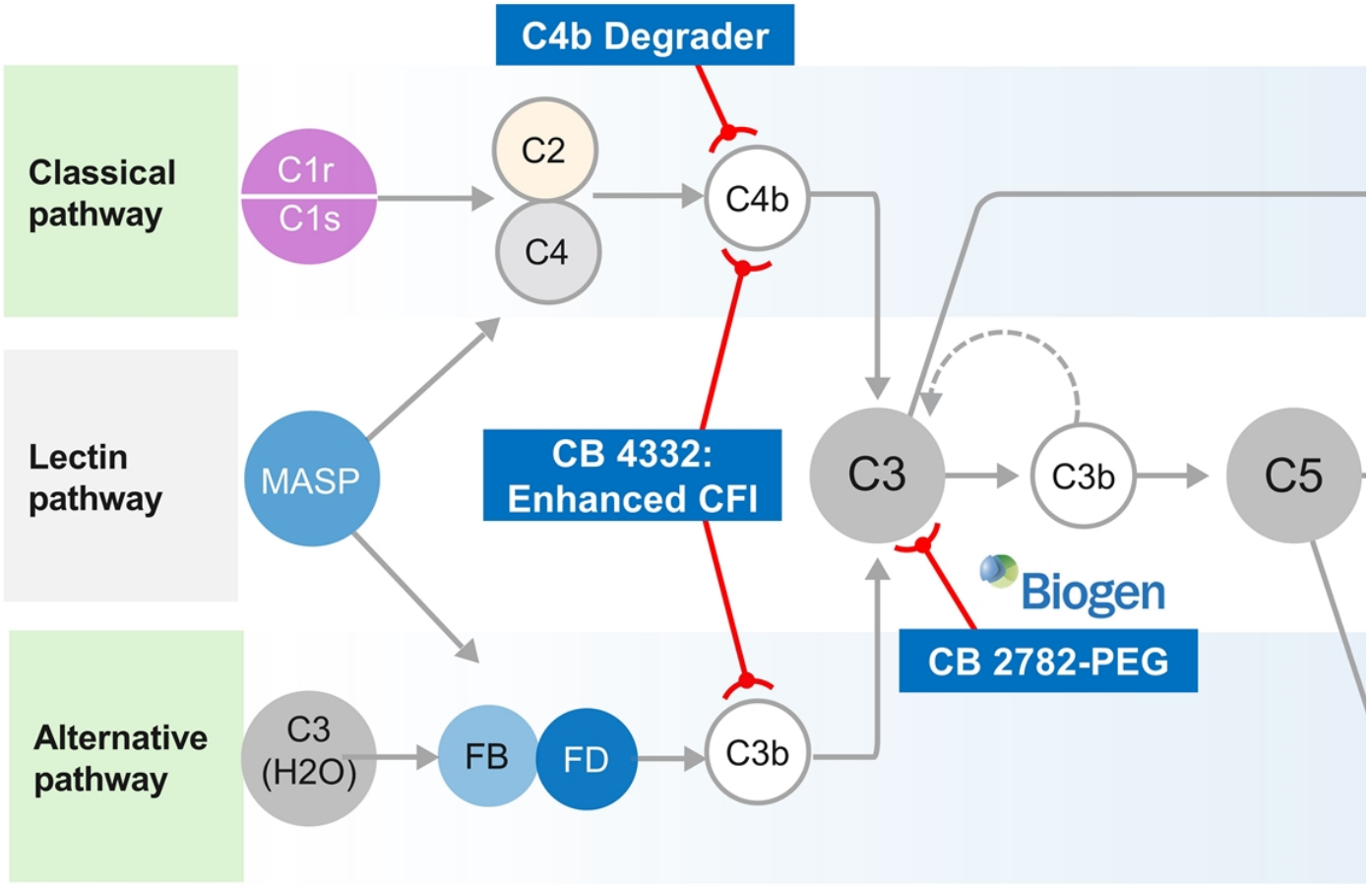
## Late-stage complement therapies projected to achi




References: Globaldata consensus net sales forecast 2020

# CBIO is taking a targeted approach to com

## Engineered proteases address the root cause of the

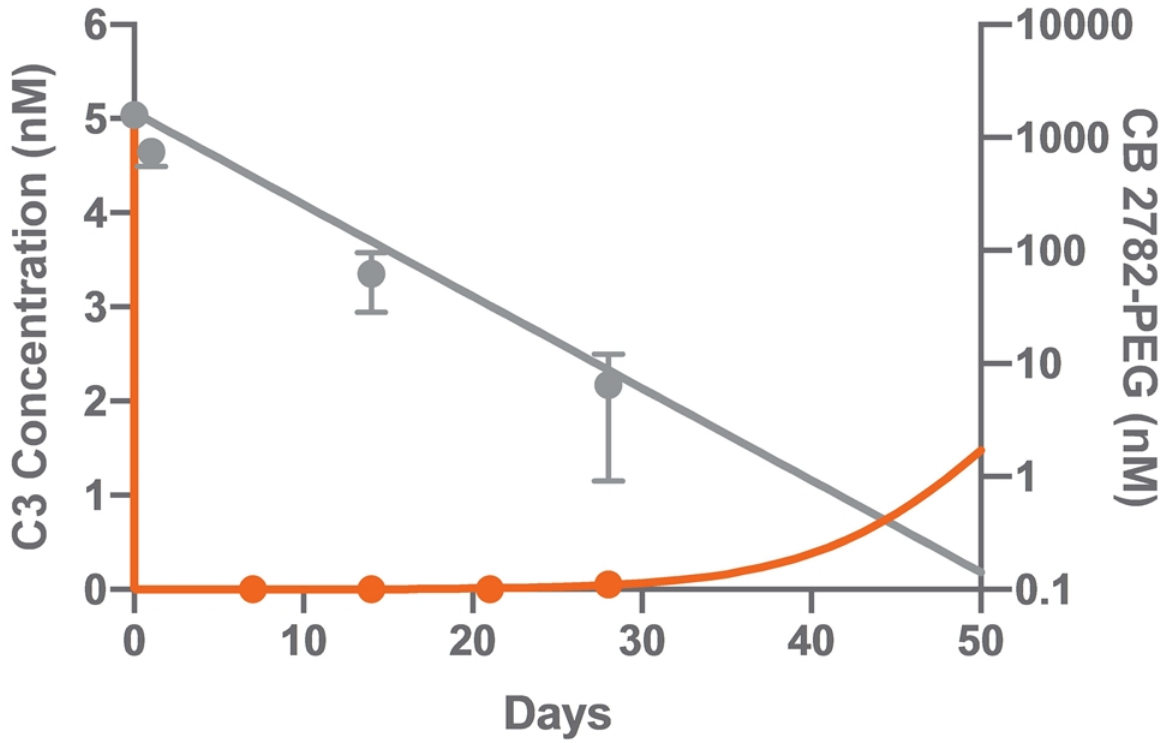



+ Current C5 blockade therapies do not address disease root cause
+ The catalytic power of proteases provides advantages over small n

# Protease advantage demonstrated *in vivo*

## CB 2782-PEG – designed as a best-in-class C3 degr

### CB 2782-PEG degrades C3 levels in the eye for at least 28 days in a non-human primate model



# CB 2782-PEG long acting anti-C3 protease

## Geographic atrophy in dry AMD can result in blindness

+ Advanced stage of dry age-related macular degeneration (dAMD)
+ dAMD affects ~1M people in the US & >5M WW, no currently approved th
+ Global market ~ >$5B
+ C3 is a clinically validated target (randomized P2) for the treatment of dAM

## Best-in-class C3 degrader for dry AMD

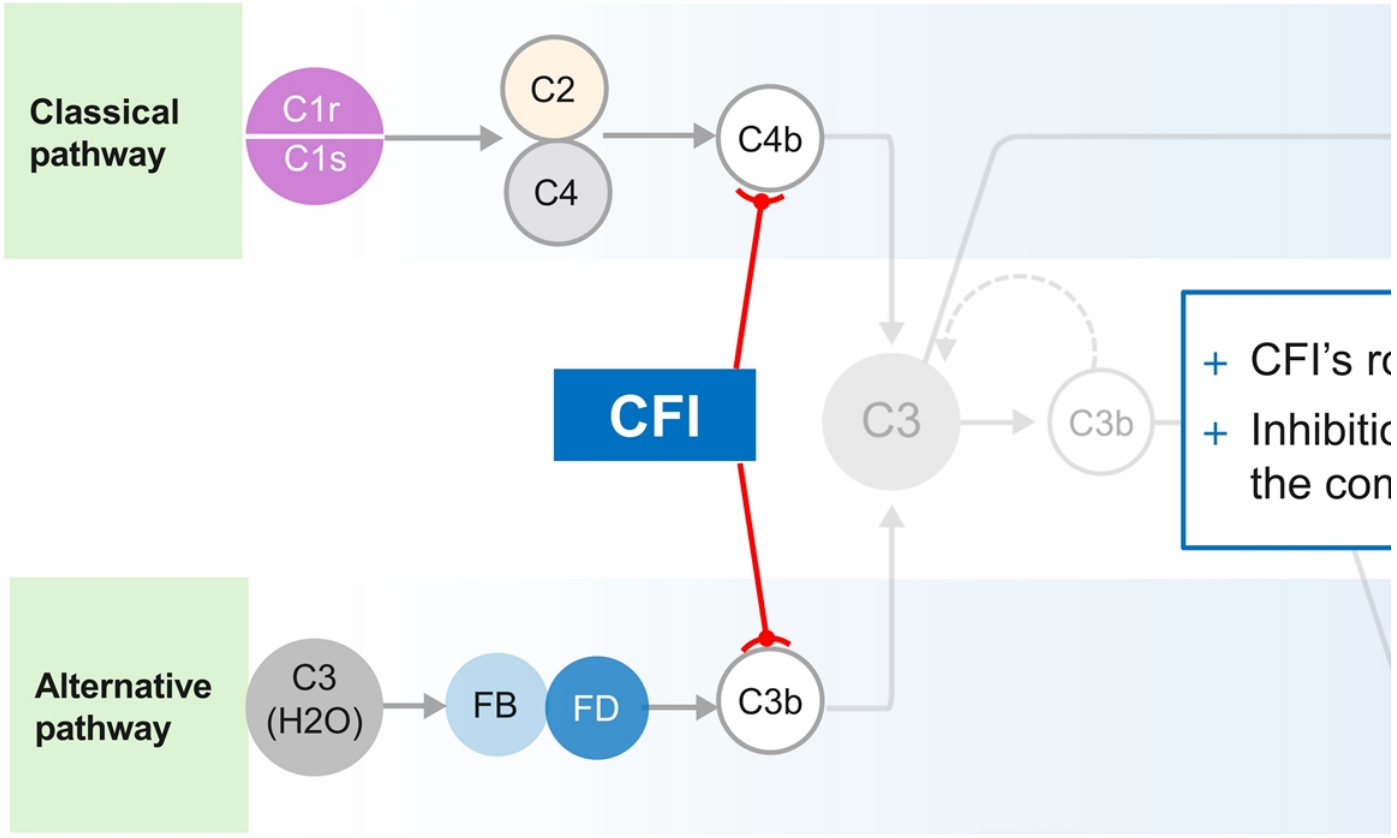
+ Generated from Catalyst's proprietary **protease engineering platform**
+ Potent, selective & long acting, degrades C3 into inactive fragments
+ Preclinical NHP PK & PD data* predict **best-in-class** human intravitreal d

## Biogen collaboration

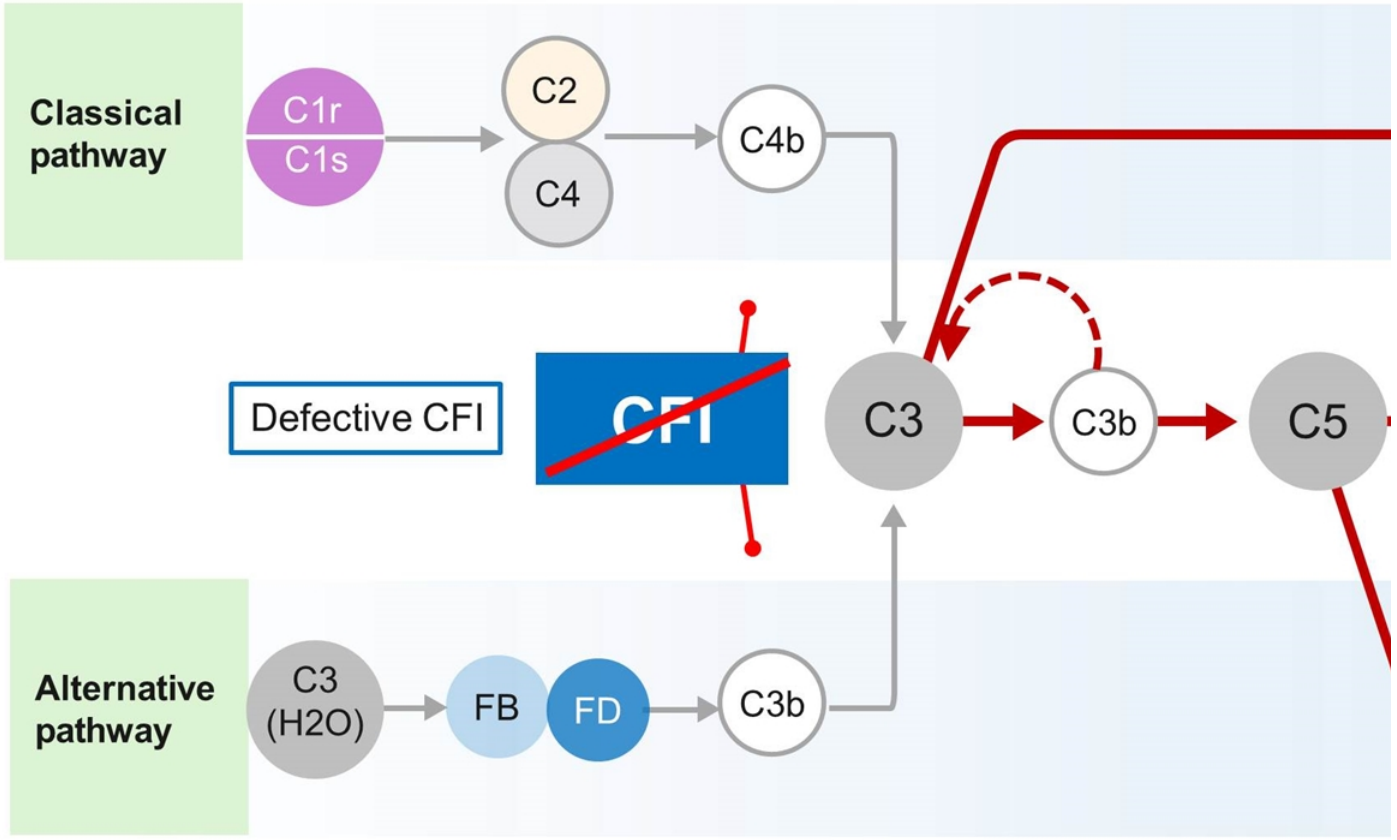
+ $15M upfront, up to $340M in milestones and tiered royalties up to low dou
+ Catalyst: fully funded pre-clinical and manufacturing activities
+ Biogen: IND-enabling activities, WW clinical development & commercializa

*Furfine *et al.* ARVO 2019

# Normal CFI: Key central regulator of comp



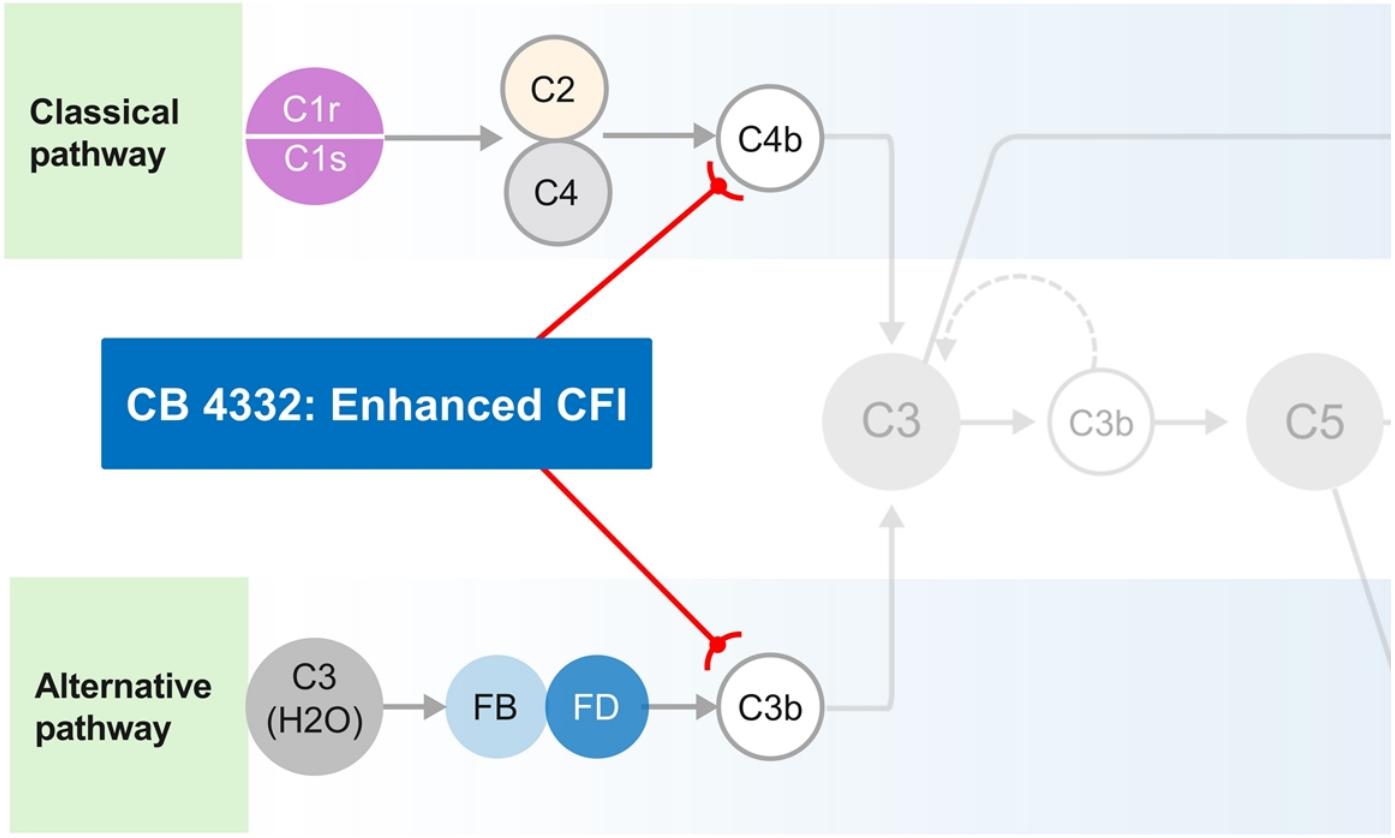
# CFI dysregulation: Lack of proteolytic CFI




+ In patients with CFI mutations, C4b and C3b cannot be sufficiently
+ Dysregulation leads to overactivation of the complement pathway a

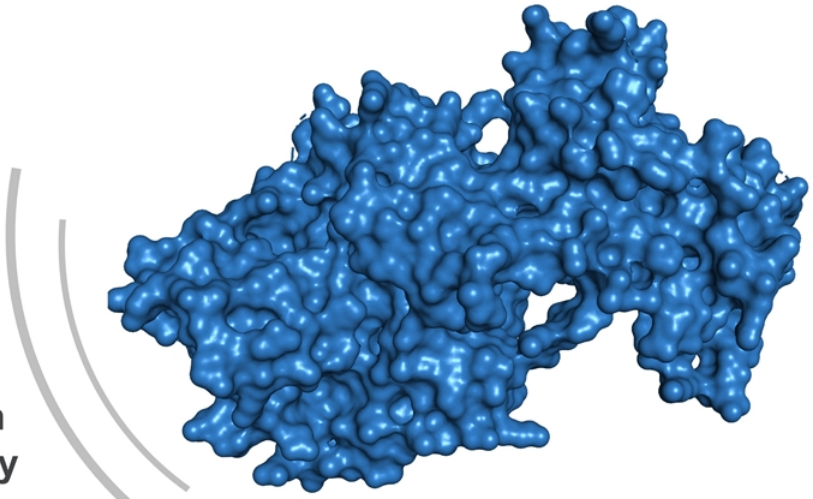
# CB 4332 – CBIO's enhanced CFI

## Specifically addresses the problem by restoring CF



# CB 4332: Enhanced Complement Factor I

## CBIO's next SQ development candidate to restore C



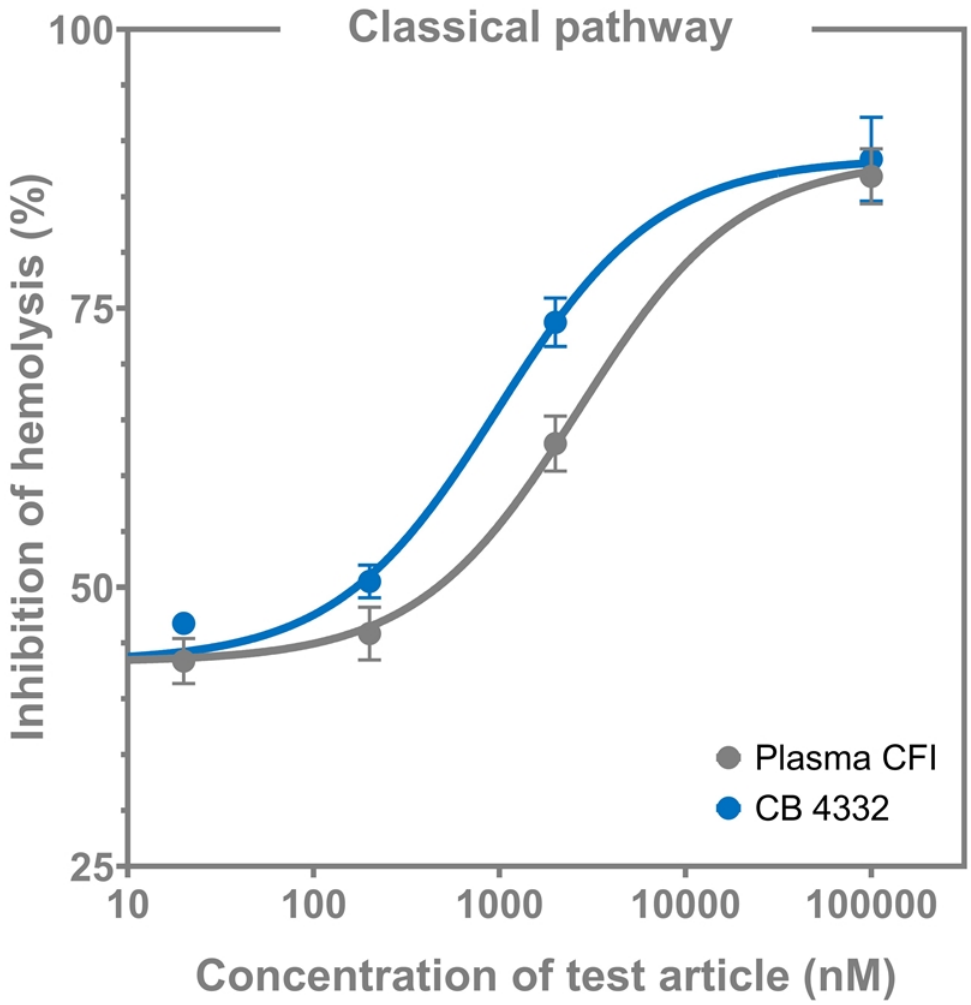
Half-life extension technology

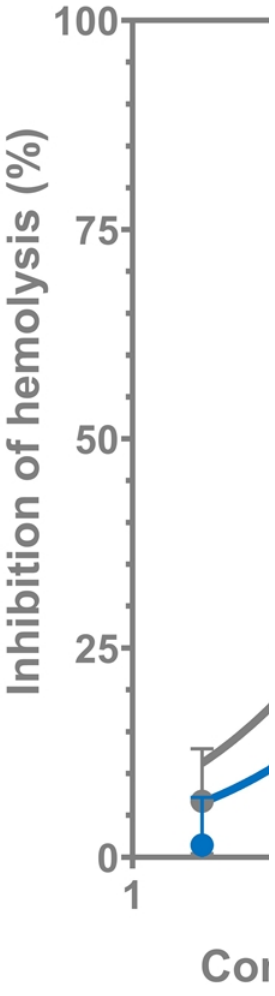
+ **Engineered for an extended half-life**
  - Once weekly SQ therapy – no PEG
+ **Full activity comparable to native CFI**
  - Classical and alternative pathway regulation
+ **Efficient high yield production process**

+ R
  sy
  dy
+ N
  co
+ Ta
  tr
  to
+ G
  p

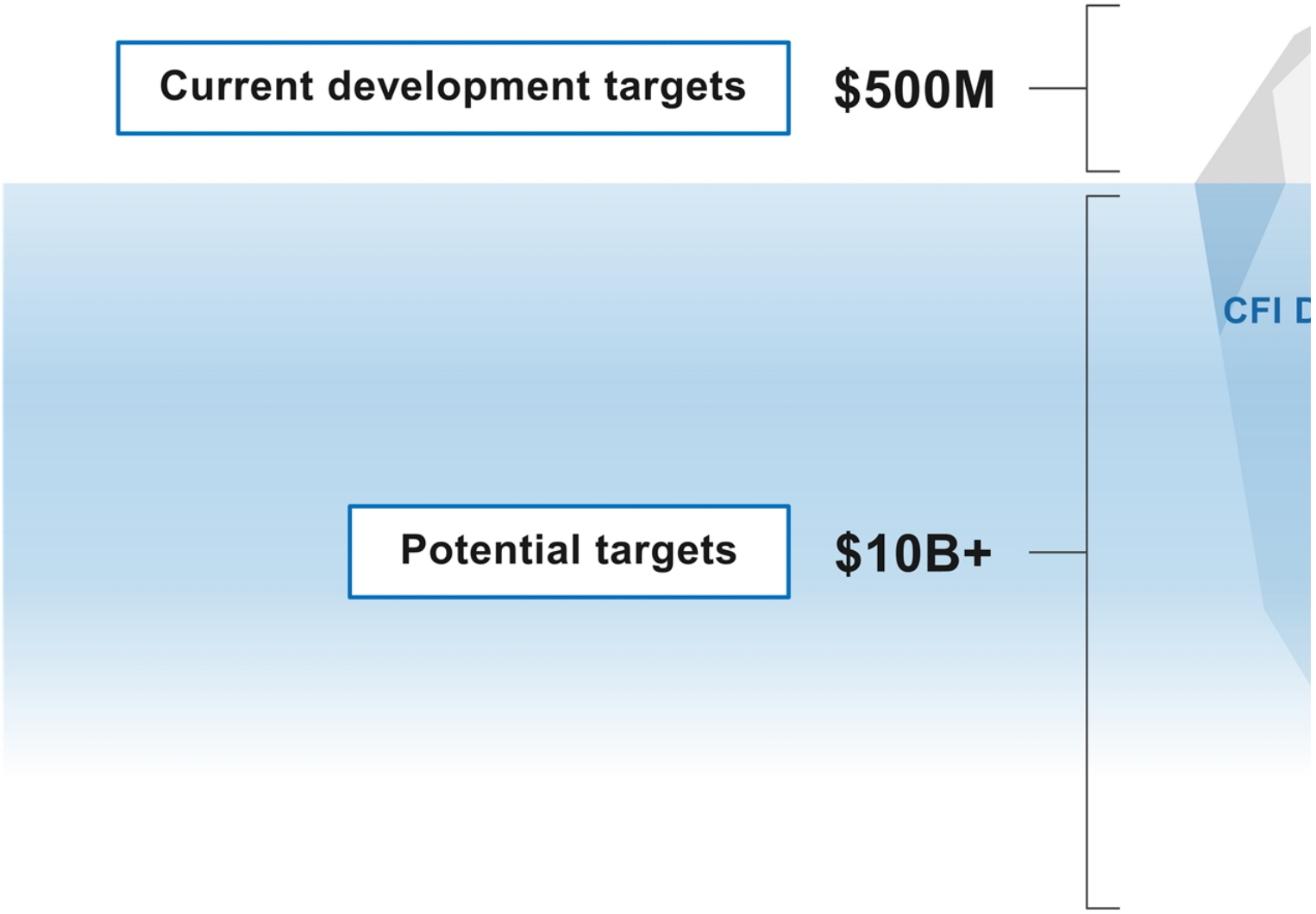
References: [1]Bienaime *et al*. Kidney Int. 2010; [2]Ferreira *et al*. Nefrologia. 2016; Note: CFH = Complement factor H; Structura

# CB 4332 & plasma CFI perform similarly ir



# Diseases with CFI mutations have tremen



# CB 4332 initial market opportunity

## US / EU5 market opportunity


Additional opportunity in CFI Deficiency outside nephrology

**$500M**

Market opportunity in CFI deficient aHUS, C3G, IC-MPGN

Signif

0 Spe for

0 The

0 App

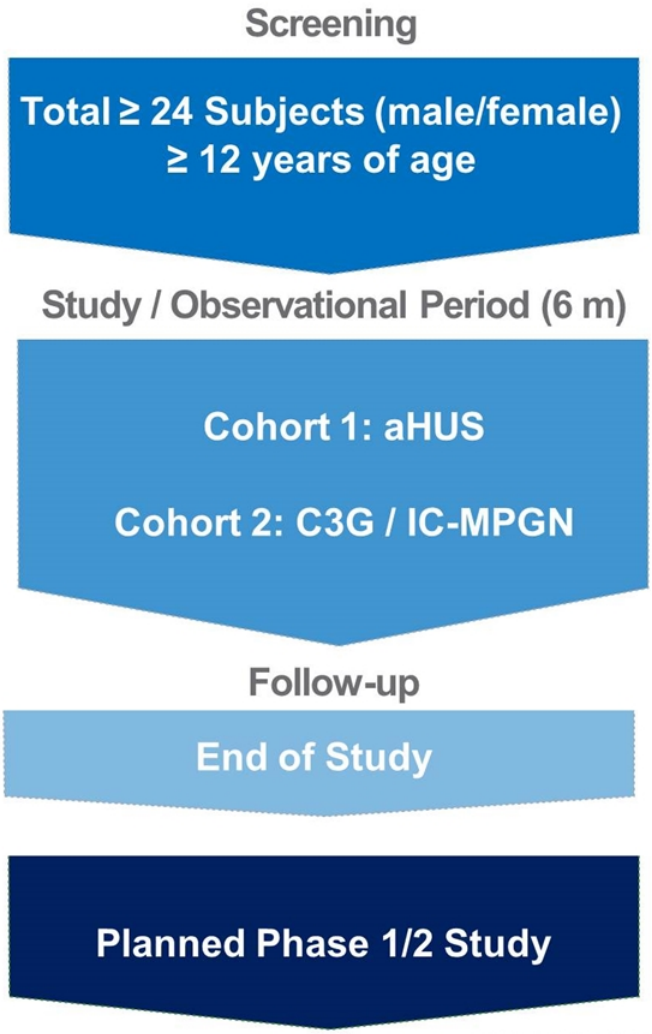
CFI muta

Note: aHUS = atypical Hemolytic Uremic Syndrome, C3G = Complement 3 Glomerulopathy, IC-MPGN = Immune-Complex M Factor I Deficiency

References: Bresin *et al*. JASN. 2013; Fremeaux-Bacchi *et al*. ASN. 2013; Rui-Ru *et al*. Jour Rare Dis Res. 2018; Servais *et al*. Kidney Int. 2014; Alba-Domiguez *et al*. J rare Dis. 2012. El Sissy *et al*. Front. Immunol. 2019; Shields *et al*. Front Immunol. Clin Epi 2020; Smith *et al*. Nature Reviews. 2019; Noris *et al*. Clin J Am Soc Nephrol. 2010; CBIO KOL interviews

# CB 4332 – CFI dysregulation observationa

## Identify CFI deficient patients for further CB 4332 cl




## Objectives

- **Primary O**

  Demonstrat
  phenotypic
  C3G, IC-MF
  subjects for

- **Secondary**

  Monitor effi
  Monitor safe
  Record dos
  Monitor QoL

## Timeline

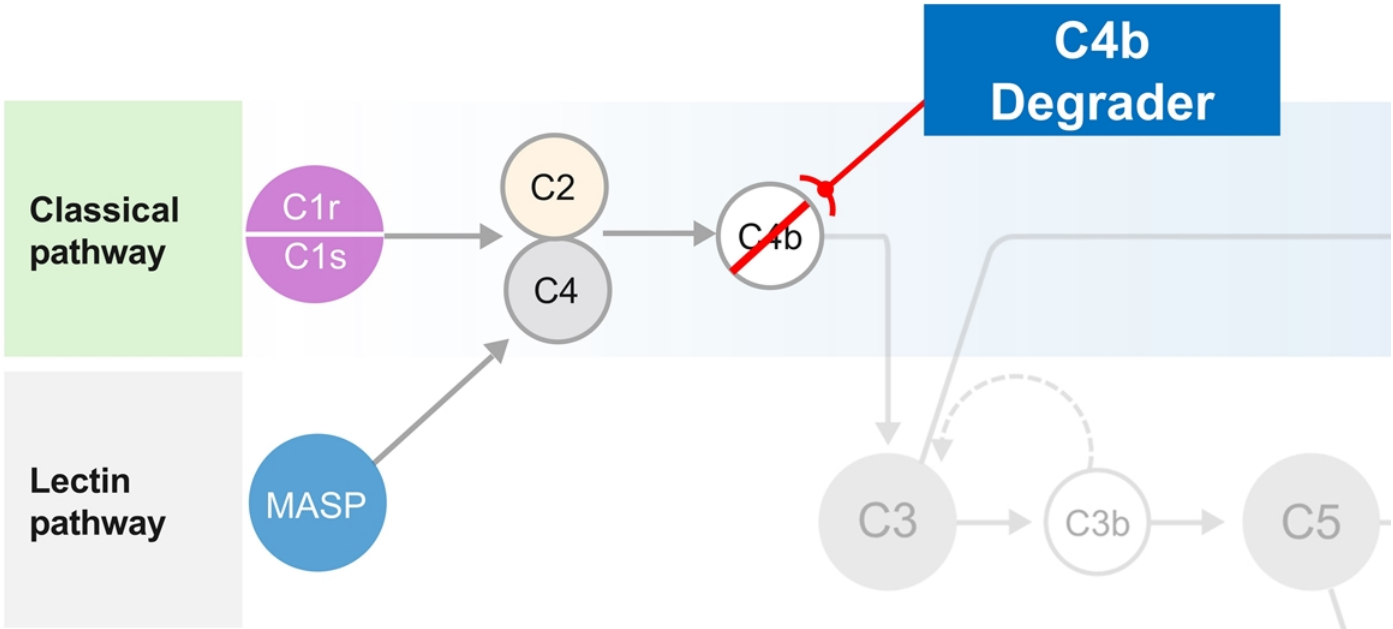
Observation

Global phas
expected in

Intend to pu

Note: aHUS = atypical Hemolytic Uremic Syndrome, C3G = Complement 3 G
= Immune-Complex Membranoproliferative Glomerulonephritis

# CBIO C4b degrader complement therapy




## Selective & potent

+ Catalyst's protease platform allows for tuning specificity to individual targets
+ Leverages CB 4332 protease scaffold & efficient high yield pro
+ No competitors specifically targeting C4b or planning a weekly
  - Approaches targeting C1q and C1s with antibodies require substantial &

# C4b degraders target multiple high unmet

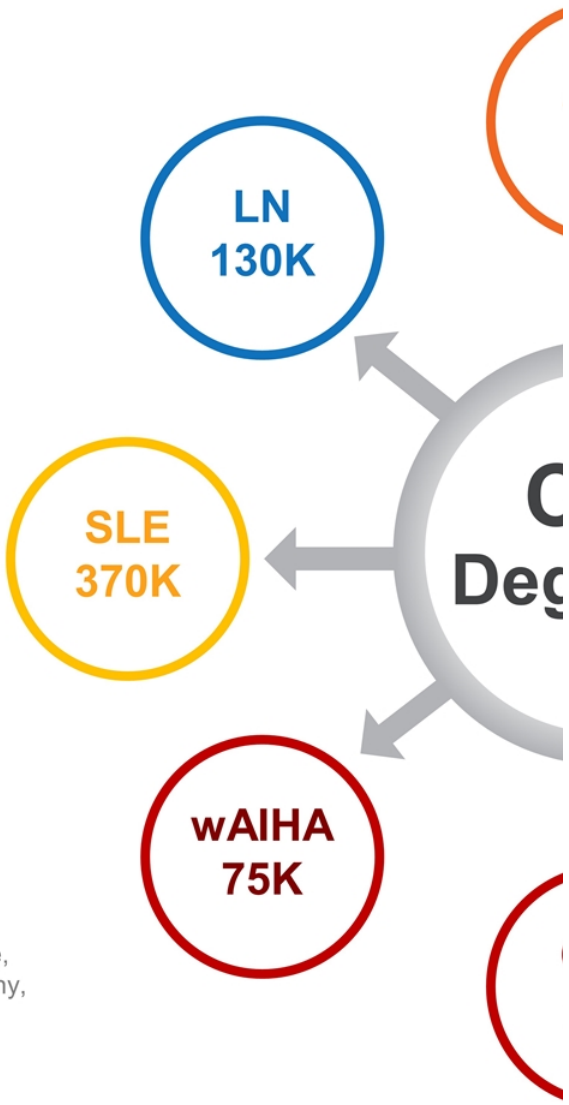
## US & EU5 patient opportunity

Nephrology

Immunology

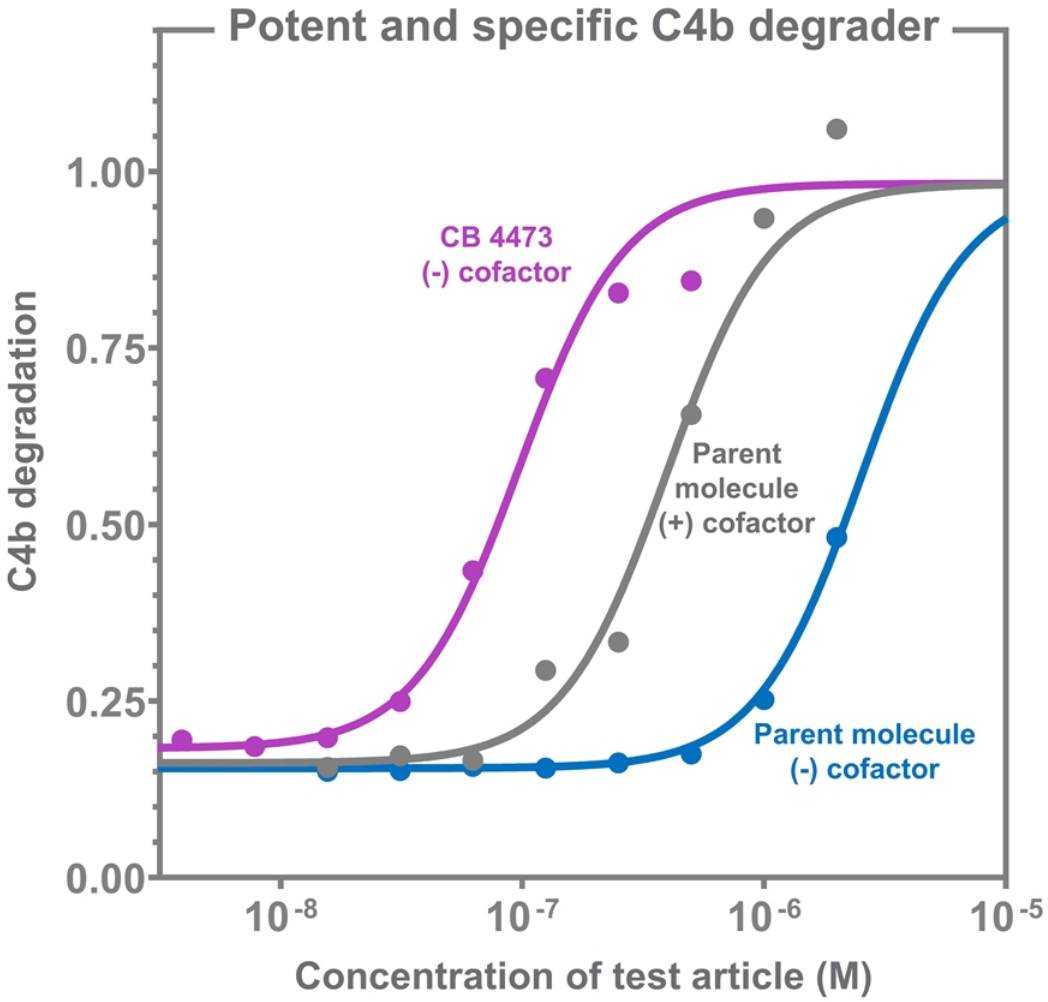
Hematology

Neurology




Note: ALS = Amyotrophic lateral sclerosis, GBS = Guillain-Barré syndrome, gMG = Generalized Myasthenia Gravis, MMN = multifocal motor neuropathy, CAD = Cold agglutinin disease, wAIHA = warm Autoimmune hemolytic anemia, SLE = Systemic lupus erythematosus, LN = Lupus Nephritis, References: Data on file

# CB 4473 demonstrates engineered C4b pc




# Milestones

## 2021

- CB 4332 observational trial (mid-year)
- MAA 202 PK data (mid-year)
- MAA 304 first DSMB (mid-year)
- C4b degrader updates
- CB 2782-PEG Biogen

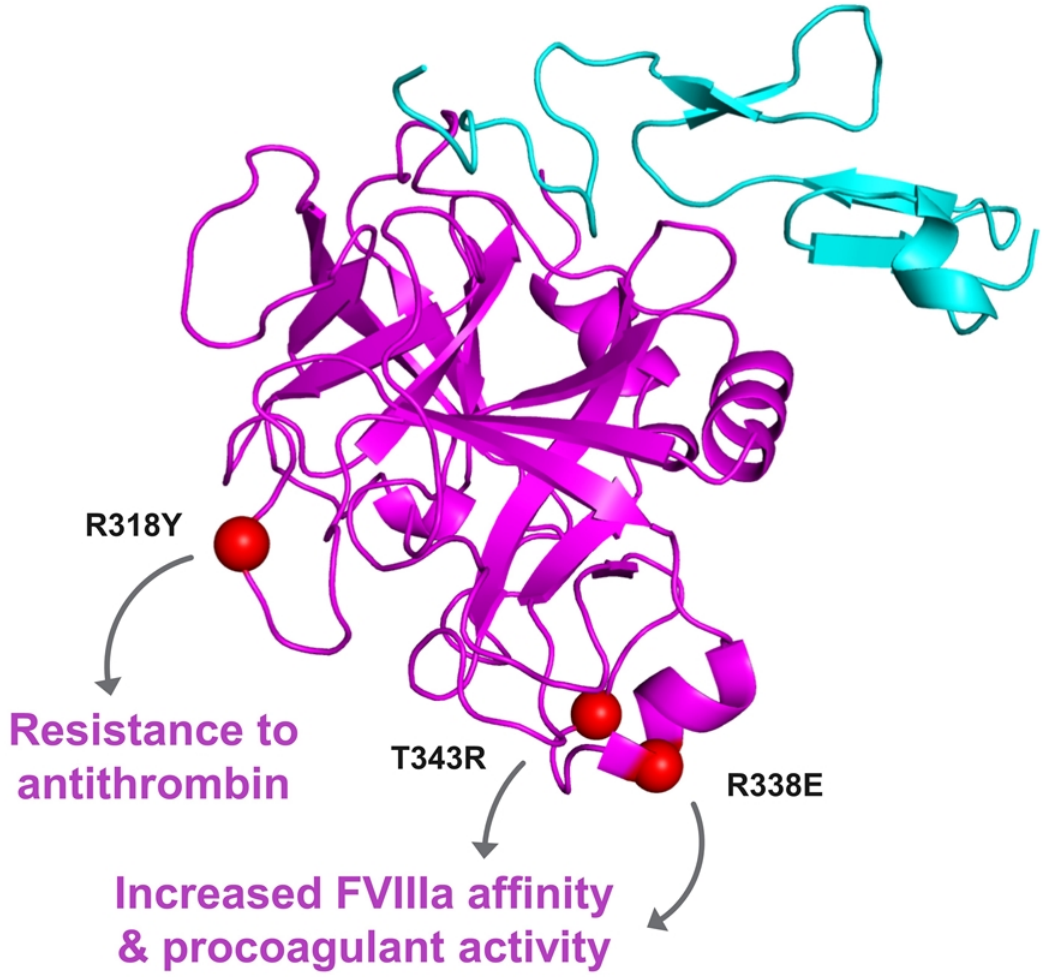
**MarzAA** (FVIIa) **CB 2782-PEG** (dAMD)

# THANK YOU

**Nasdaq: CBIO**

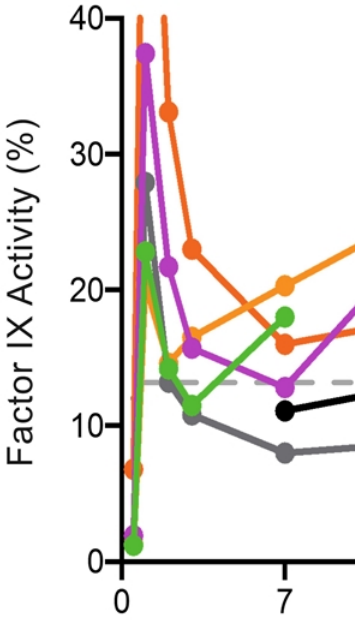
CatalystBiosciences.com

# DalcA P2b demonstrated efficacy & safety




## Differentiate

+ Small volum
+ Enhanced p
+ Excellent ex
+ **Target level 100 IU/kg d**



# Catalyst's CB 2679d gene therapy for hem

**Engineered Capsid** + **Novel Transgene** = **Lower AAV Dose**

| 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