

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): March 3, 2021

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 March 3, 2021, 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.

Date: March 3, 2021

**CATALYST BIOSCIENCES, INC.**

/s/ Clinton Musil

Clinton Musil

Chief Financial Officer

# CATALYST BIOSCIENCES

**Corporate Overview**

3 March 2021

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

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# 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  
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events to differ  
and studies ma  
that trials may i  
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manufacturing  
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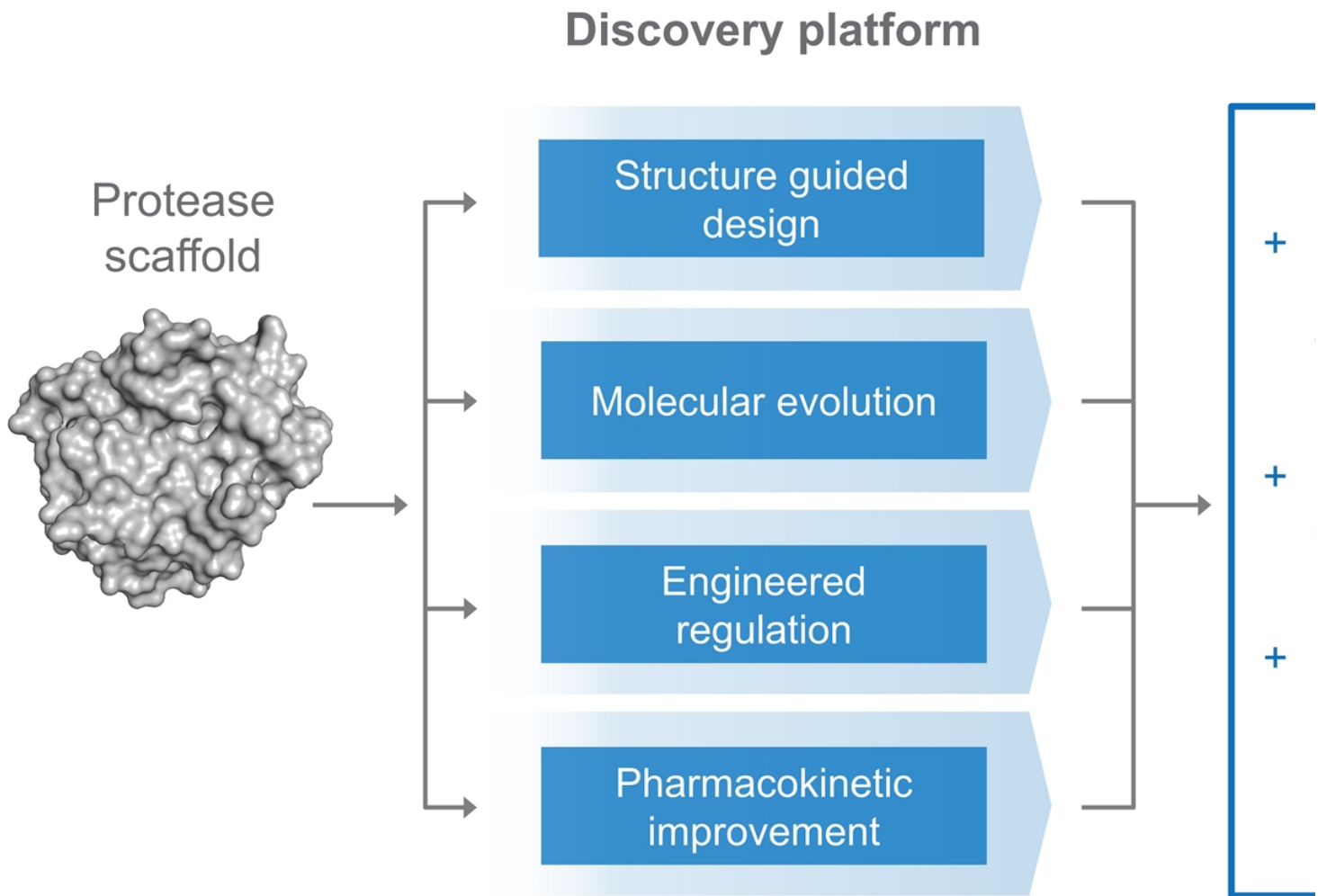
## The Protease Medicines Company

Harnessing the catalytic power of protea

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

# Catalyst's protease platform generates dif

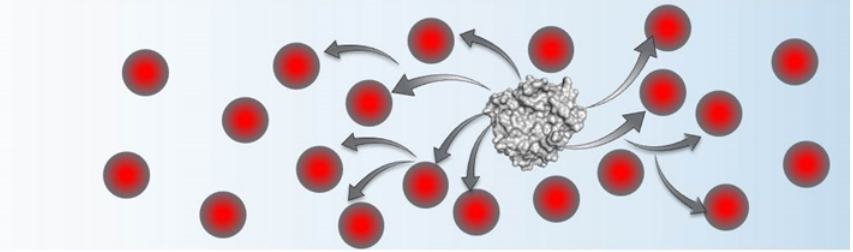
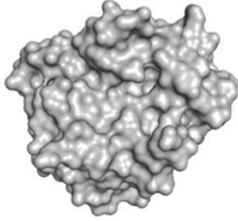
Unique expertise in protease biology enables design of op



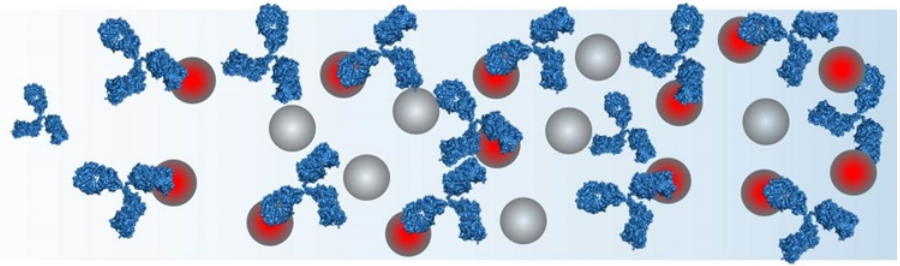
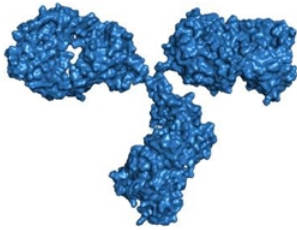
# Proteases are ideal for high abundance targets

A better way to regulate biological processes compared with

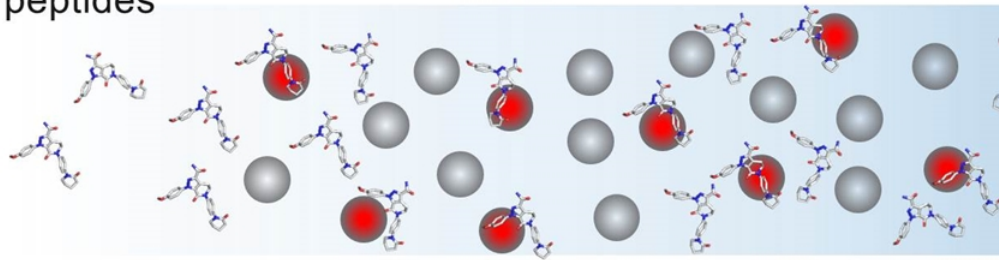
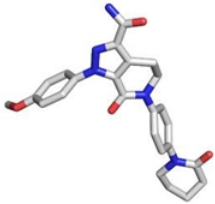
Proteases



Antibodies



Small molecules / peptides



# Pipeline

## Hemostasis

- SQ Marzeptacog alfa (FVIIa) "MarzAA"**  
Hemophilia A or B with inhibitors – ToB
- FVIID/Glanzmann/Hemlibra** – ToB

R

## Complement

- IVT CB 2782-PEG**  
C3 degrader for Dry AMD
- SQ CB 4332** Enhanced CFI
- C4b Degradar**
- Additional programs**



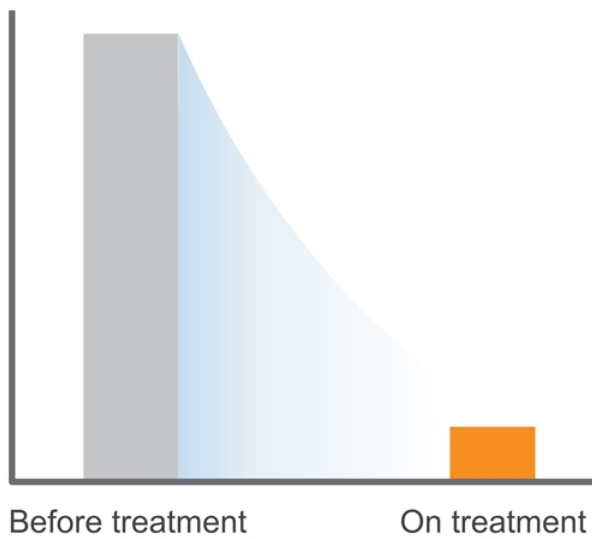
## Hemostasis

- SQ Dalcinonacog alfa (FIX) "DalcA"**  
Hemophilia B
- CB 2679d-GT**  
Hemophilia B FIX Gene Therapy

# Clinical & partnering success of the CBIO

## Marzeptacog alfa (activated)

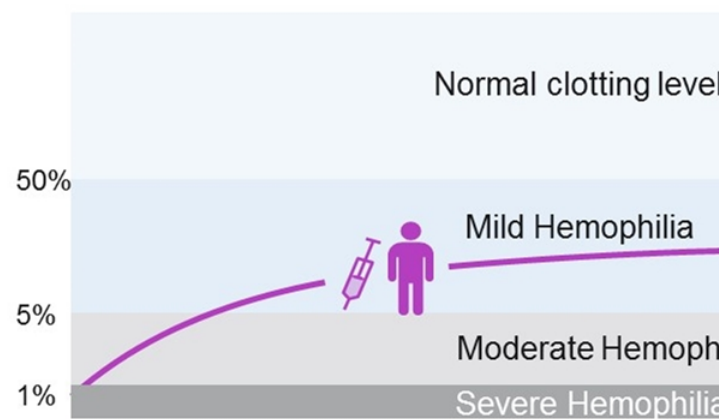
90% reduction in annualized bleed rate



✓ Engineered rFVIIa protease

## Dalcinonacog alfa

Achieved sustained & high target levels of FIX

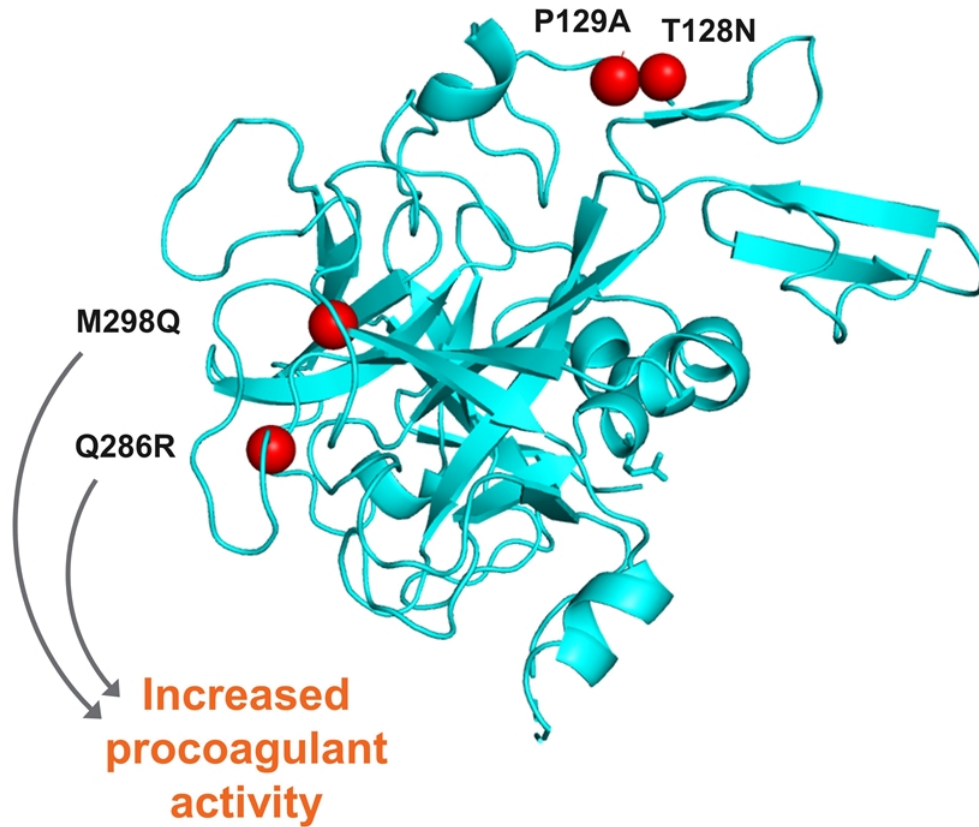


✓ Engineered rFIX protease



# Marzeptacog alfa (activated) – MarzAA: SC

## Addresses a clear unmet need in hemophilia & other



### 9-fold higher a

- + Potency allows
- + Simple, small v

### Preclinical effi

- + HA mouse afte

### P2/3 prophylax HB with inhibi

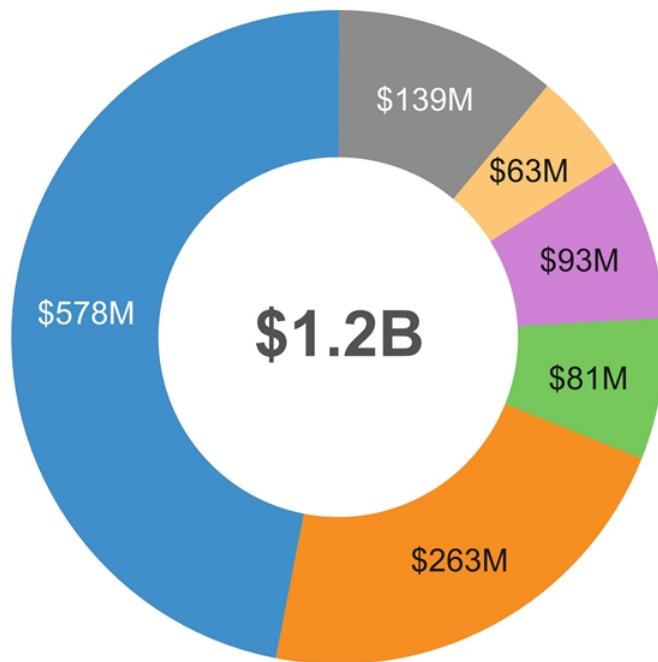
- + 46 patients treat  
3 SQ doses/da

### FDA Fast Trac episodic bleec

- + Granted on 2 I

# SQ MarzAA is a large commercial opportunity

## Global NovoSeven sales breakdown by indication (2019)



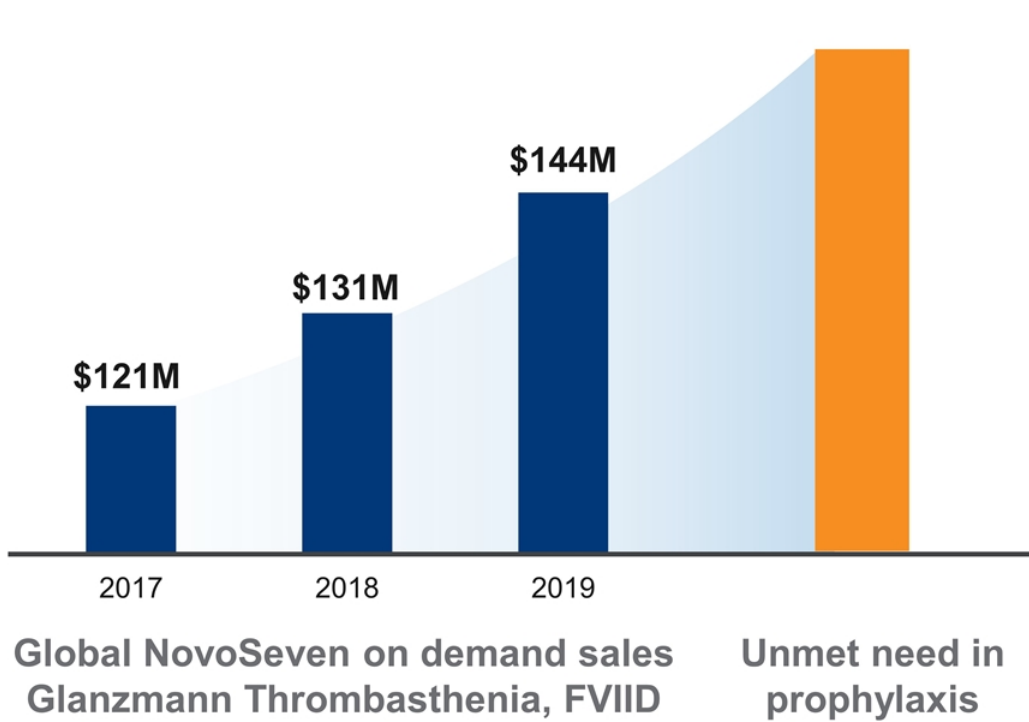
## SQ MarzAA

- ✓ Faster & every 2
- ✓ MarzAA
- ✓ Potential
- ✓ Can be *in vitro*
- ✓ Ideal for access
- ✓ Prophyl

Source: Adivo Ass research. Data on



# MarzAA could be the first prophylaxis for



Source: C  
Data on f  
multiple t  
needing t

# 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<sup>1,2,3</sup>

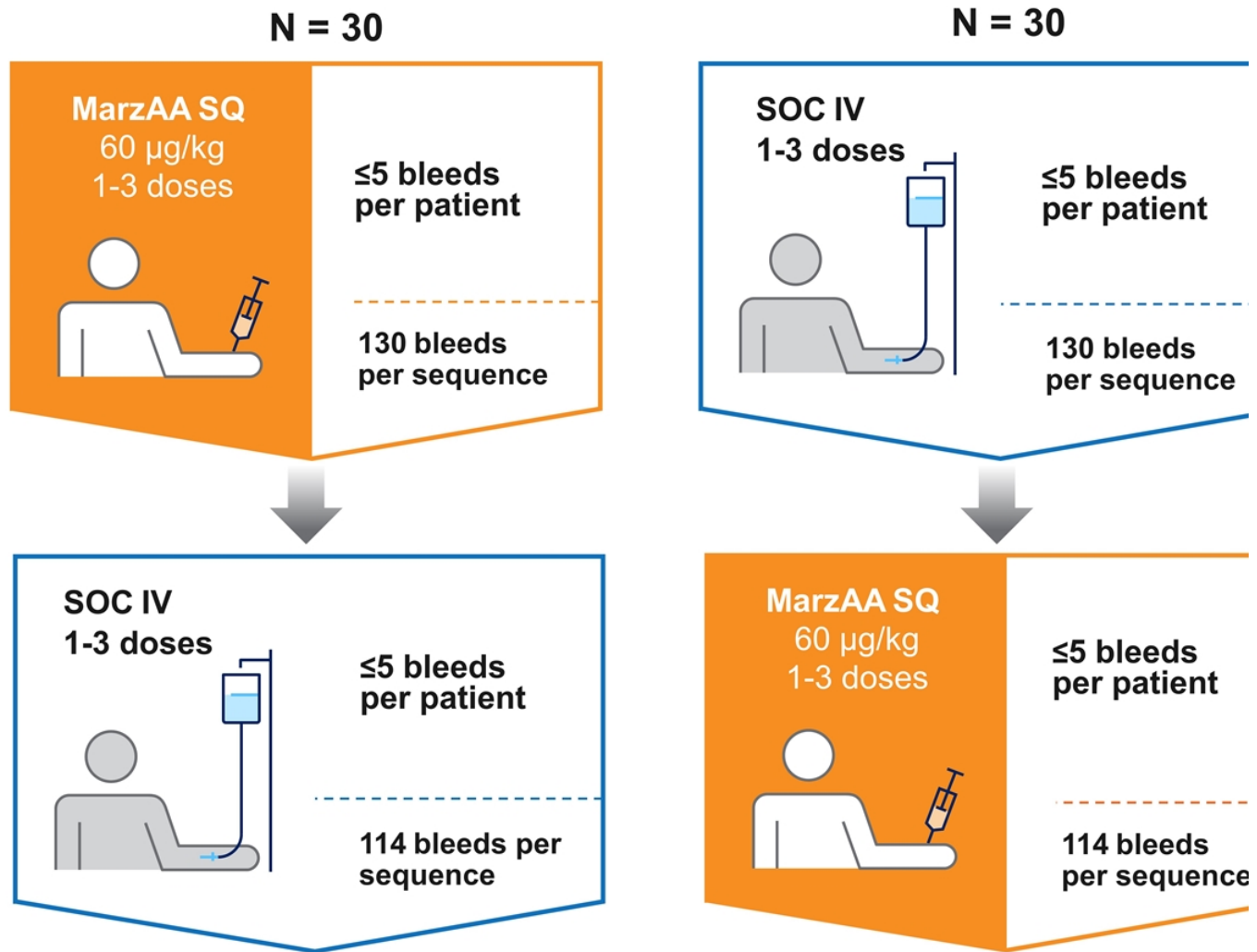
- + MA sup
- + Tar
- + Tar, 18 | 60 |

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

**Clini**

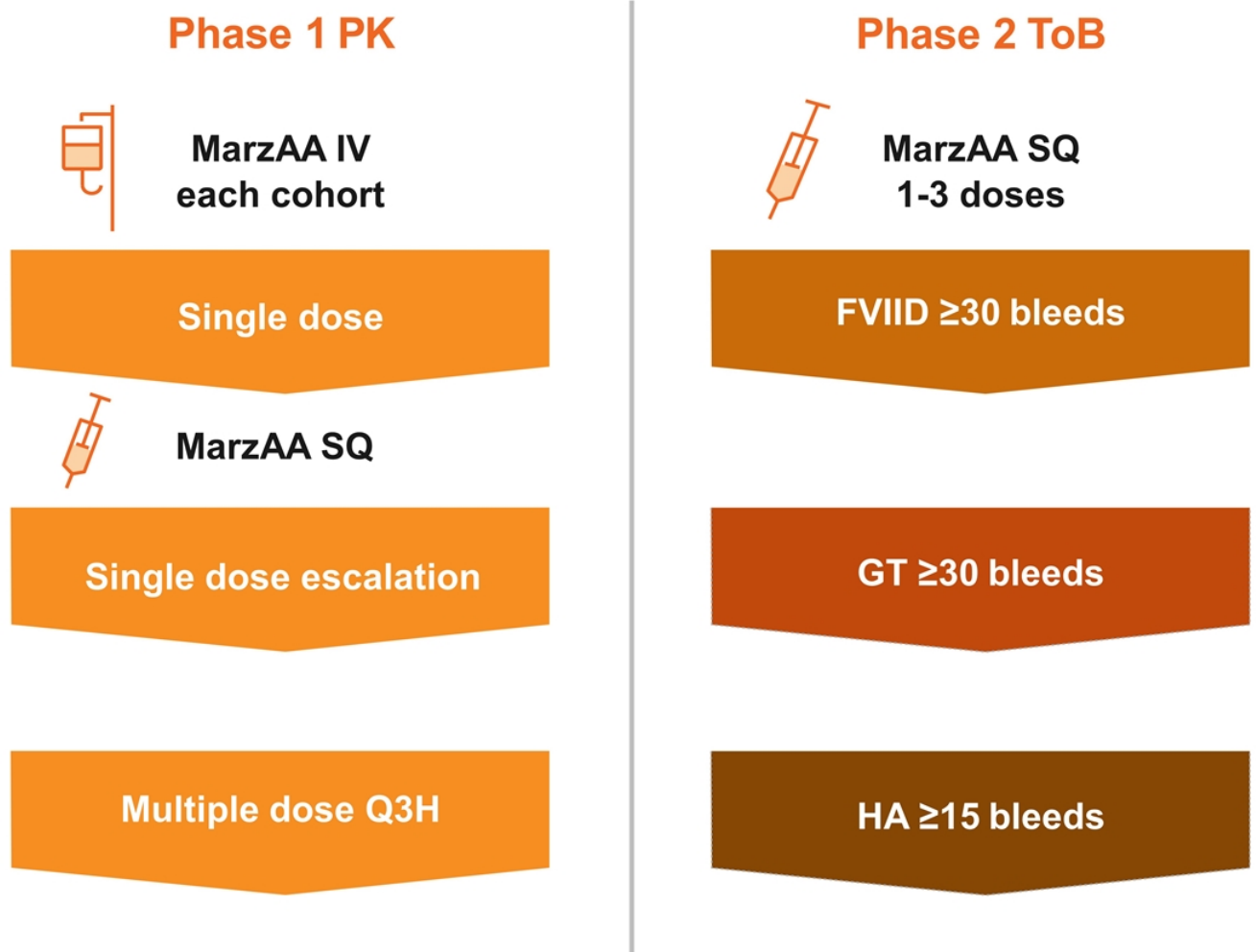
Source: <sup>1</sup>NovoSeven PI Rev 7/2020; <sup>2</sup>Adivo Associates market research; <sup>3</sup>Catalyst Biosciences market

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

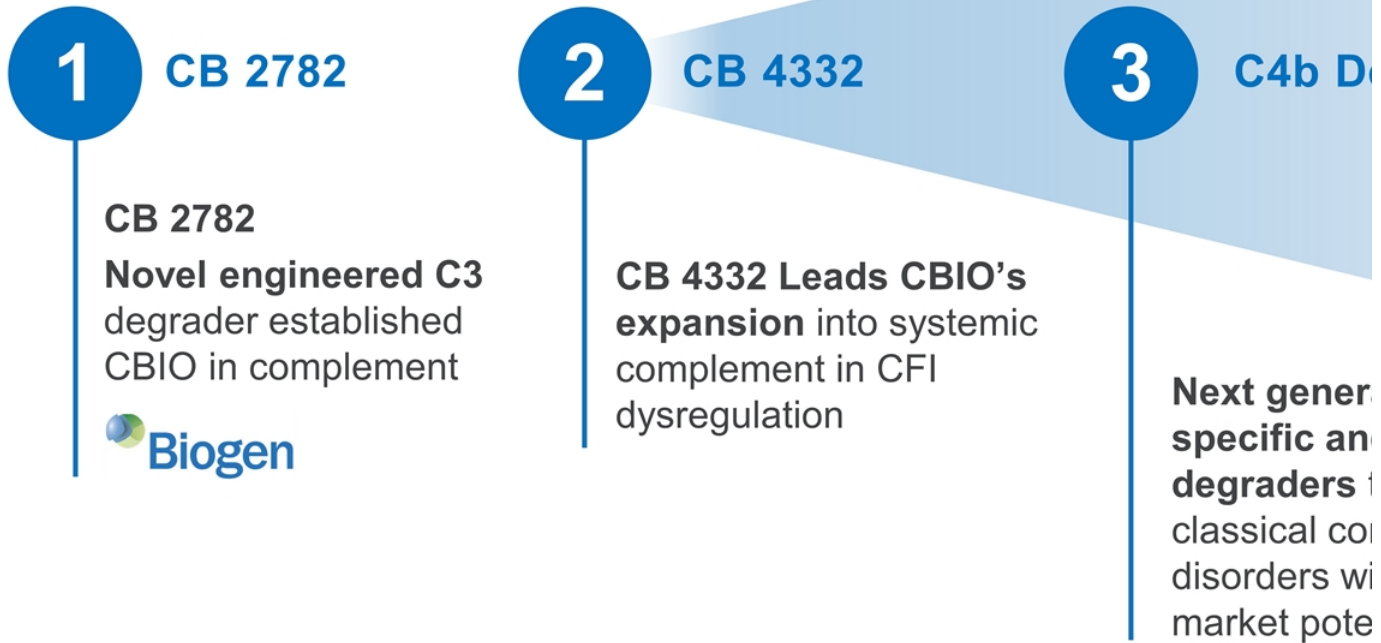


# MAA-202 Phase 1/2 study design

**FVII deficiency, Glanzmann Thrombasthenia and HA**

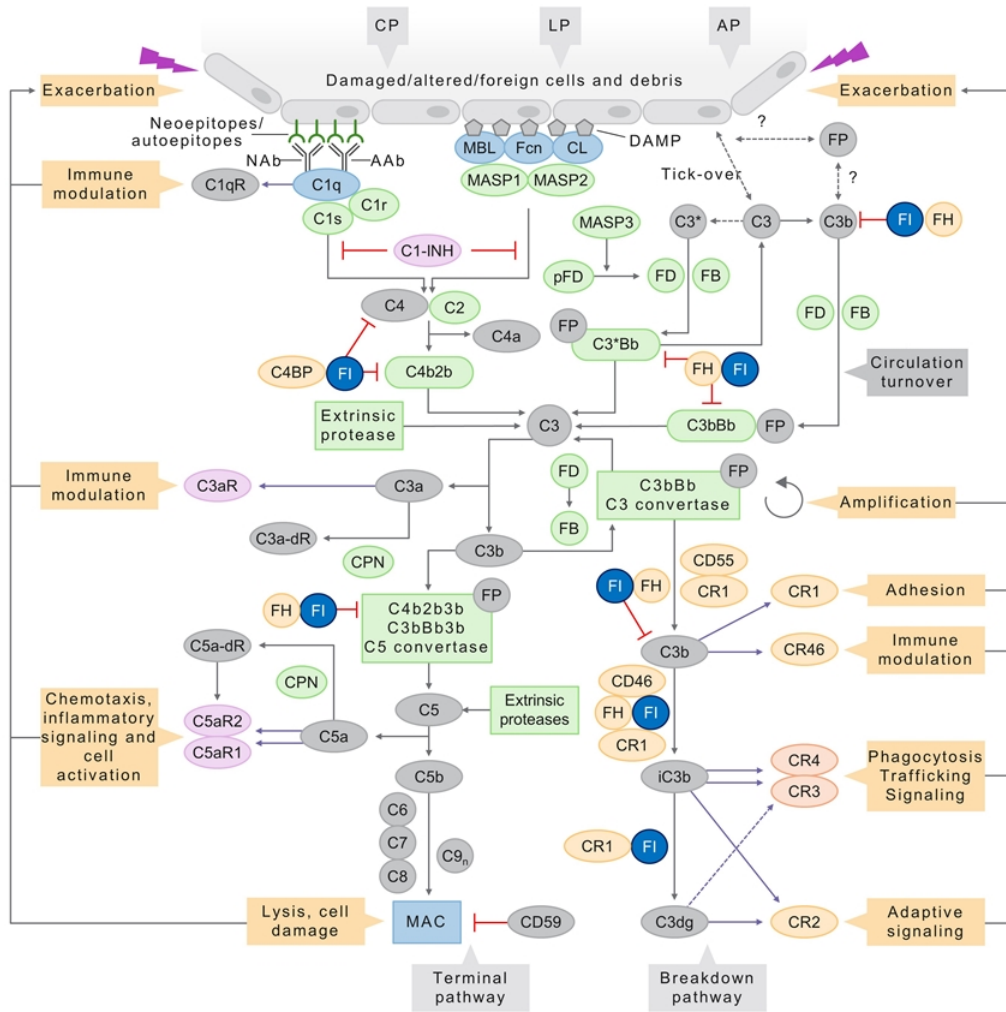


# CBIO's complement pipeline



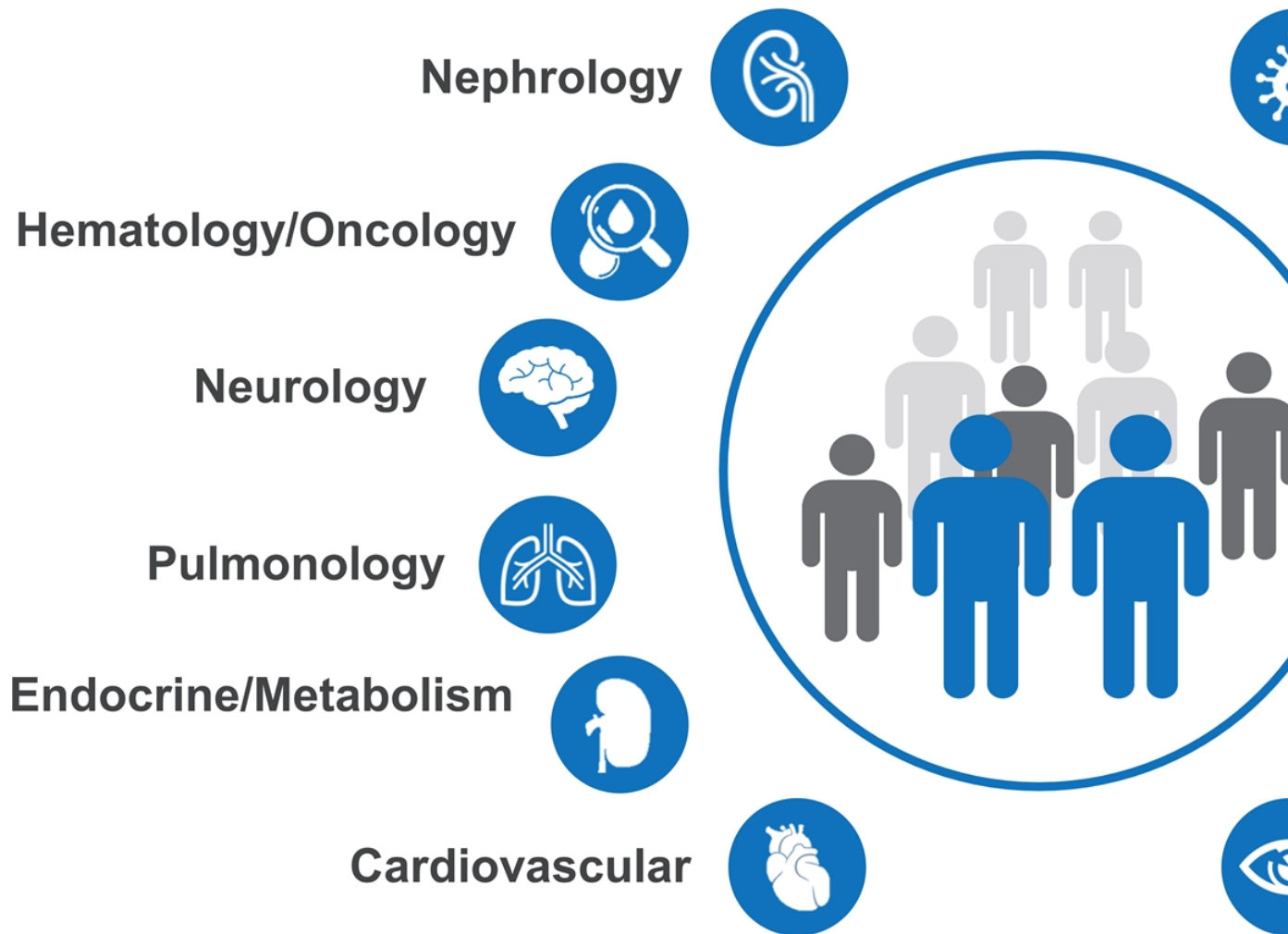
# Complement is a perfect fit to develop pro

## The complement pathway is driven by a protease ca



# Complement plays a critical role in many of

## Late-stage complement therapies projected to achieve

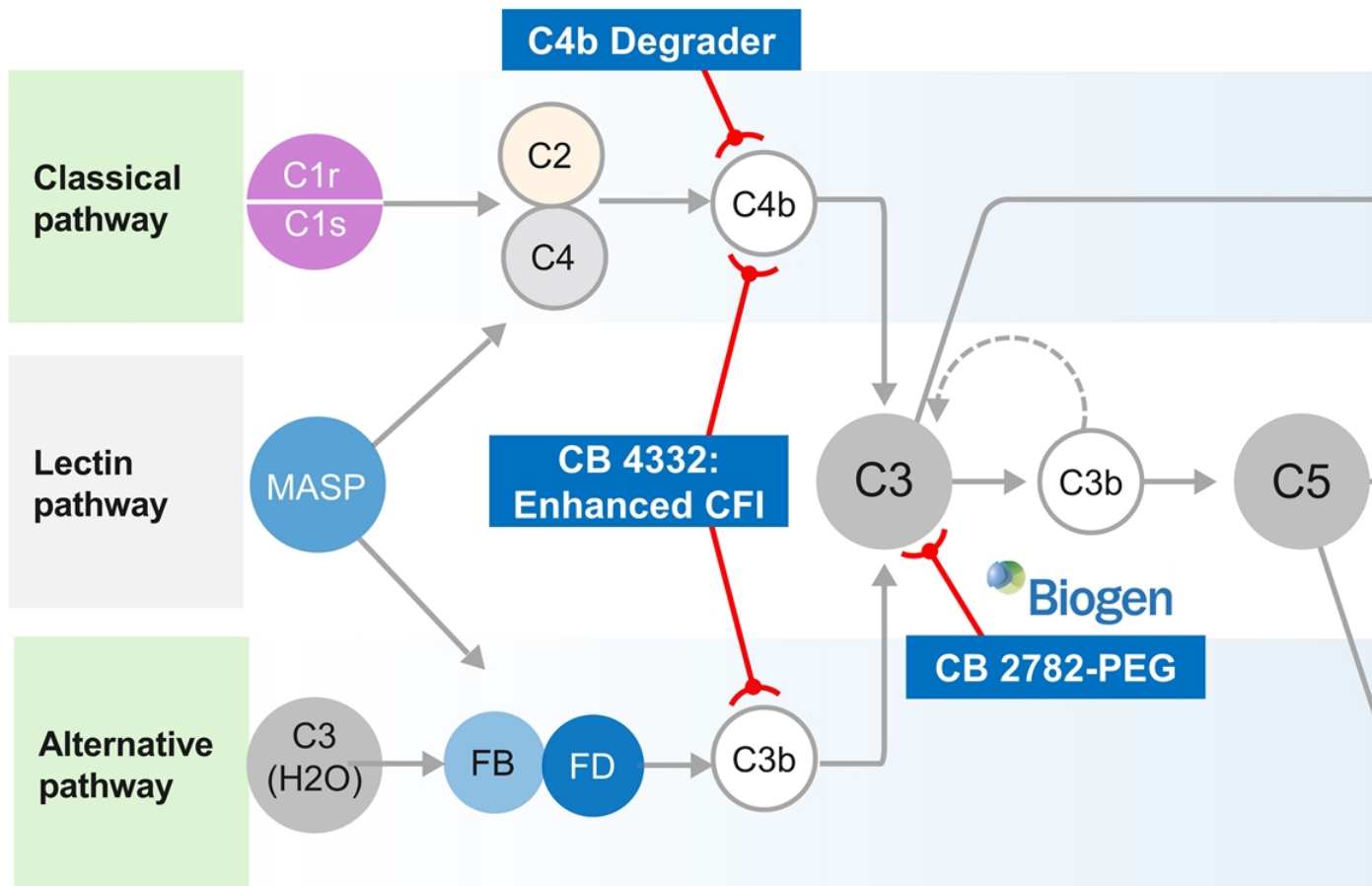


References: Globaldata consensus net sales forecast 2020

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# CBIO is taking a targeted approach to complement inhibition

## Engineered proteases address the root cause of the disease



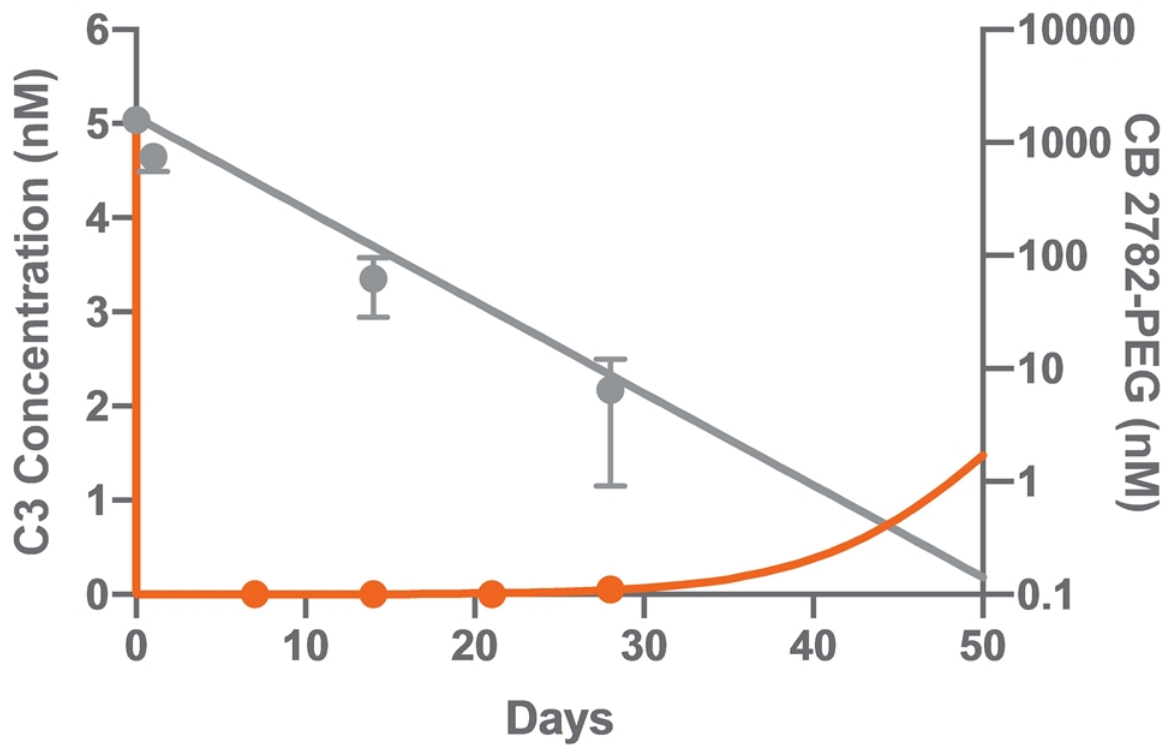
- + Current C5 blockade therapies do not address disease root cause
- + The catalytic power of proteases provides advantages over small molecules



# Protease advantage demonstrated *in vivo*

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

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

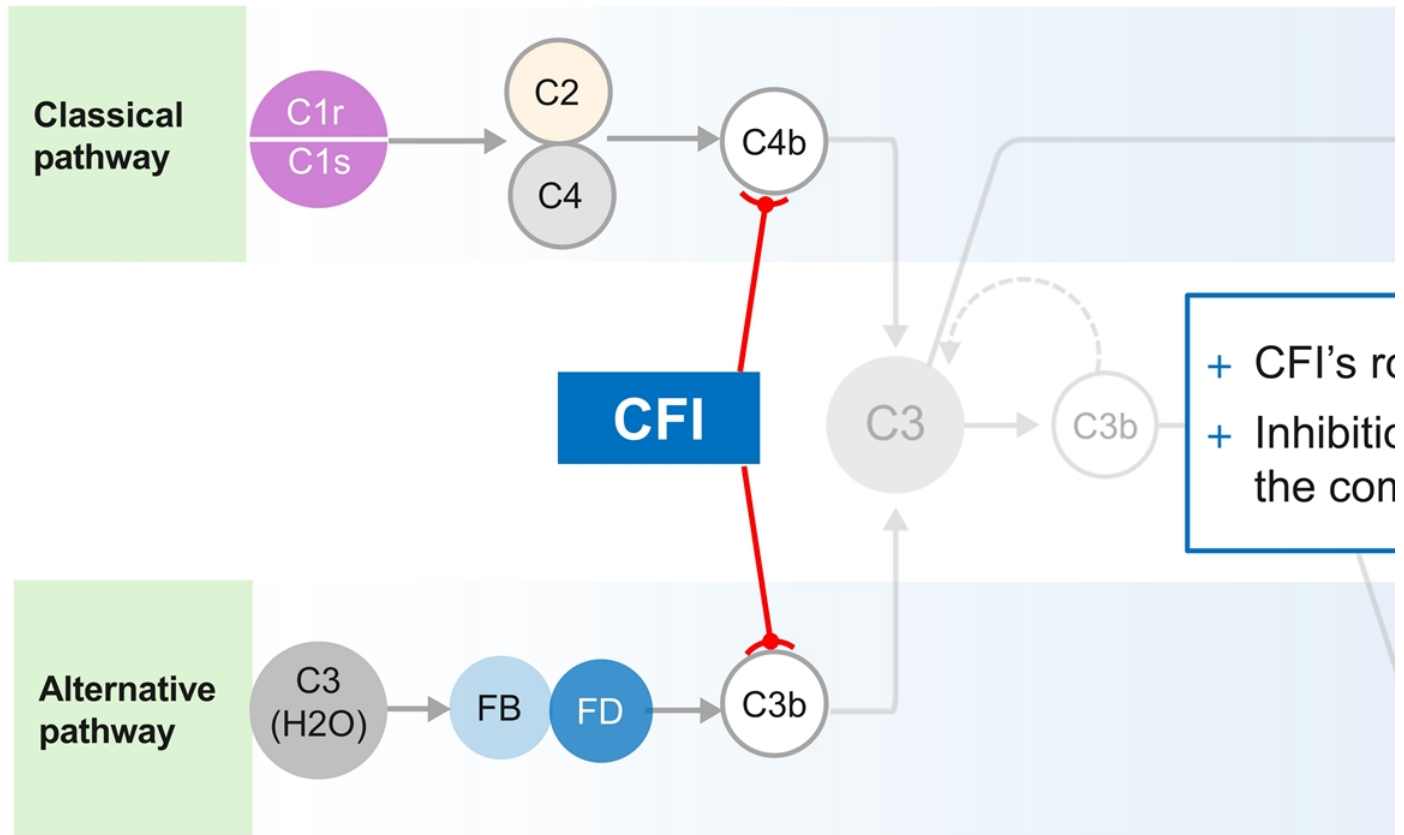
- + Generated from Catalyst's proprietary **protease engineering platform**
- + Potent, selective & long acting, degrades C3 into inactive fragments
- + Preclinical NHP PK & PD data\* predict **best-in-class** human intravitreal d

## Biogen collaboration

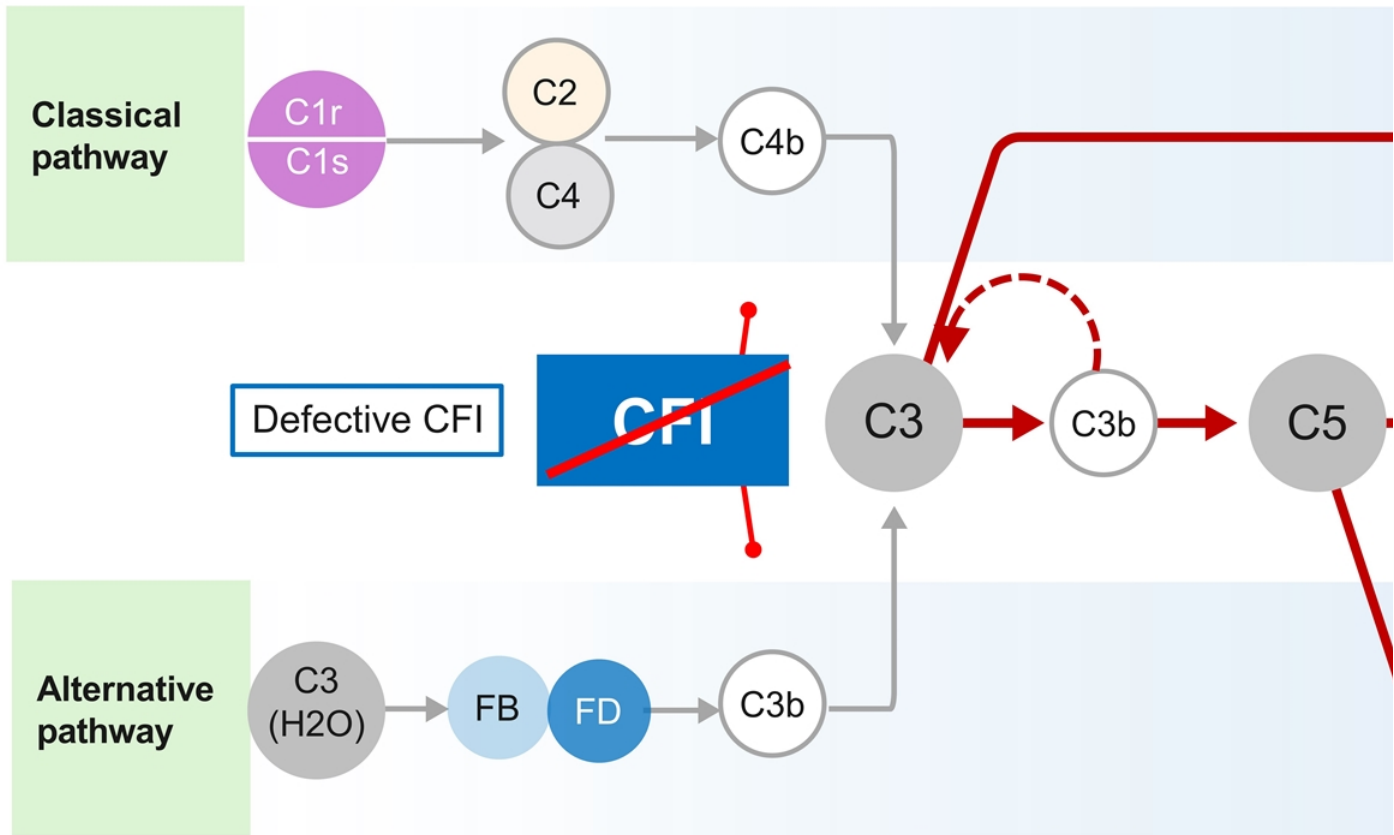
- + \$15M upfront, up to \$340M in milestones and tiered royalties up to low do
- + Catalyst: fully funded pre-clinical and manufacturing activities
- + Biogen: IND-enabling activities, WW clinical development & commercializa

\*Furfine *et al.* ARVO 2019

# Normal CFI: Key central regulator of comp



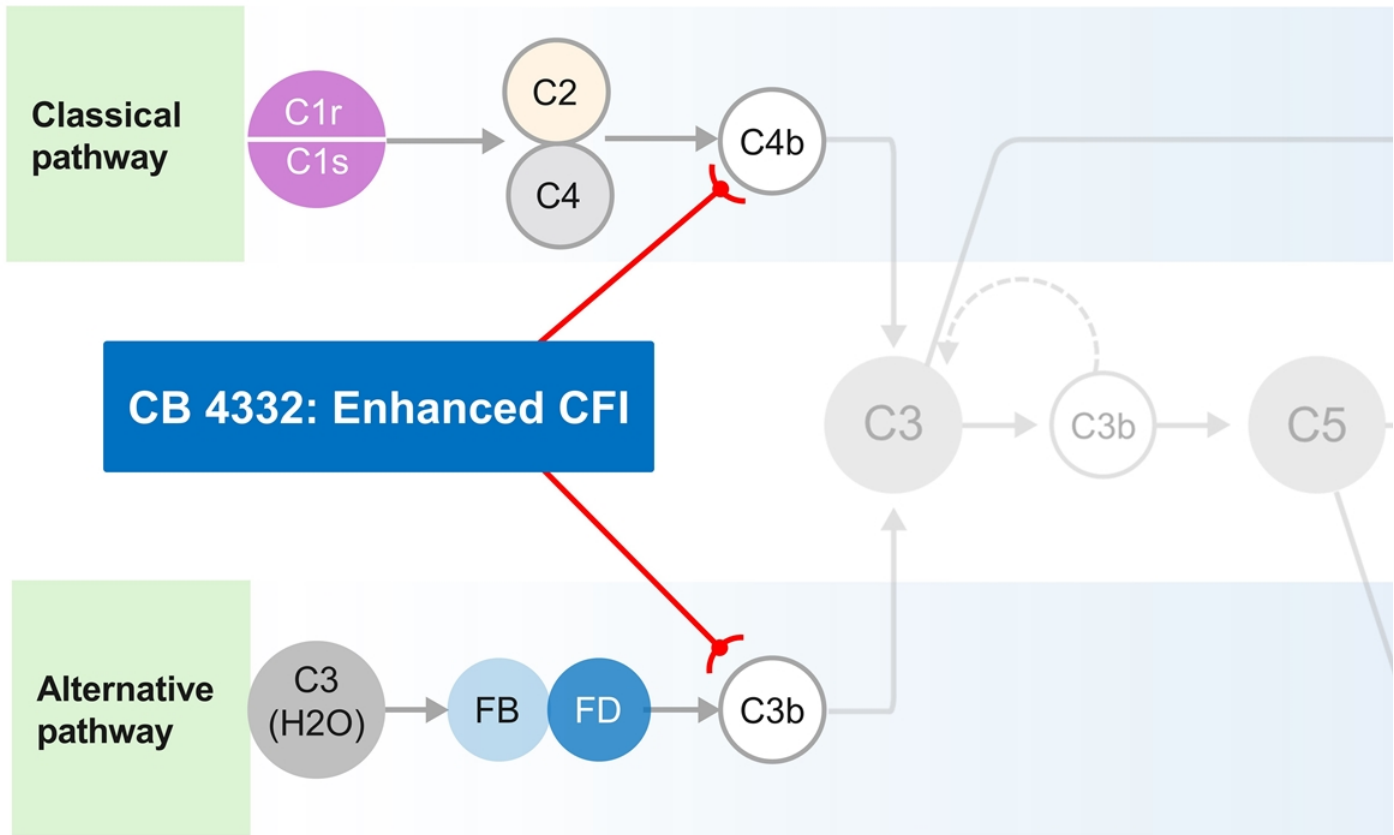
# CFI dysregulation: Lack of proteolytic CFI



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

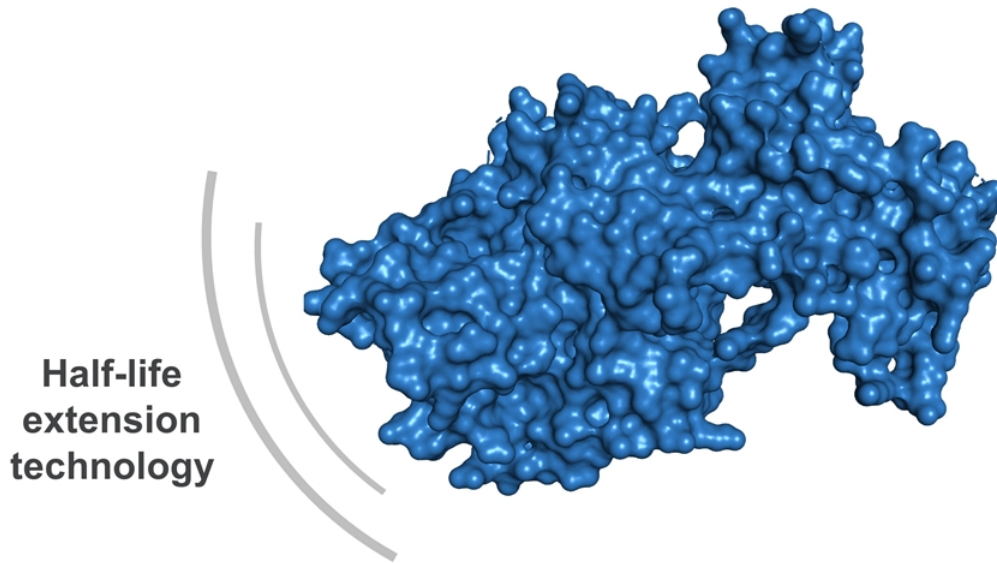
# CB 4332 – CBIO's enhanced CFI

Specifically addresses the problem by restoring CF



# CB 4332: Enhanced Complement Factor I

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

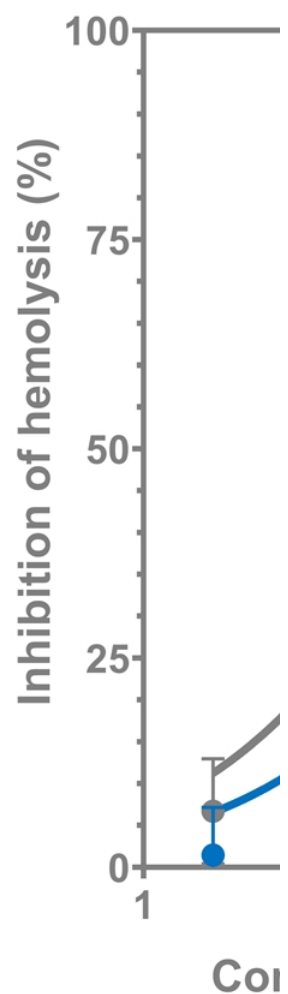
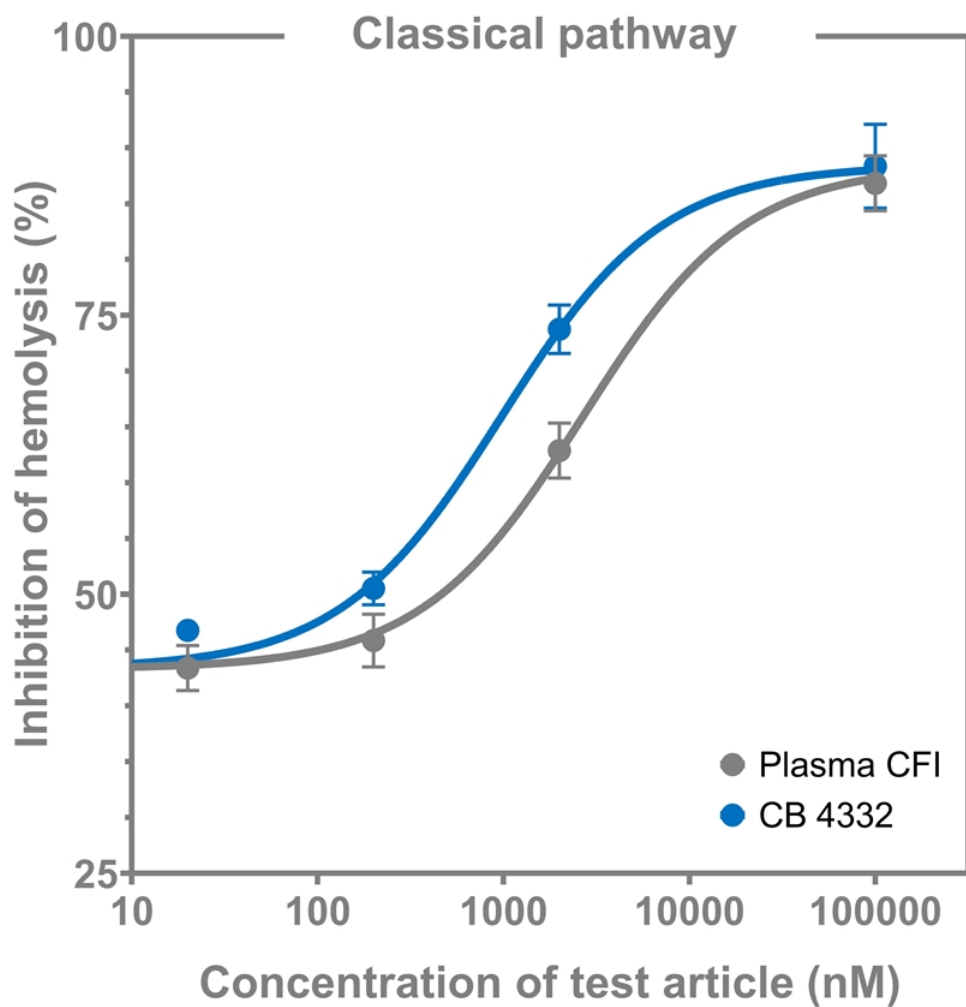


- + **Engineered for an extended half-life**
  - Once weekly SQ therapy – no PEG
- + **Full activity comparable to native CFI**
  - Classical and alternative pathway regulation
- + **Efficient high yield production process**

- + R
- + N
- + T
- + G

References:  
2010; <sup>2</sup>Ferre  
Complement  
PDB 2XRC.

# CB 4332 & plasma CFI perform similarly in



# Diseases with CFI mutations have tremendous

**Current development targets**

**\$500M**

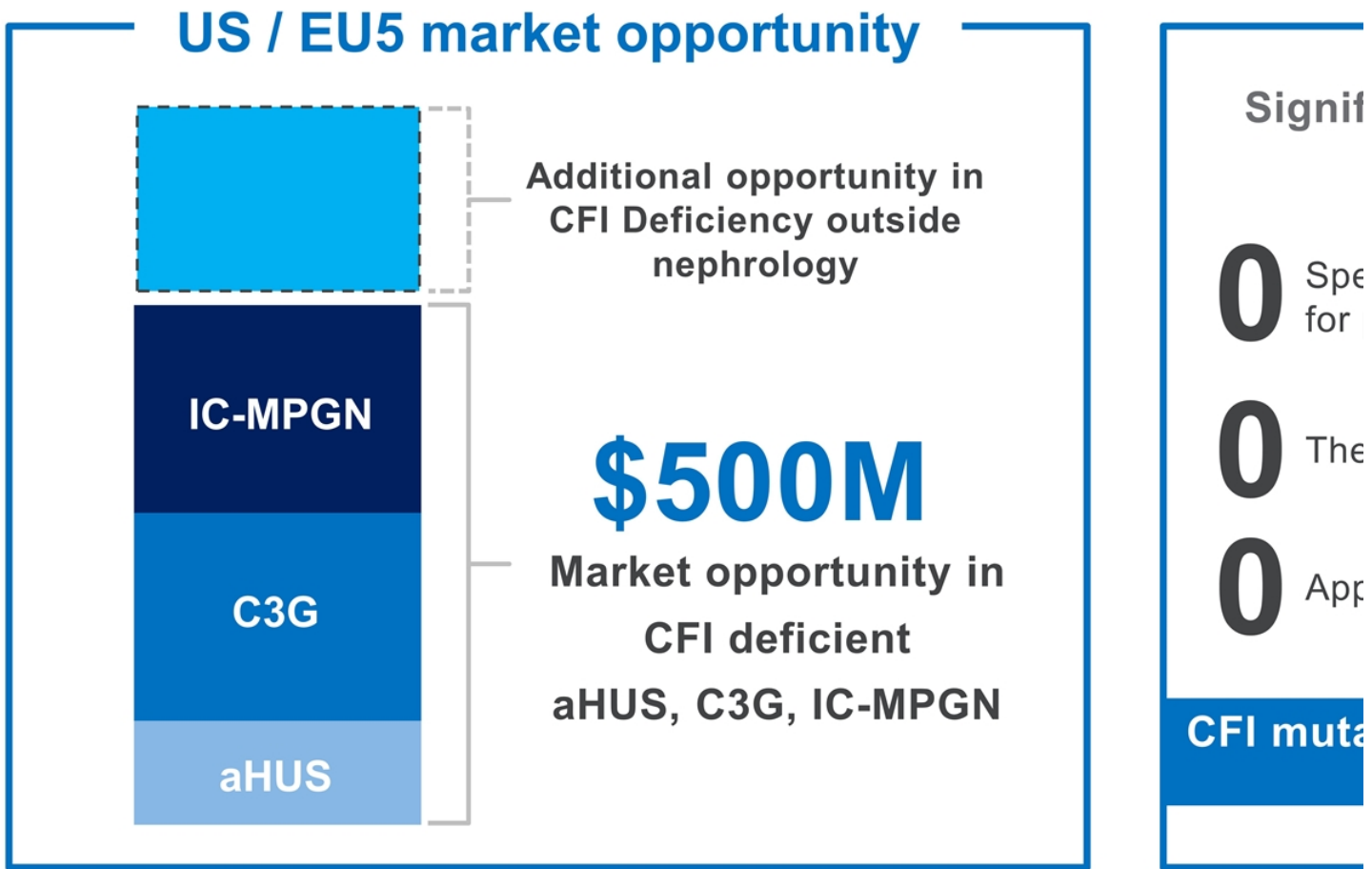
**Potential targets**

**\$10B+**

CFID



# CB 4332 initial market opportunity

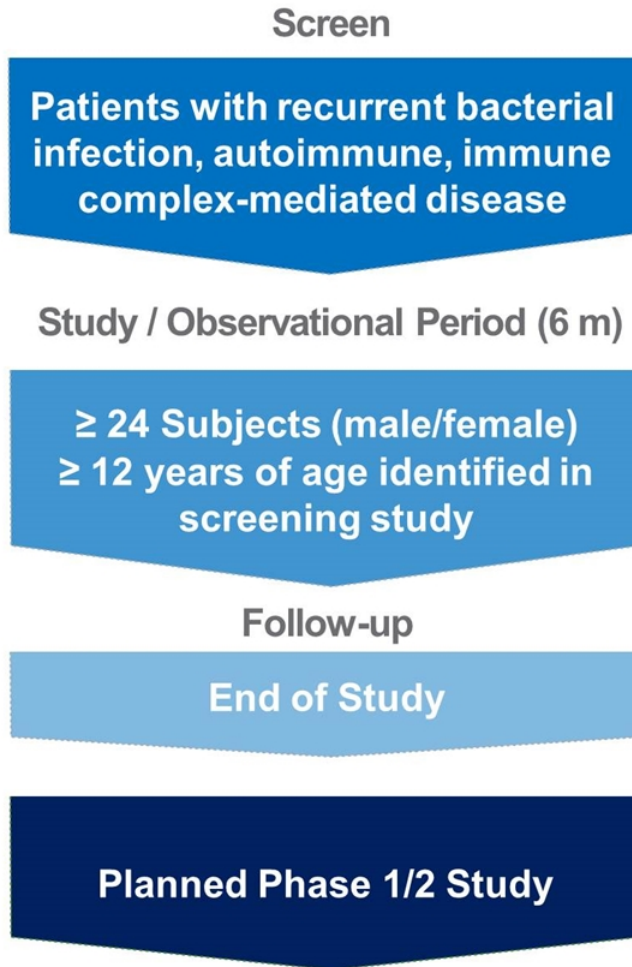


Note: aHUS = atypical Hemolytic Uremic Syndrome, C3G = Complement 3 Glomerulopathy, IC-MPGN = Immune-Complex Mediated Postinfectious Glomerulonephritis

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 observational

## Natural history of CFI deficient patients for subsequent

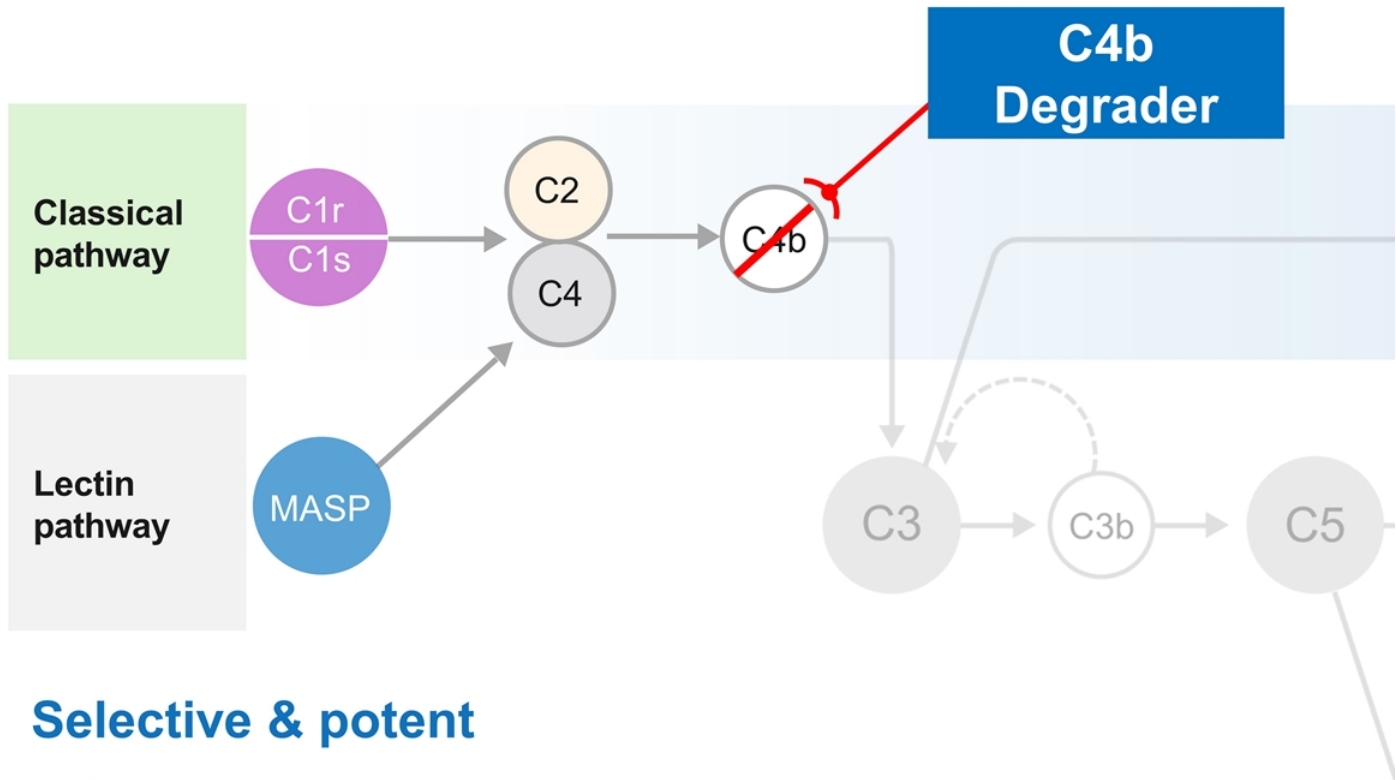


- **Primary O**
  - Demonstrat
  - mutations in
  - immune cor
  - Phase 1/2 s
- **Secondary**
  - Monitor effi
  - Monitor safe
  - Record dos
  - Monitor QoL

### Timeline

Observation  
Global phas  
expected in  
Intend to pu

# 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 process
- + 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



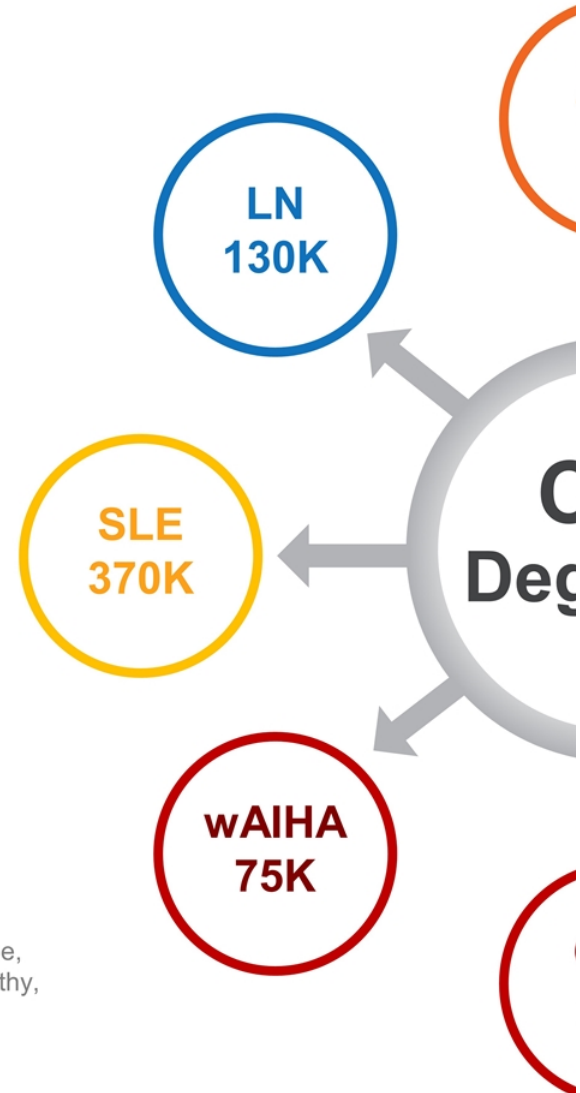
Hematology



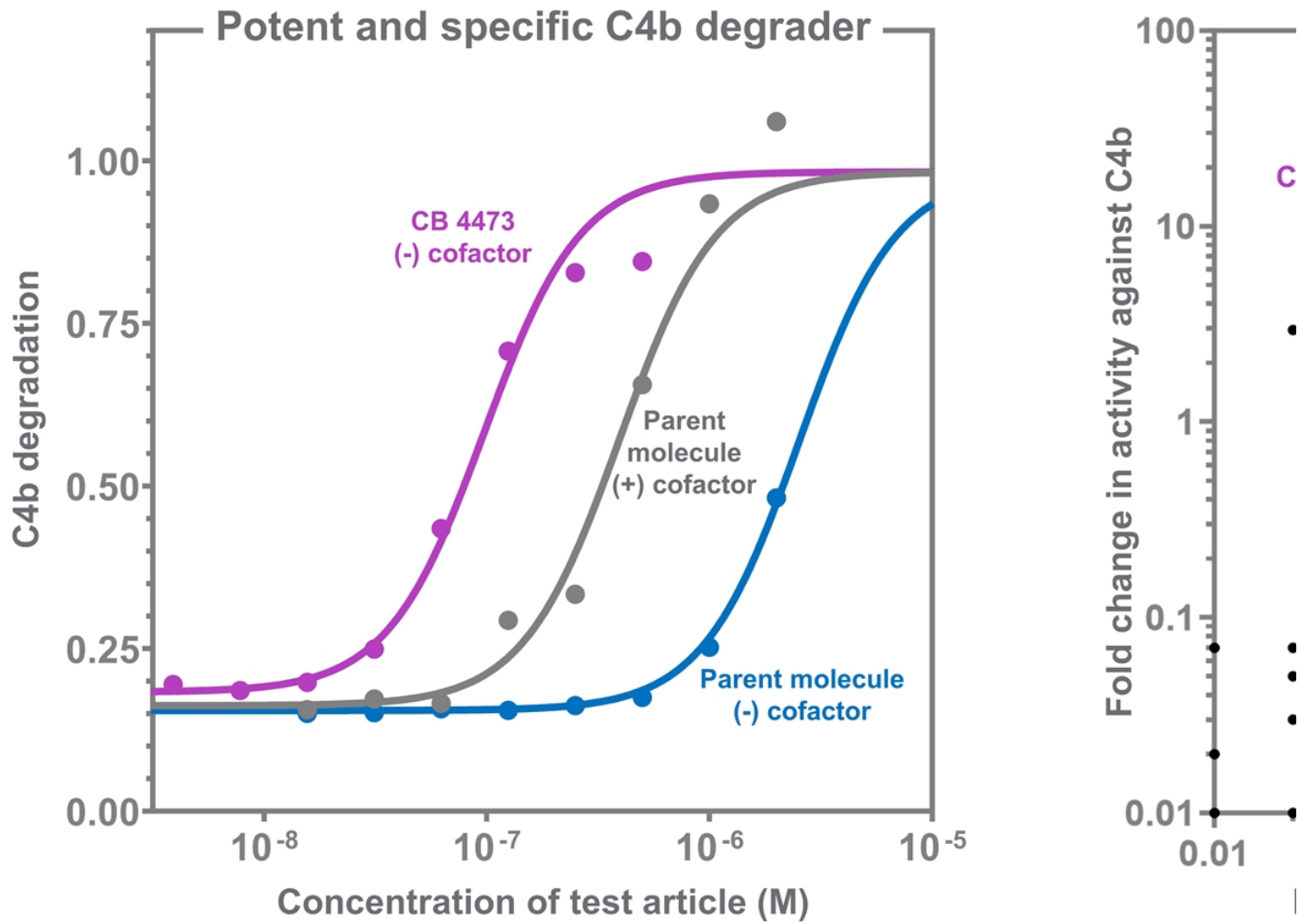
Neurology

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

© Catalyst Biosciences




# CB 4473 demonstrates engineered C4b pc



# Milestones

2021

- CB 4332 observational trial
- MAA 202 PK data
- MAA 304 first DSMB
- C4b degrader updates
- CB 2782-PEG  Biogen.

 MarzAA (FVIIa)

 CB 2782-PEG (dAMD) 

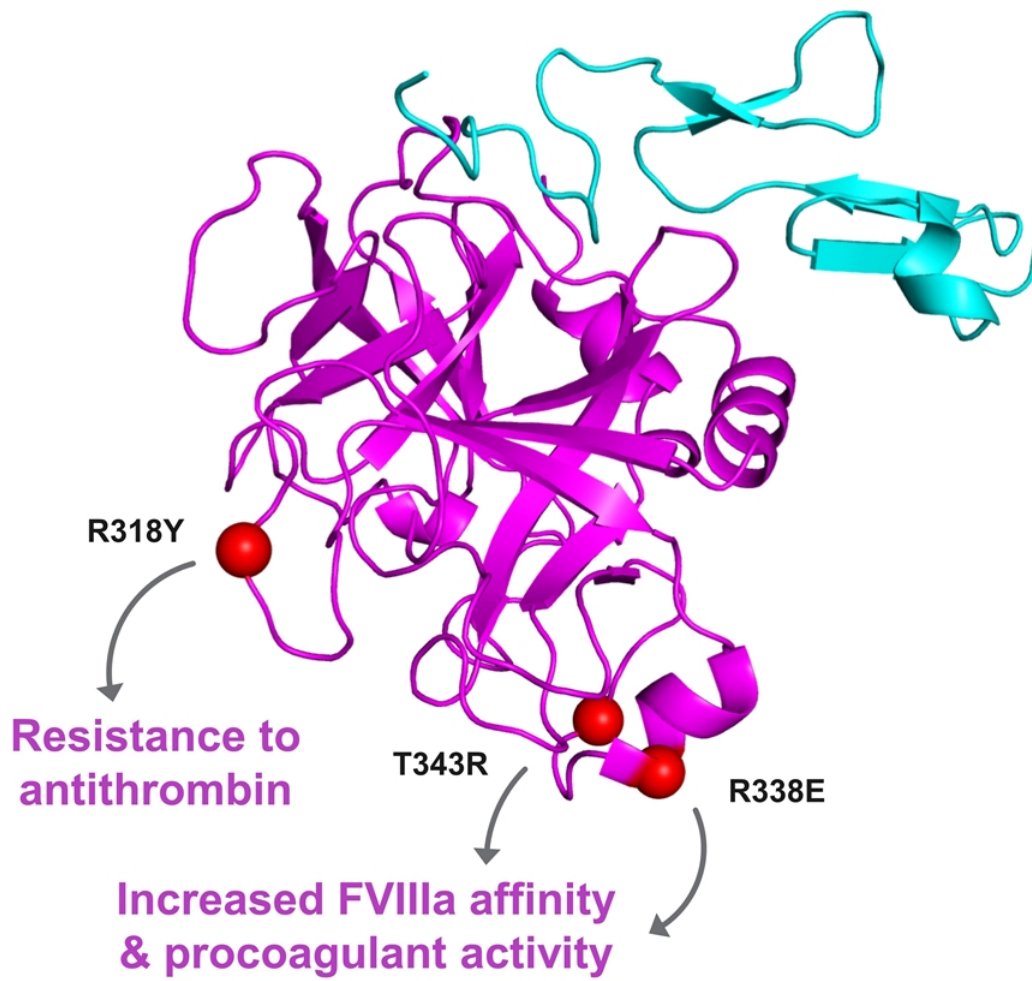
# THANK YOU

**Nasdaq: CBIO**

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

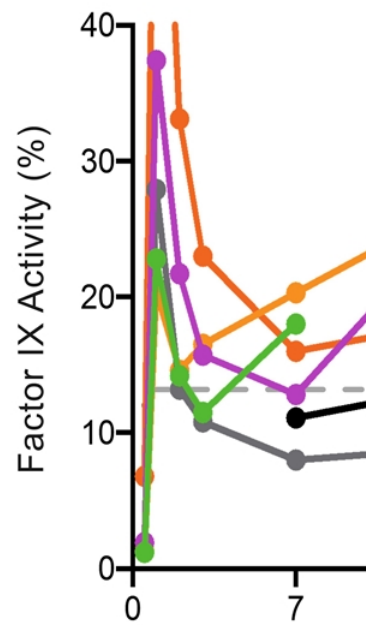
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# DalcA P2b demonstrated efficacy & safety



## Differentiate

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






# Catalyst's CB 2679d gene therapy for hem



FIX Transgene	AAV Capsid	Study Dose (vg/kg)	FIX Activity (U/mL)
<b>CB 2679d-GT</b>	<b>Novel Chimeric</b>	<b>8.0x10<sup>10</sup></b>	<b>20</b>
Padua	TAK-748*	7.4x10 <sup>11</sup>	20
Padua	TAK-748*	7.4x10 <sup>10</sup>	1

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



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