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): May 6, 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 2.02 Results of Operations and Financial Condition.

On May 6, 2021, Catalyst Biosciences, Inc., (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2021. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information set forth in this Item 2.02 (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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, (the "Securities Act") or the Exchange Act, regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure.

On May 6, 2021, 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 99.2.

The information in this Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.2) is being furnished and shall not be deemed "filed" for purposes of Section 18 of 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 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	Press release dated May 6, 2021.
99.2	Presentation slide deck.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: May 6, 2021

/s/ Clinton Musil
Clinton Musil
Chief Financial Officer

Catalyst Biosciences Reports First Quarter 2021 Operating & Financial Results and Provides a Corporate Update

SOUTH SAN FRANCISCO, Calif. – May 6, 2021 – Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced its operating and financial results for the first quarter ended March 31, 2021 and provided a corporate update.

"We made significant progress across our Protease Medicines platform, specifically in our complement and hemostasis programs. We are preparing to initiate an observational trial in patients who have diseases related to CFI deficiency in mid-year 2021 to support our SQ enhanced CFI development candidate CB 4332 that will enter the clinic in 2022," said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. "In hemostasis, we dosed our first subject in the Crimson 1 Phase 3 registrational study of MarzAA, our next generation SQ FVIIa, in hemophilia A or B with inhibitors and are enrolling patients in a Phase 1/2 trial in other rare bleeding disorders."

Recent Milestones

- **Marzeptacog alfa (activated) – MarzAA:** Catalyst announced the dosing of the first patient in the Company's Phase 3 registration trial (Crimson 1– MAA-304).
- **Complement Factor 3 Degrader Program:** Catalyst expanded its intellectual property estate and protection of its complement assets with the issuance of U.S. Patent Number 10,954,501 B2 entitled: "Nucleic Acid Encoding Modified Membrane Type Serine Protease 1 (MTSP-1) Polypeptides and Methods of Use." The patent covers nucleic acids encoding modified proteases that selectively cleave and degrade complement factor 3 (C3) including CB 2782-PEG licensed to Biogen for dry age-related macular degeneration.
- **Factor IX (FIX) Gene Therapy Program:** Catalyst announced publication of preclinical FIX gene therapy data for CB 2679d-GT in *Blood*, the Journal of American Society of Hematology. The paper, entitled: "Gene Therapy for Hemophilia B Using CB 2679d-GT: A Novel Factor IX Variant with Higher Potency than Factor IX Padua," demonstrated superiority of the Company's CB 2679d-GT gene therapy candidate over that of the R338L-Padua variant, which is currently used in clinical trials.

Expected Milestones

- **Systemic Complement Program:**
  - Commence enrollment of an observational trial in mid-2021 assessing the blood levels of CFI in patients who have diseases related to CFI deficiency in order to identify those who would benefit from CB 4332 treatment;
  - Provide additional preclinical data supporting continued development of the C4b degrader program and other complement assets.
- **MarzAA**
  - Announce first patient dosed in the Phase 1/2 trial (MAA 202) for the treatment of episodic bleeding in FVII Deficiency, Glanzmann Thrombasthenia, and Hemlibra patients;
  - Submit the first Crimson 1 report to the Data and Safety Monitoring Board (DSMB).

First Quarter 2021 Results and Financial Highlights

- Cash, cash equivalents and short-term investments, as of March 31, 2021 were $107.0 million.
- Research and development expenses were $17.0 million and $13.3 million during the three months ended March 31, 2021 and 2020, respectively, an increase of $3.7 million, or 28%. The increase was due primarily to preclinical and personnel related costs.
- General and administrative expenses were $5.4 million and $3.7 million during the three months ended March 31, 2021 and 2020, respectively, an increase of $1.7 million, or 47%. The increase was due primarily to an increase of $0.8 million in personnel-related costs, and an increase of $0.8 million in professional services.
- Interest and other (expense), net was $0.0 million and $1.0 million during the three months ended March 31, 2021 and 2020, respectively, a decrease of $1.0 million, or 100%. The decrease was primarily due to a decreased interest rate and due to the payment received in the first quarter of 2020 under an agreement associated with neuronal nicotinic receptor asset sold in 2016.
- Net loss attributable to common stockholders for the three-months ended March 31, 2021 was $22.4 million, or ($0.79) per basic and diluted share, compared with $4.1 million, or ($0.28) per basic and diluted share, for the prior year period.
- As of March 31, 2021, the Company had 28,385,432 shares of common stock outstanding.

About Catalyst Biosciences, the Protease Medicines company

Catalyst is a research and clinical development biopharmaceutical company focused on addressing unmet medical needs in rare disorders of the complement and coagulation systems. Our protease engineering platform has generated two late-stage clinical programs, including MarzAA, a subcutaneously (SQ) administered next-generation engineered coagulation Factor VIIa (FVIIa) for the treatment of episodic bleeding in subjects with rare bleeding disorders. Our complement pipeline includes a preclinical C3-degrader program licensed to Biogen for dry age-related macular degeneration, an improved complement factor I protease for SQ replacement therapy in patients with CFI deficiency and C4b-degraders designed to target disorders of the classical complement pathway as well as other complement programs in development.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements about the potential benefits of products based on Catalyst's engineered protease platform, plans to continue enrolling a Phase 3 open-label trial and a Phase 1/2 trial of MarzAA, submit the first report to the Data and Safety Monitoring Board (DSMB), commence enrollment of an observational trial in CB 4332 in mid-2021 and a clinical trial in 2022, and the scope of the Company's intellectual property protection for its complement programs. 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 or events to differ materially, including, but not limited to, the risk that trials and studies may be delayed as a result of COVID-19, competitive products and other factors, that trials may not have satisfactory outcomes, that additional human trials will not replicate the results from earlier trials, that potential adverse effects may arise from the testing or use of MarzAA, including the generation of neutralizing antibodies, the risk that costs required to develop or manufacture the Company's products will be higher than anticipated, including as a

result of delays in trial enrollment, development and manufacturing resulting from COVID-19 and other factors, the risk that the Company's patents may be held invalid or may not provide the scope of coverage anticipated, competition and other risks described in the "Risk Factors" sections of the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 4, 2021, and in other filings with the Securities and Exchange Commission. The Company does not assume any obligation to update any forward-looking statements, except as required by law.

Contact:

Ana Kapor
Catalyst Biosciences, Inc.
investors@catbio.com

Catalyst Biosciences, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	March 31, 2021 (Unaudited)	December 31,2020
Assets		
Current assets:		
Cash and cash equivalents	$ 83,044	$ 30,360
Short-term investments	23,956	48,994
Accounts receivable	1,006	3,313
Prepaid and other current assets	8,514	6,843
Total current assets	116,520	89,510
Long-term investments	—	2,543
Other assets, noncurrent	528	528
Right-of-use assets	1,646	1,832
Property and equipment, net	382	433
Total assets	$ 119,076	$ 94,846
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,956	$ 5,931
Accrued compensation	2,232	2,476
Deferred revenue	1,332	1,983
Other accrued liabilities	6,983	6,743
Operating lease liability	678	663
Total current liabilities	14,181	17,796
Operating lease liability, noncurrent	806	981
Total liabilities	14,987	18,777
Commitments and Contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized; zero shares issued and outstanding	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized; 31,331,027 and 22,097,820 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	31	22
Additional paid-in capital	441,252	390,803
Accumulated other comprehensive income	5	5
Accumulated deficit	(337,199)	(314,761)
Total stockholders' equity	104,089	76,069
Total liabilities and stockholders' equity	$ 119,076	$ 94,846

Catalyst Biosciences, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31, 2021	Three Months Ended March 31, 2020
License	$ —	$ 15,045
Collaboration	1,467	1,321
License and collaboration revenue	1,467	16,366
Operating expenses:		
Cost of license	—	3,047
Cost of collaboration	1,480	1,432
Research and development	17,013	13,264
General and administrative	5,412	3,691
Total operating expenses	23,905	21,434
Loss from operations	(22,438)	(5,068)
Interest and other income (expense), net	—	1,015
Net loss	$ (22,438)	$ (4,053)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.79)	$ (0.28)
Shares used to compute net loss per share attributable to common stockholders, basic and diluted	28,385,432	14,592,451

CATALYST BIOSCIENCES

Corporate Overview

6 May 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 dosing of a first patient in 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
filed with the SE
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Company's viev
does not assun
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CATALYST BIOSCIENCES

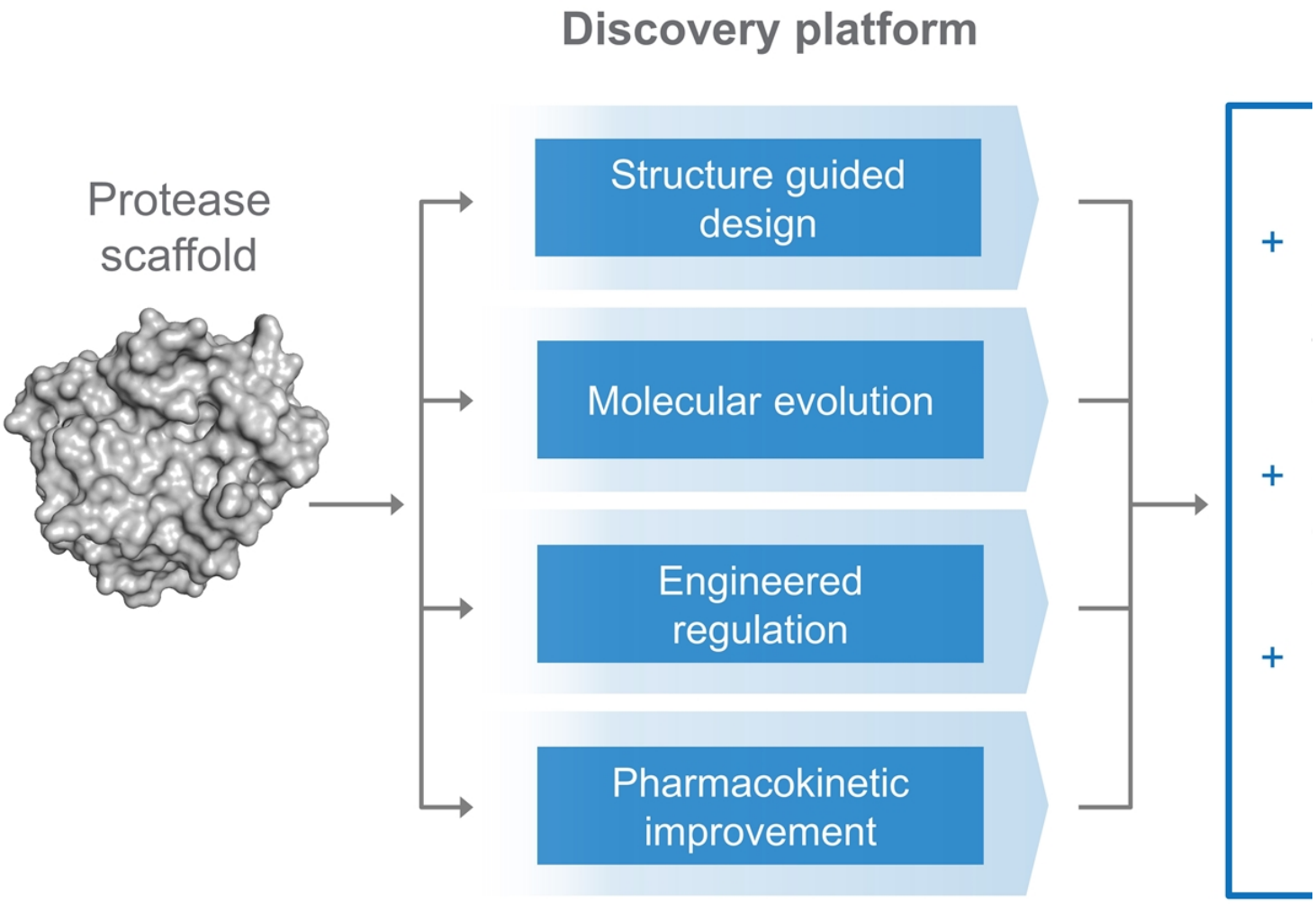
The Protease Medicines Company

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

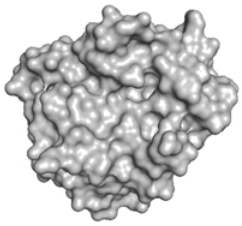
Unique expertise in protease biology enables design of op

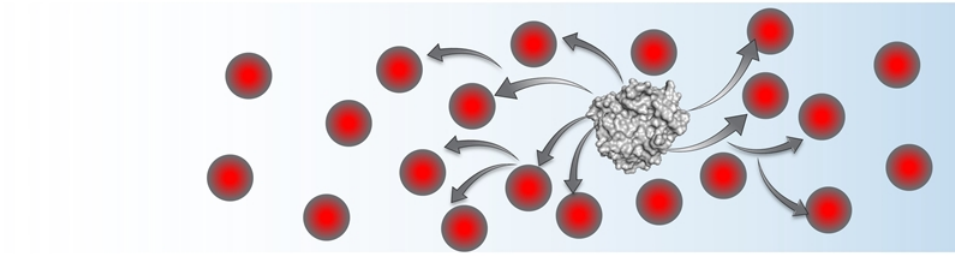


Proteases are ideal for high abundancy ta

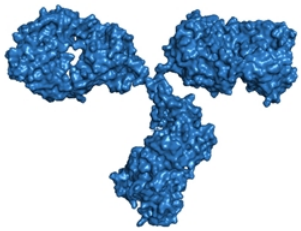
A better way to regulate biological processes compared w

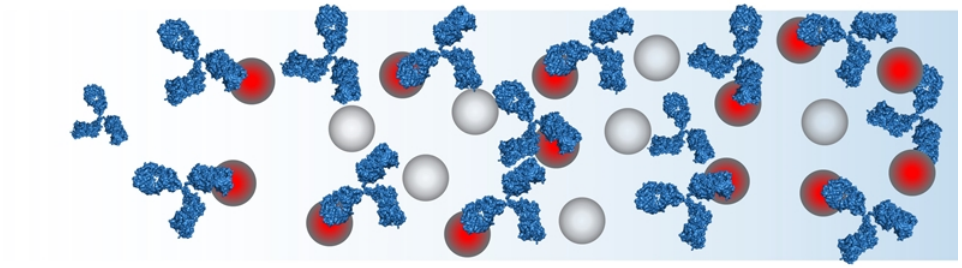
Proteases



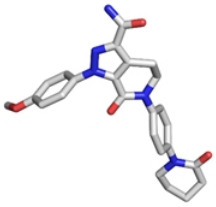


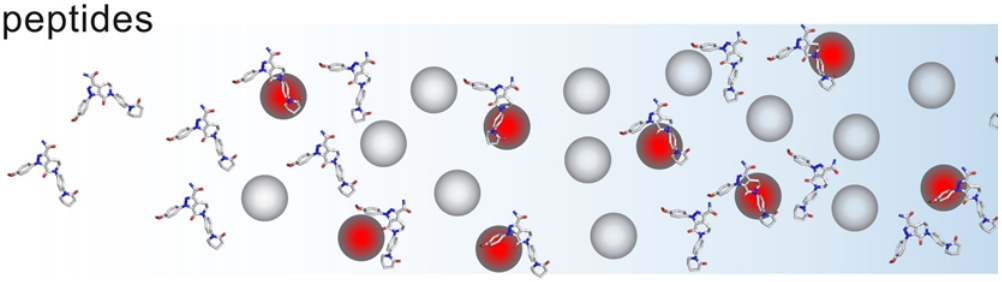
Antibodies



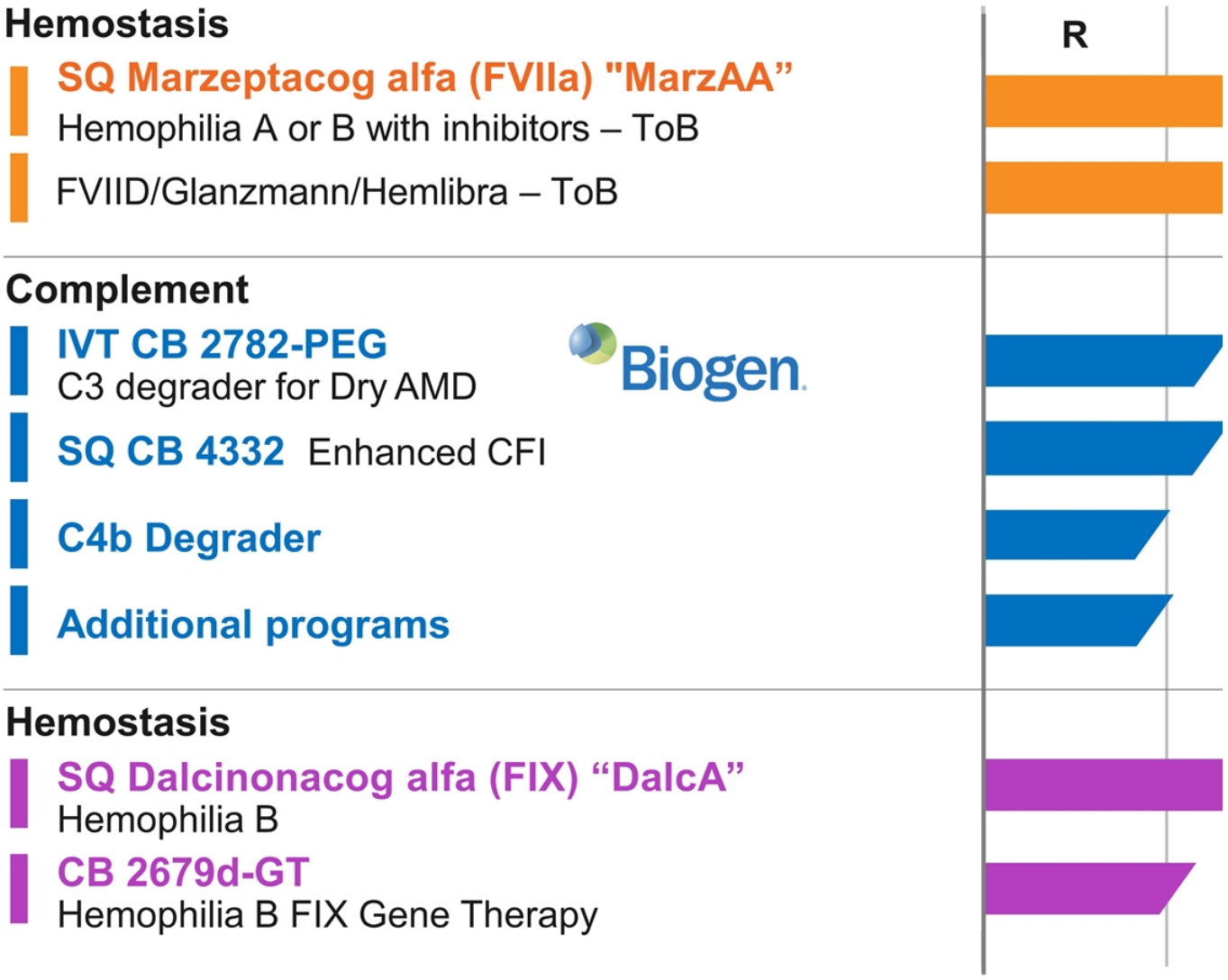


Small molecules / peptides





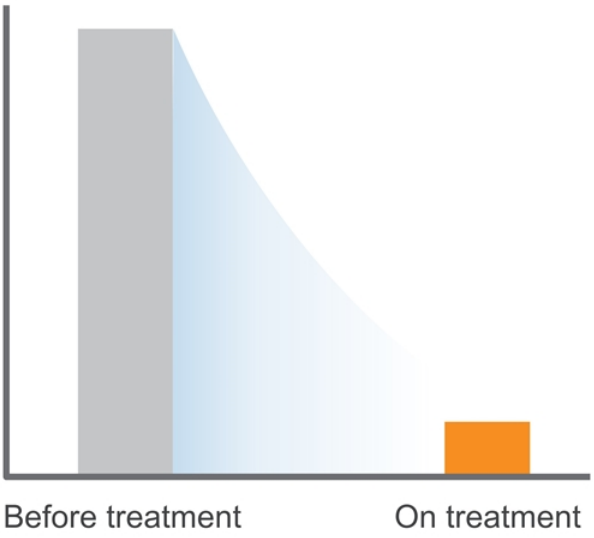
Pipeline



Clinical & partnering success of the CBIO

Marzeptacog alfa (activated)

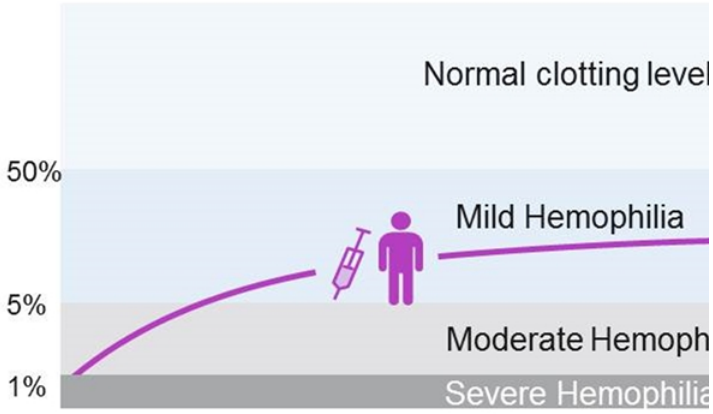
90% reduction
in annualized bleed rate



Engineered
rFVIIa protease

Dalcinonacog alfa

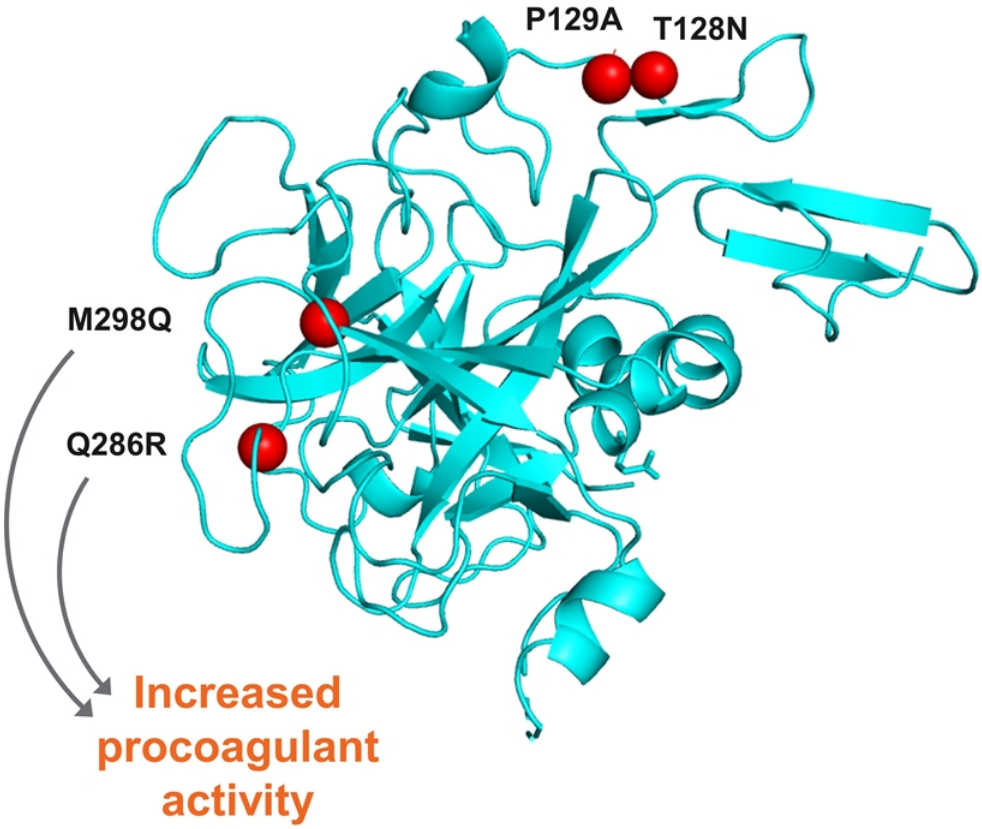
Achieved sustained
& high target levels of FIX



Engineered
rFIX protease

Marzeptacog alfa (activated) – MarzAA: SC

Addresses a clear unmet need in hemophilia & othe



9-fold higher a

+ Potency allows
+ Simple, small v

Preclinical effi

+ HA mouse afte

P2/3 prophylax HB with inhibi

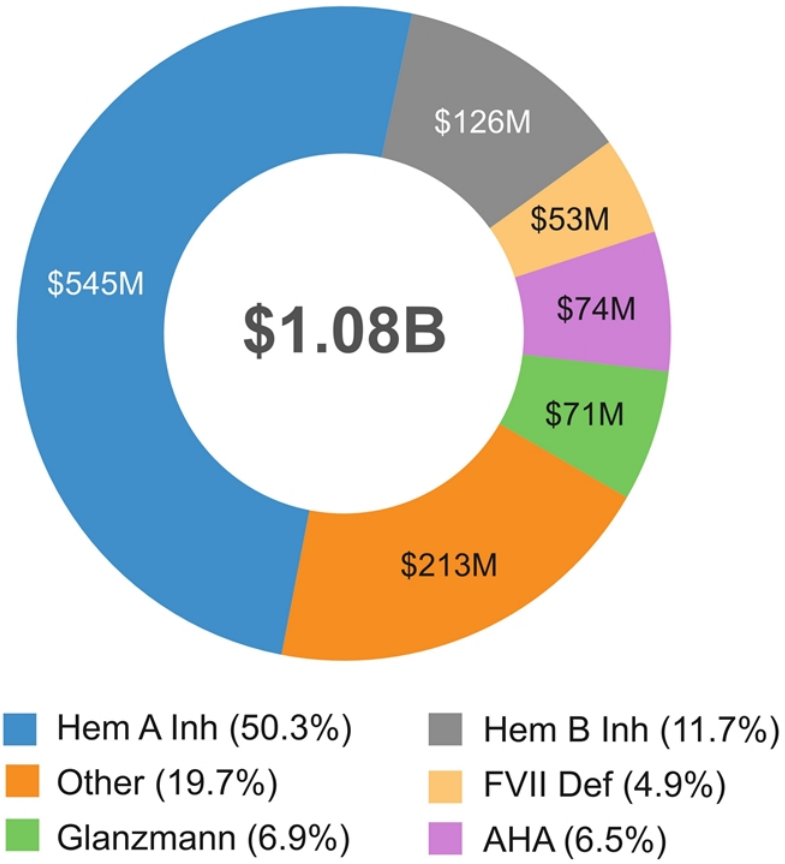
+ 46 patients trea
  3 SQ doses/da

FDA Fast Trac episodic bleed

+ Granted on 2 D

SQ MarzAA is a large commercial opportu

Global NovoSeven sales breakdown by indication (2020)

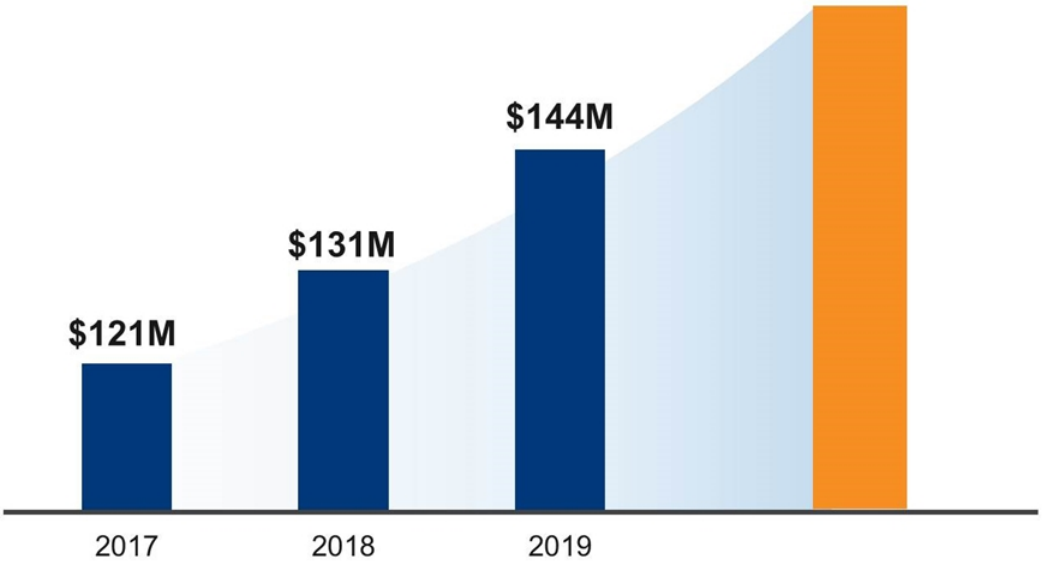


SQ MarzA

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

Source: Adivo Ass
research. Data or

MarzAA could be the first prophylaxis for



Global NovoSeven on demand sales Glanzmann Thrombasthenia, FVIID

Unmet need in prophylaxis

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]

+ MA
sup
+ Tar
+ Tar
18
60

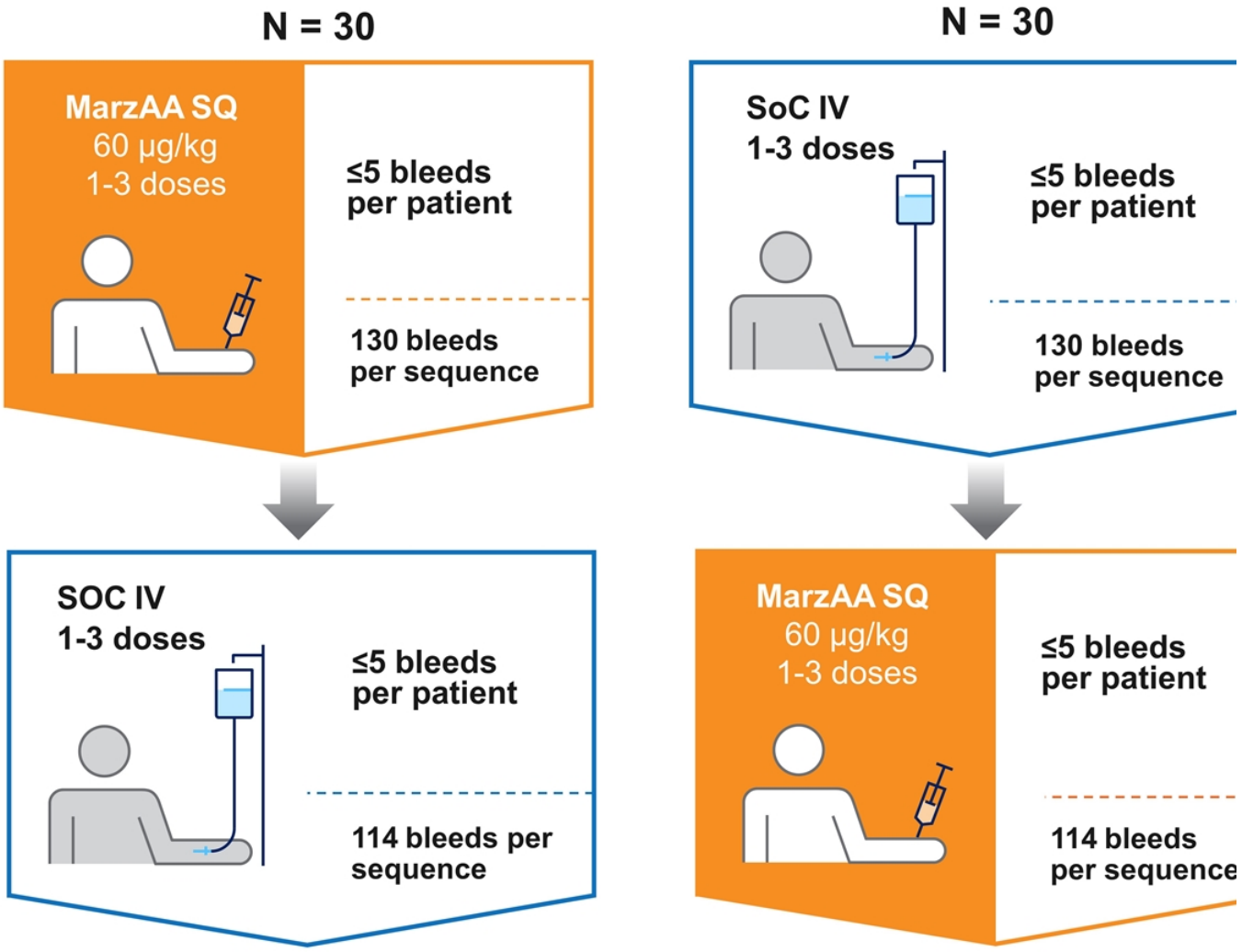
Current bypass agents require multiple infusions over the course of hours

Clini

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

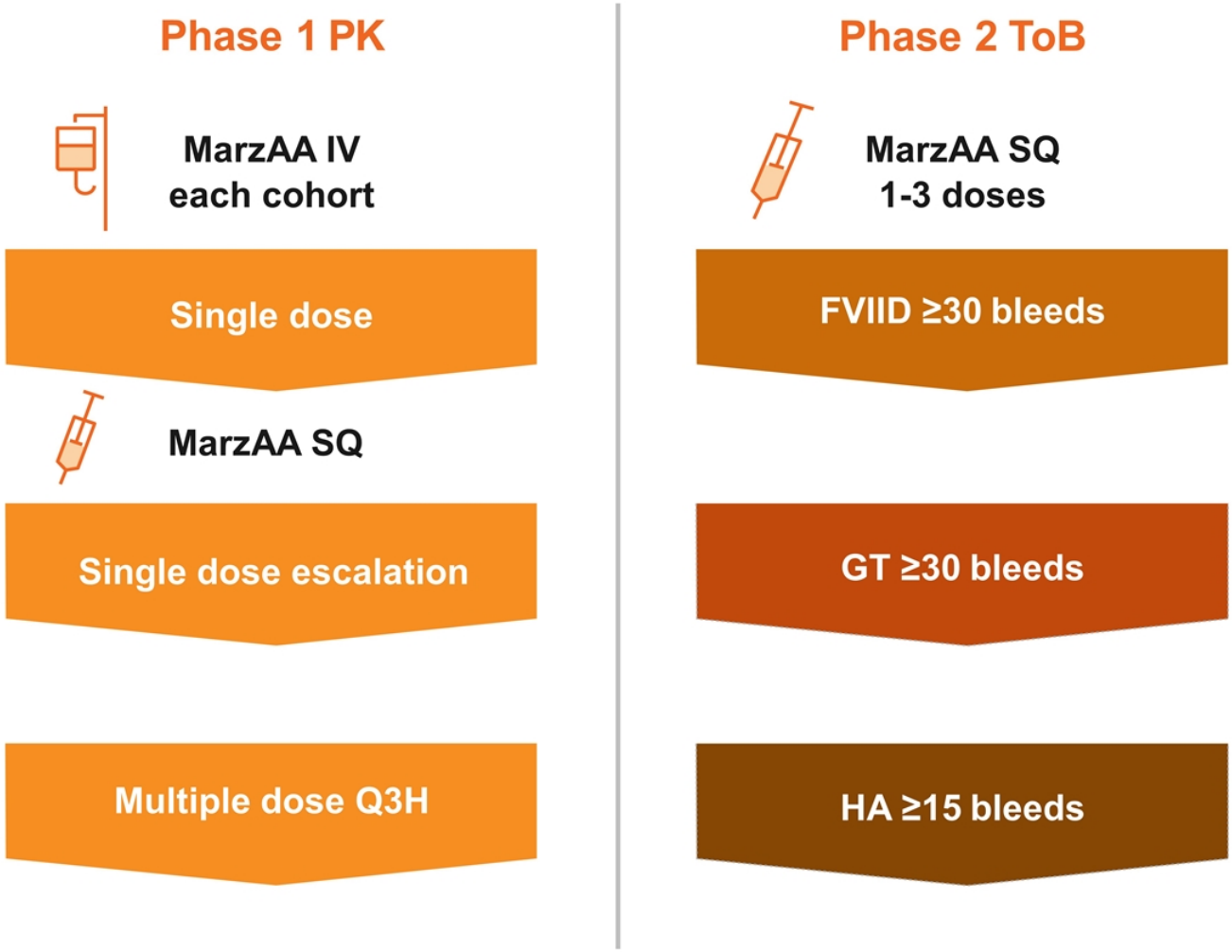
Crimson 1 Phase 3 study: Treatment of ep

Hemophilia A or B with inhibitors, ABR ≥ 8

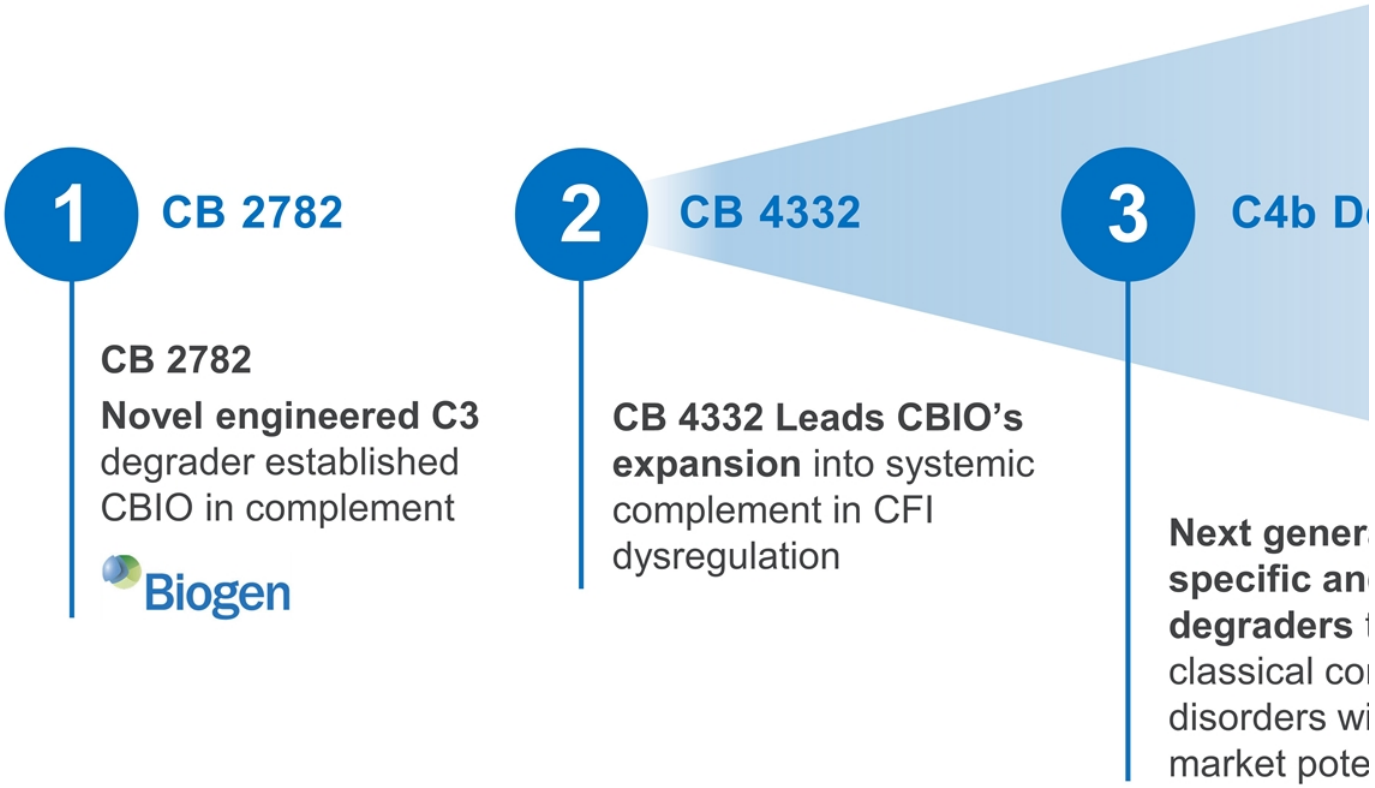


MAA-202 Phase 1/2 study design

FVII deficiency, Glanzmann Thrombasthenia and HA

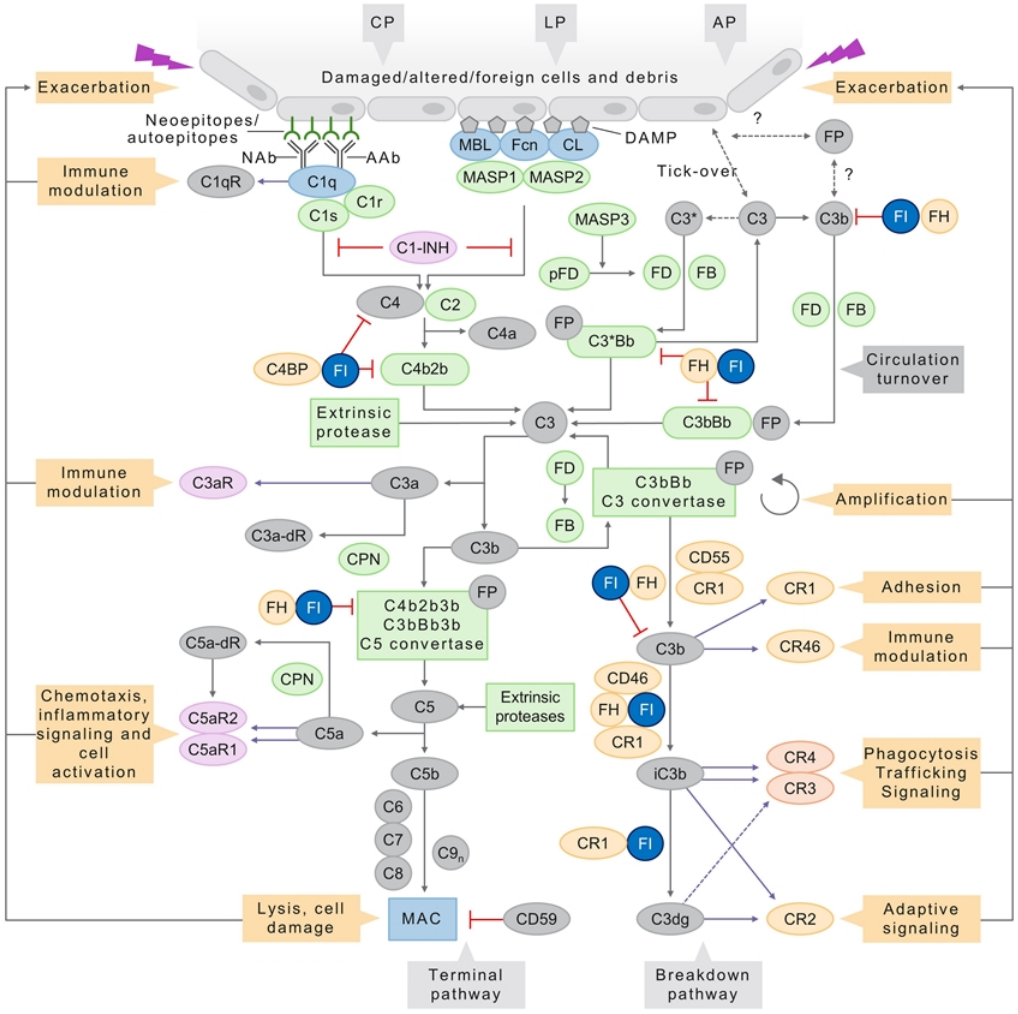


CBIO's complement pipeline



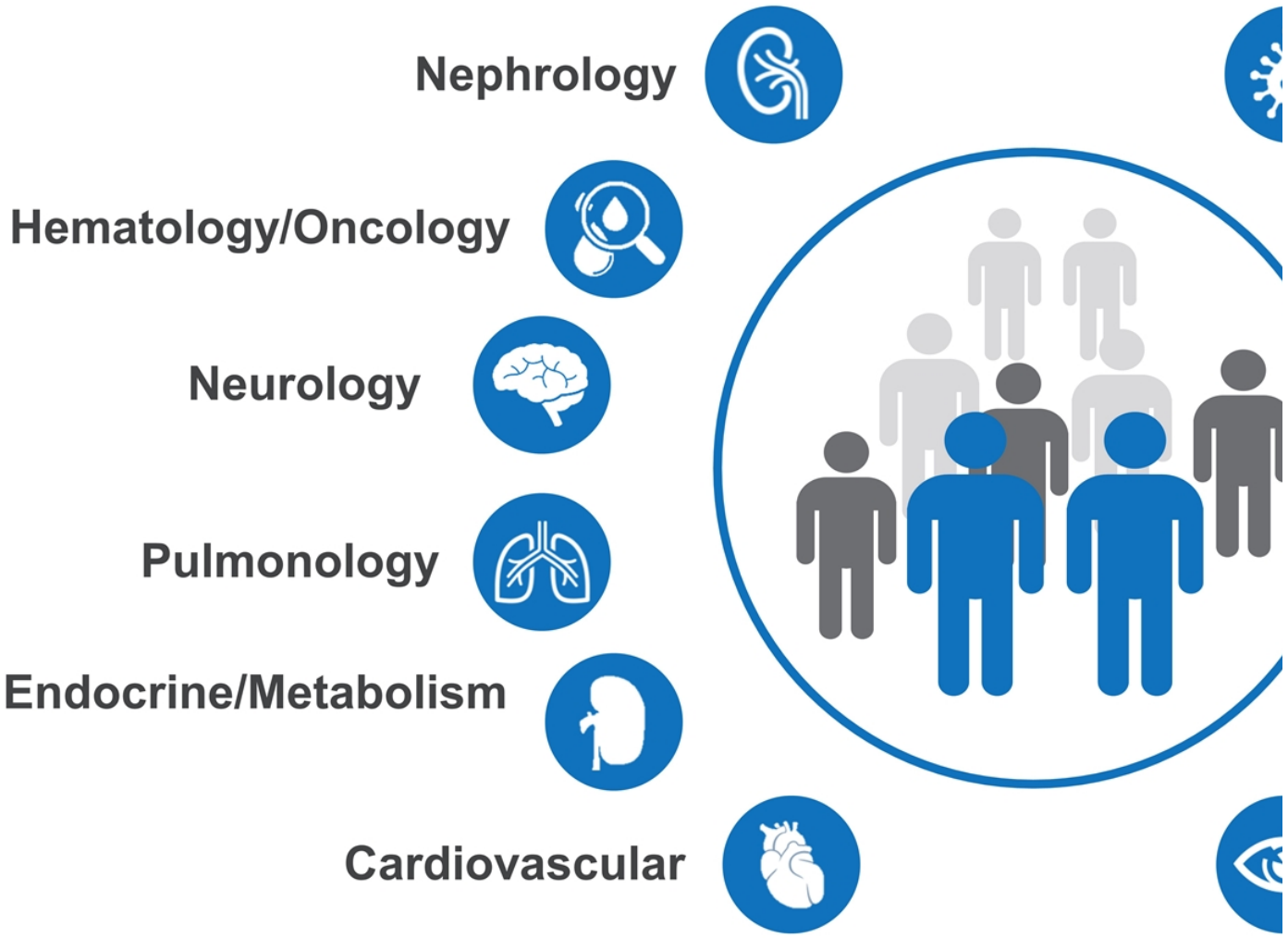
Complement is a perfect fit to develop pro

The complement pathway is driven by a protease ca



Complement plays a critical role in many

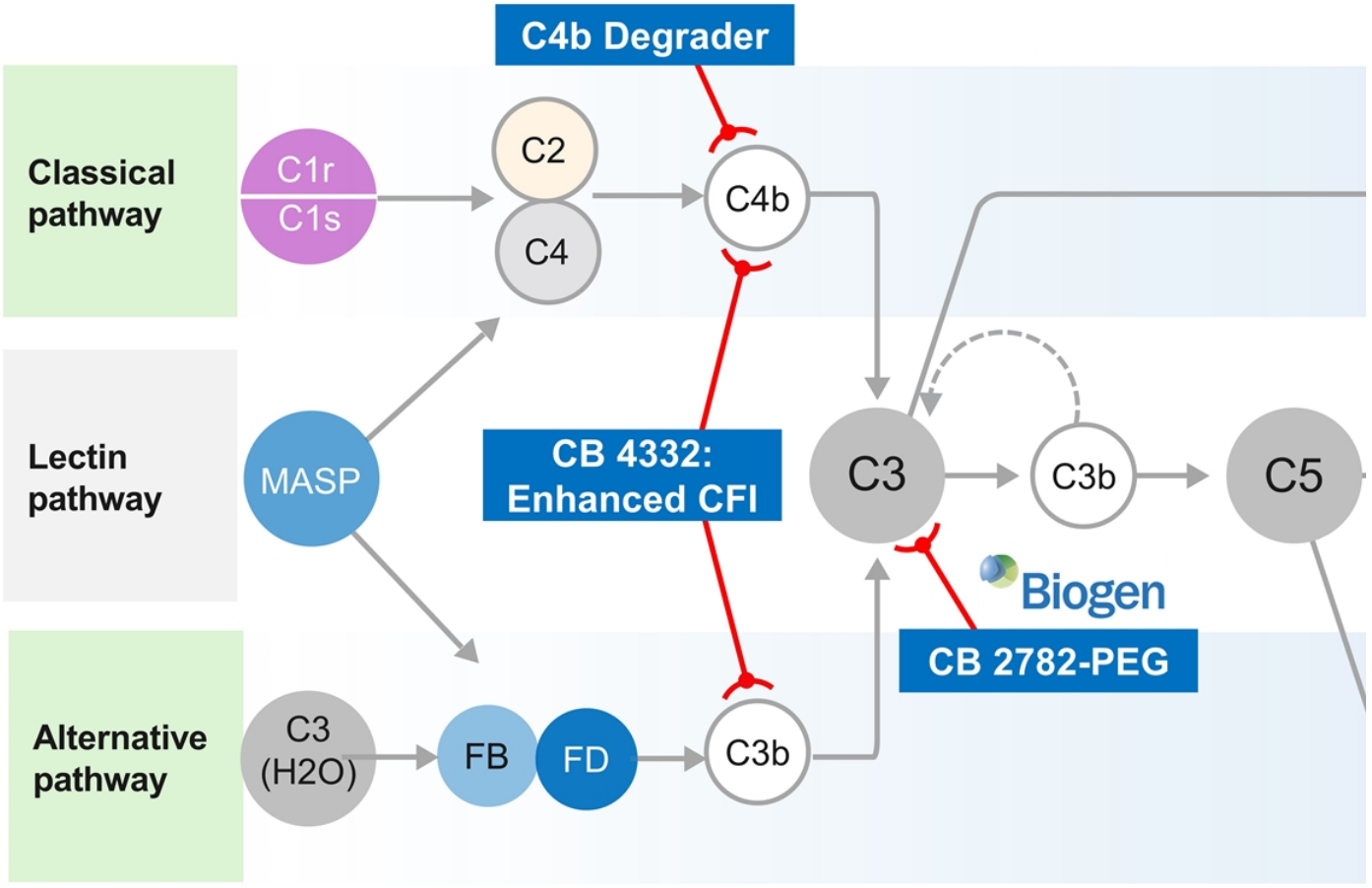
Late-stage complement therapies projected to achi



References: Globaldata consensus net sales forecast 2020

CBIO is taking a targeted approach to com

Engineered proteases address the root cause of the

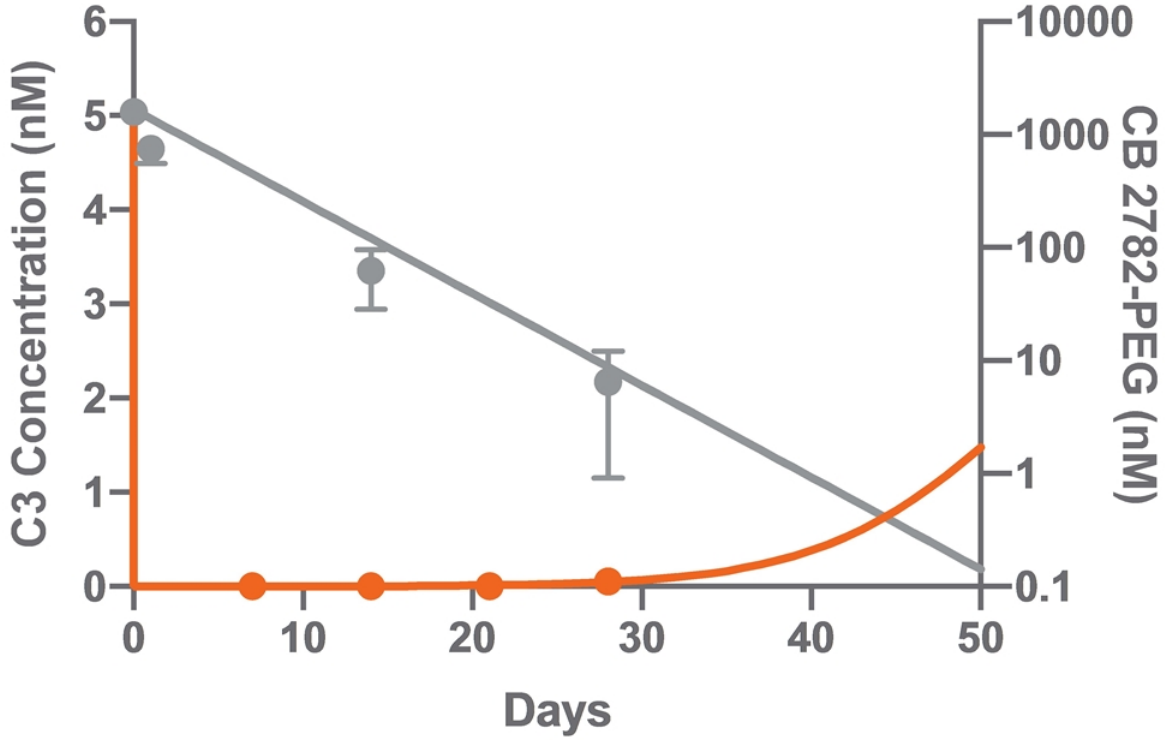


+ Current C5 blockade therapies do not address disease root cause
+ The catalytic power of proteases provides advantages over small r

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

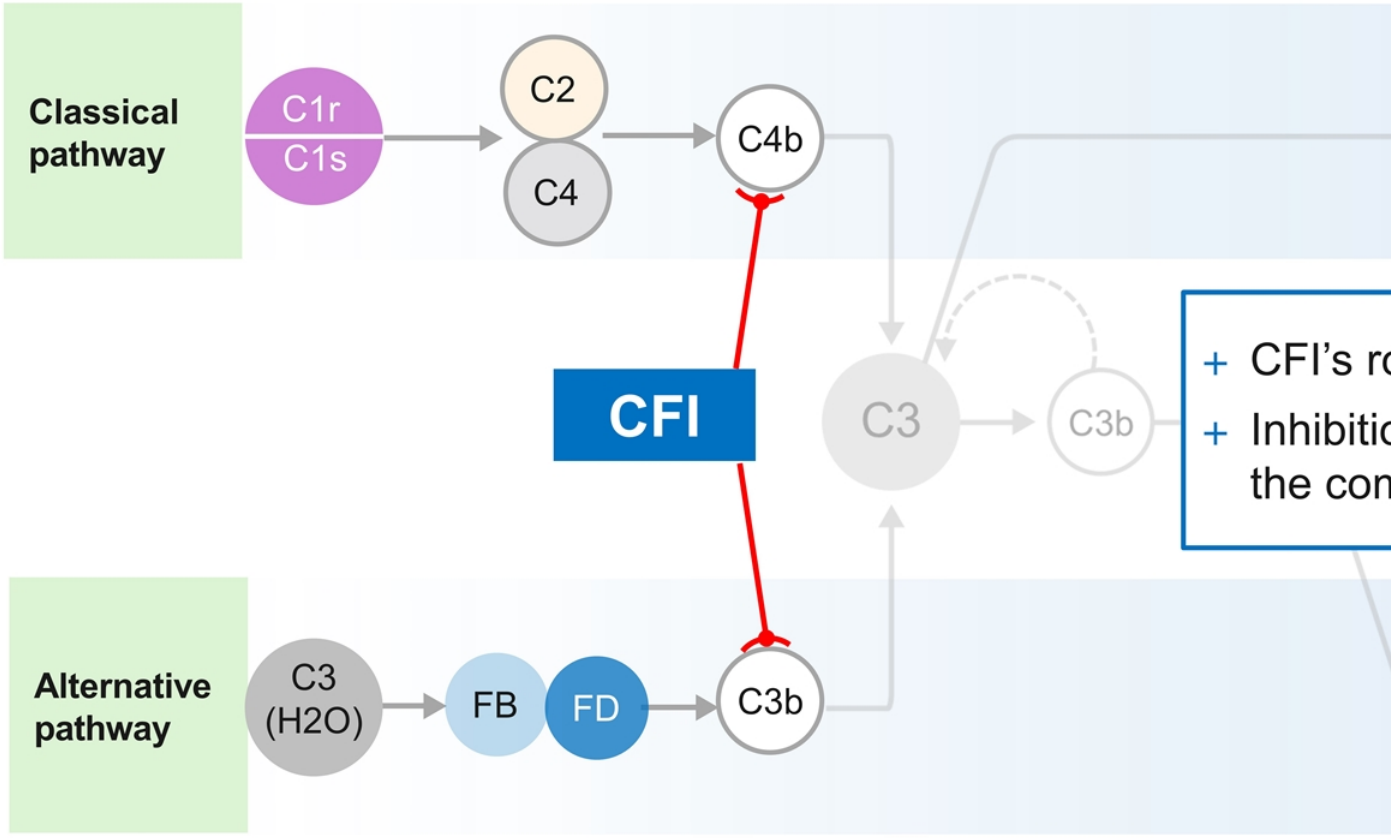
+ Generated from Catalyst's proprietary **protease engineering platform**
+ Potent, selective & long acting, degrades C3 into inactive fragments
+ Preclinical NHP PK & PD data* predict **best-in-class** human intravitreal d

Biogen collaboration

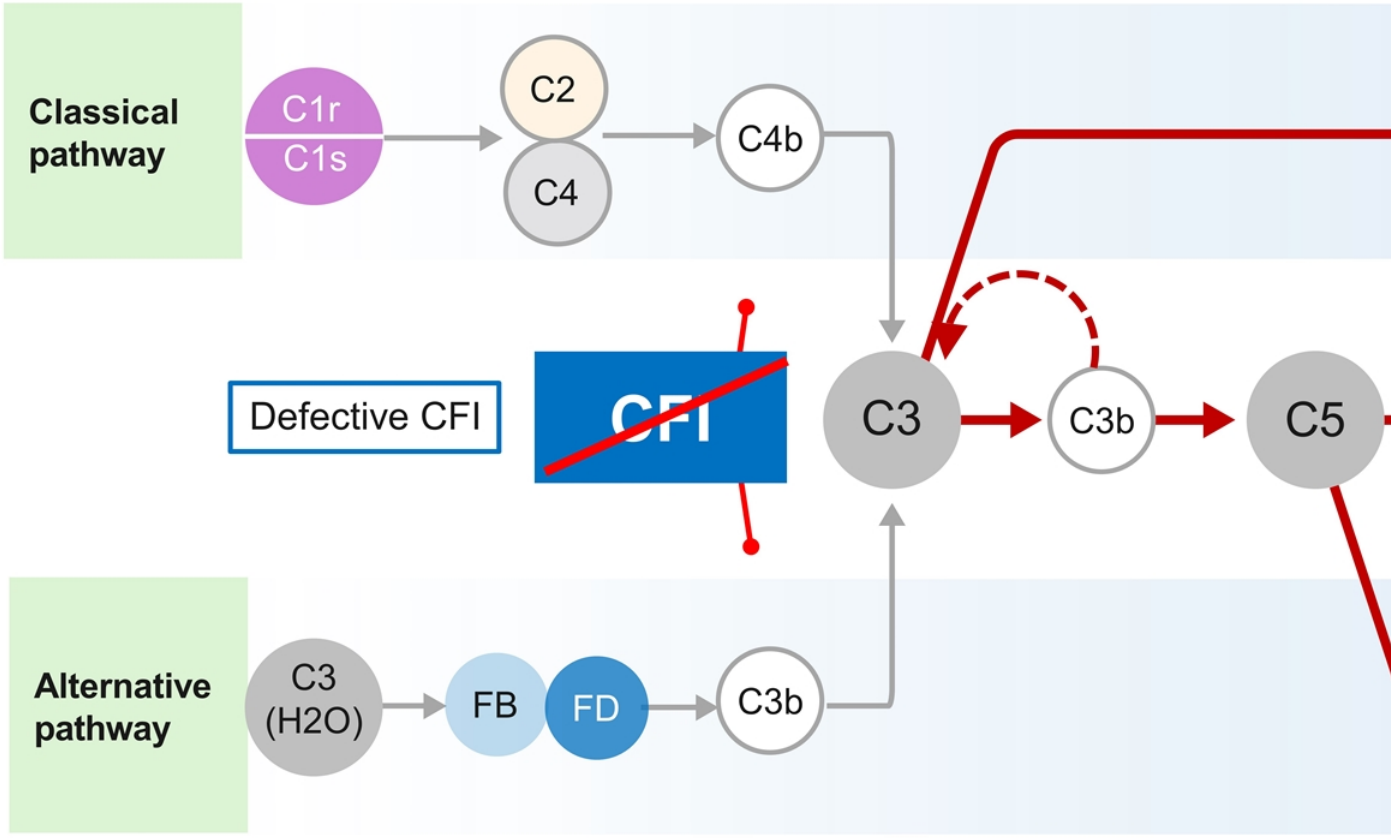
+ $15M upfront, up to $340M in milestones and tiered royalties up to low dou
+ Catalyst: fully funded pre-clinical and manufacturing activities
+ Biogen: IND-enabling activities, WW clinical development & commercializa

*Furfine *et al.* ARVO 2019

Normal CFI: Key central regulator of comp



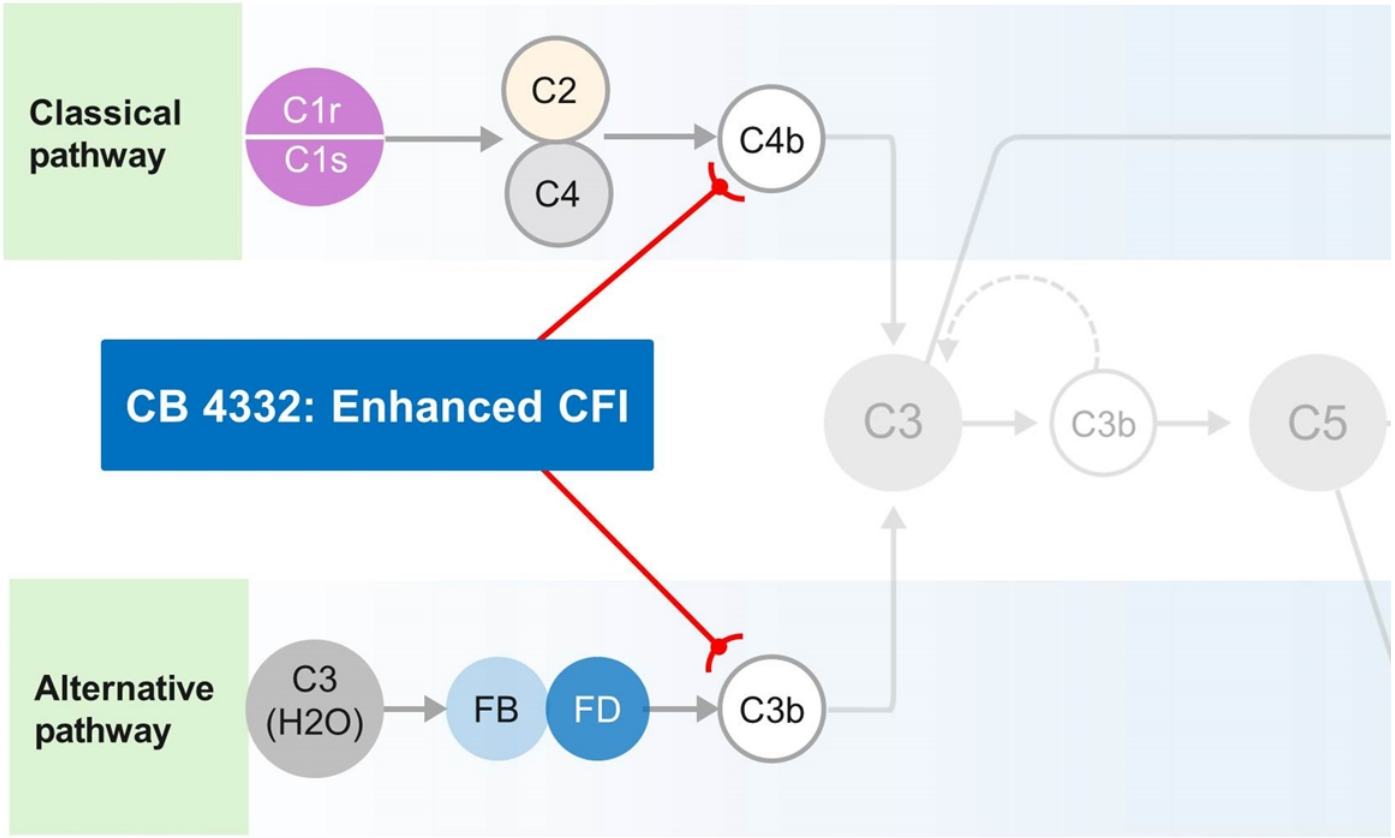
CFI dysregulation: Lack of proteolytic CFI



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

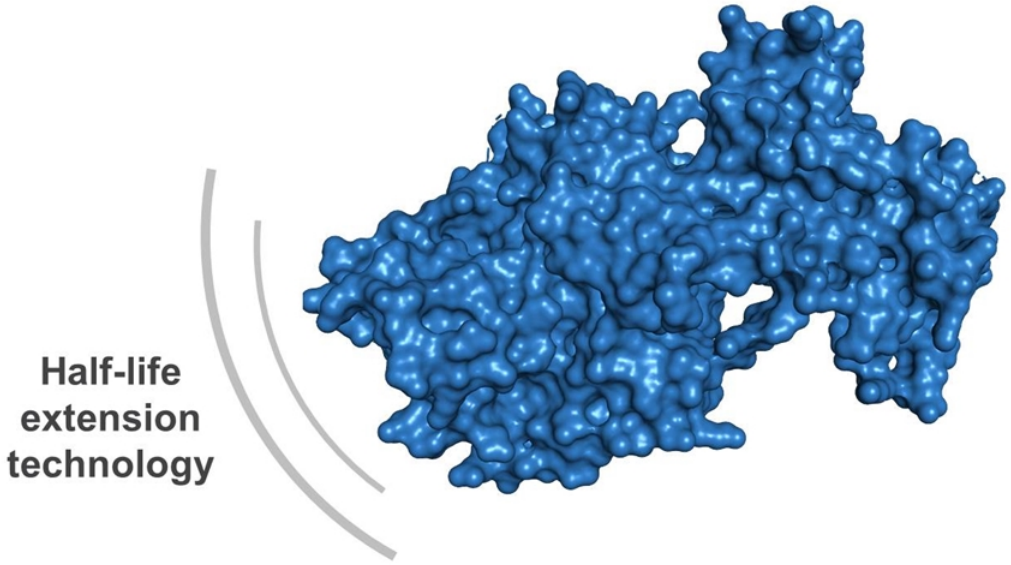
CB 4332 – CBIO's enhanced CFI

Specifically addresses the problem by restoring CF



CB 4332: Enhanced Complement Factor I

CBIO's next SQ development candidate to restore C



+ **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**

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References:
2010; [2]Ferre
Complement
PDB 2XRC.
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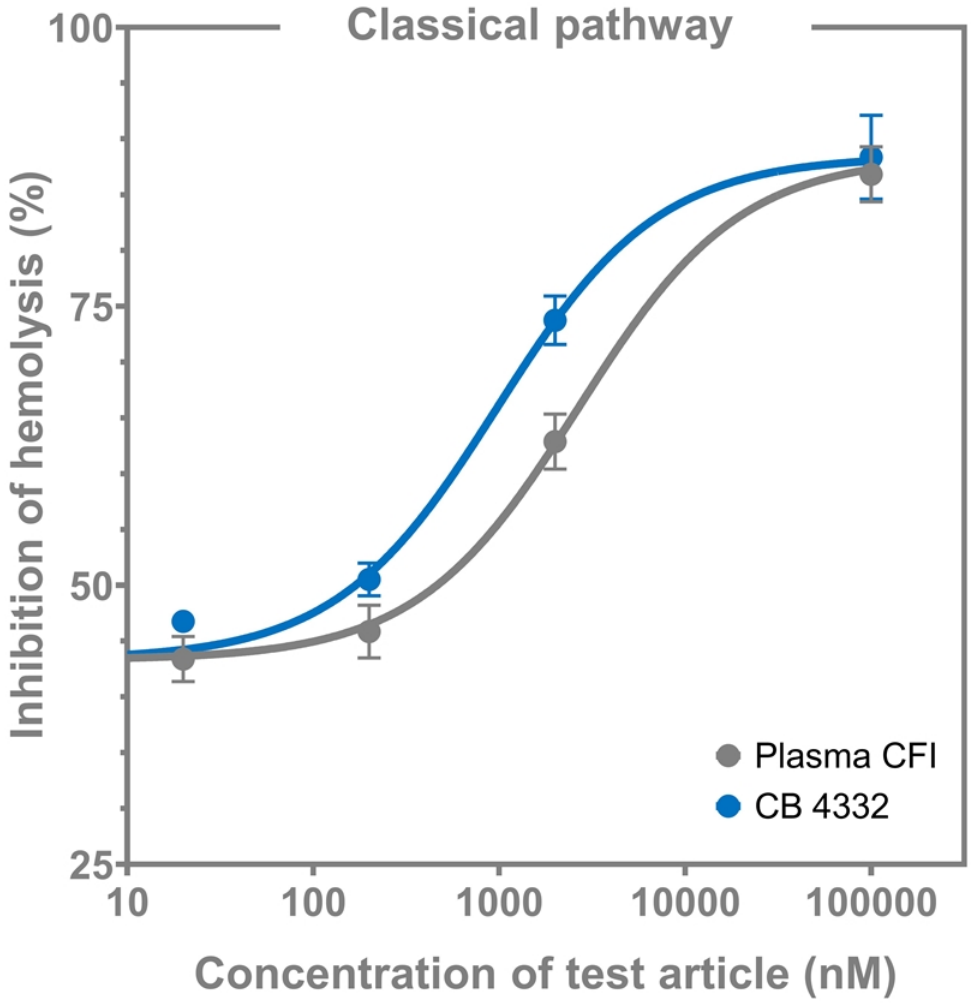
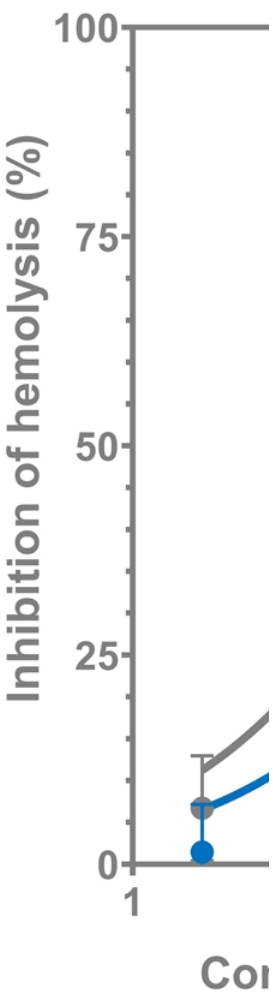
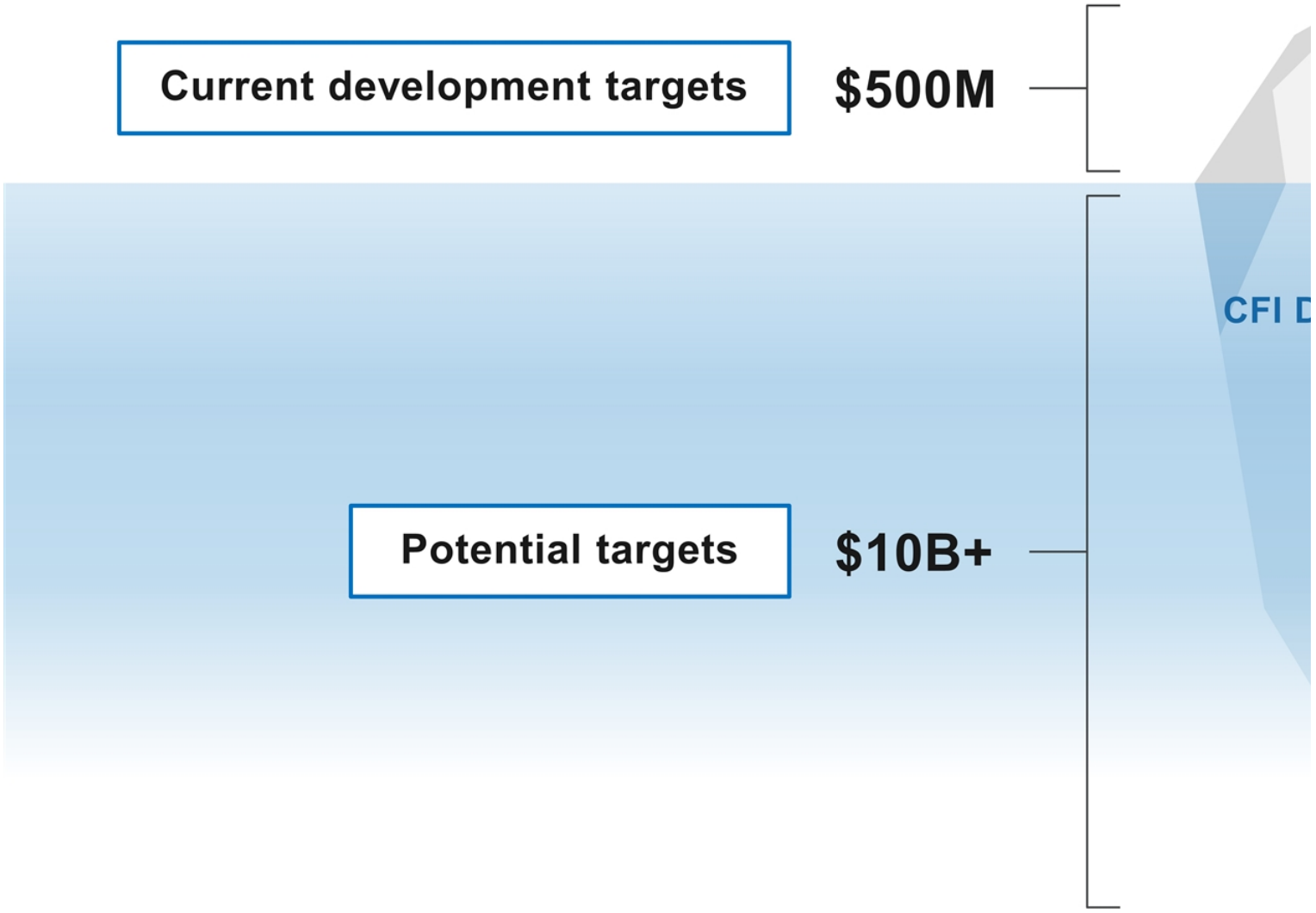
CB 4332 & plasma CFI perform similarly ir





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

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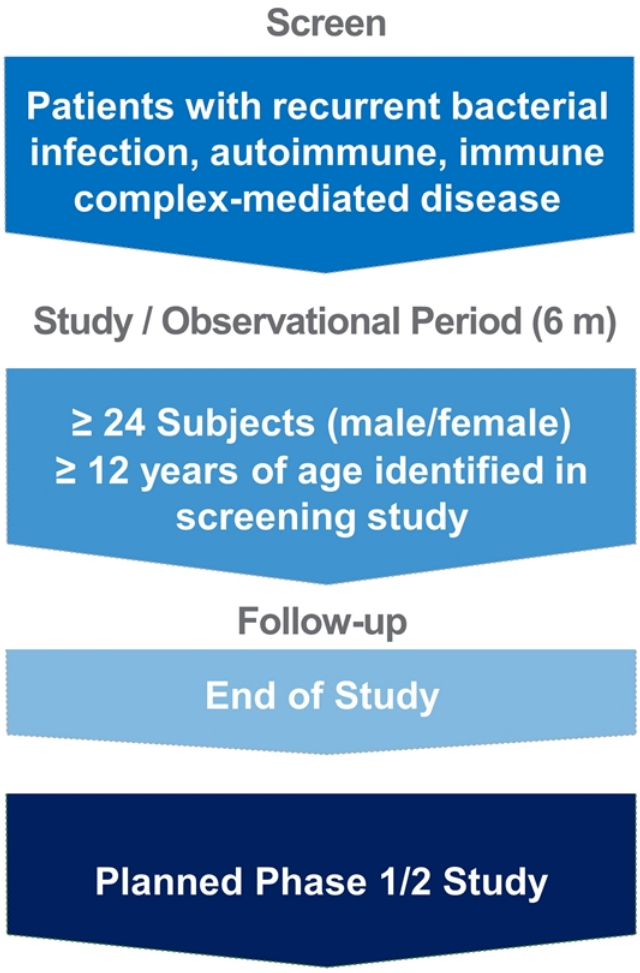
CFI muta

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

Natural history of CFI deficient patients for subsequ



- **Primary Objective**

  Demonstrate the phenotyp
  deficiency in recurrent bac
  immune complex-mediate
  Phase 1/2 study

- **Secondary Objectives**

  Monitor efficacy / disease

  Monitor safety and tolerab

  Record dosing and compl

  Monitor QoL measures

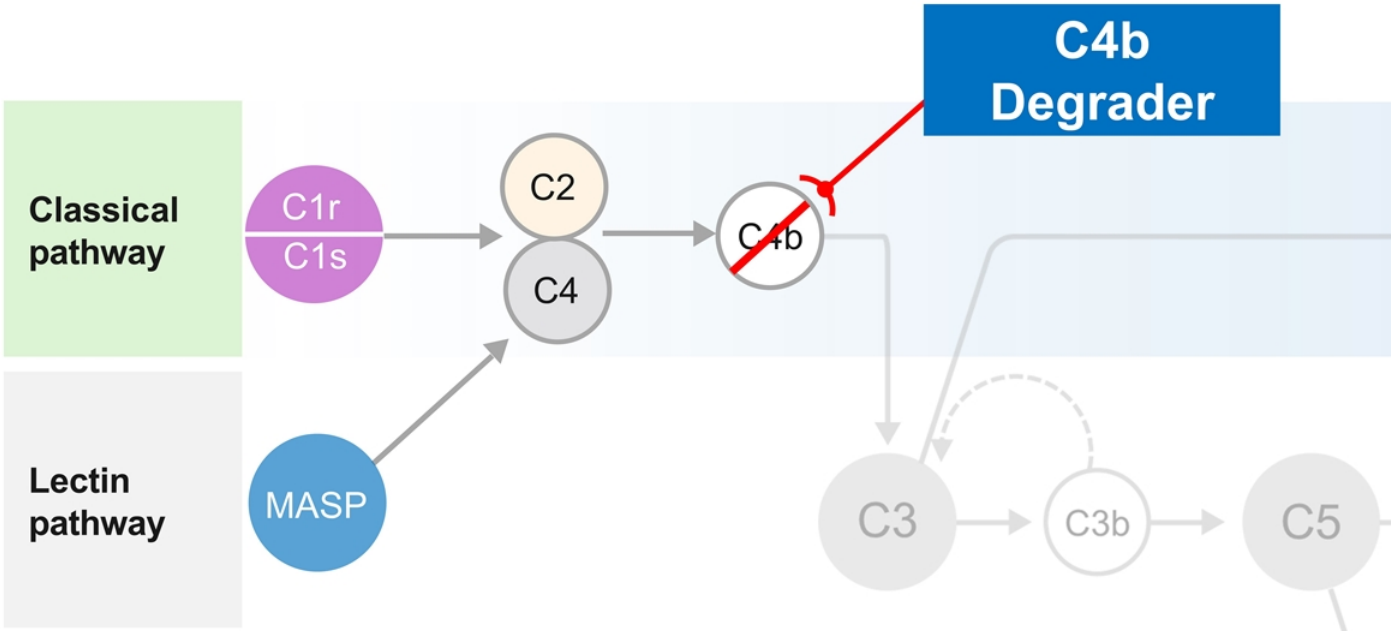
- **Timeline**

  Observational stage to sta

  Global phase 1/2 in patier
  expected in 2022

  Intend to pursue an accele
  path

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

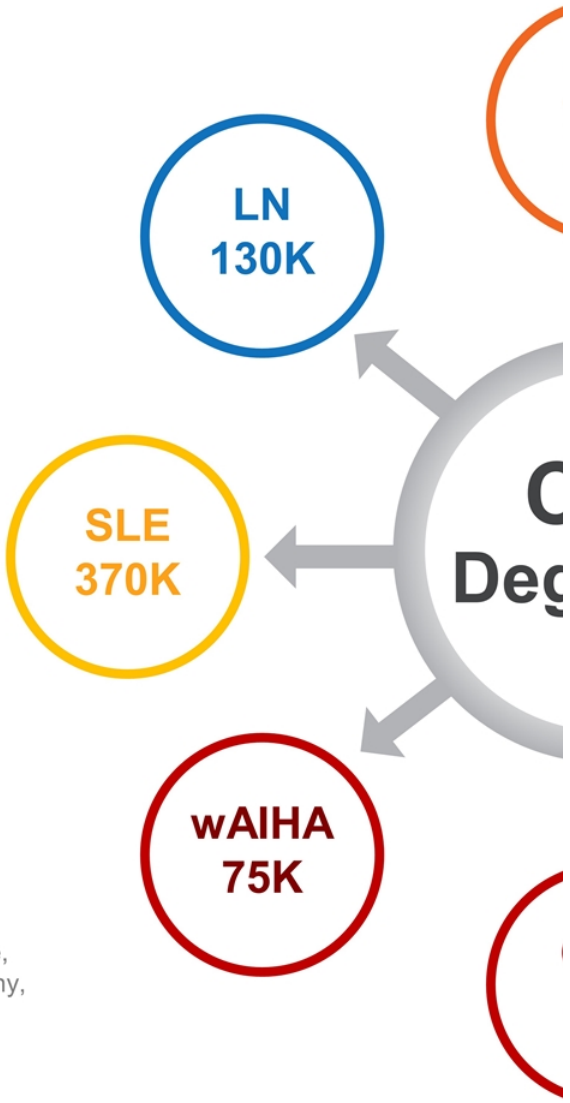
US & EU5 patient opportunity

Nephrology

Immunology

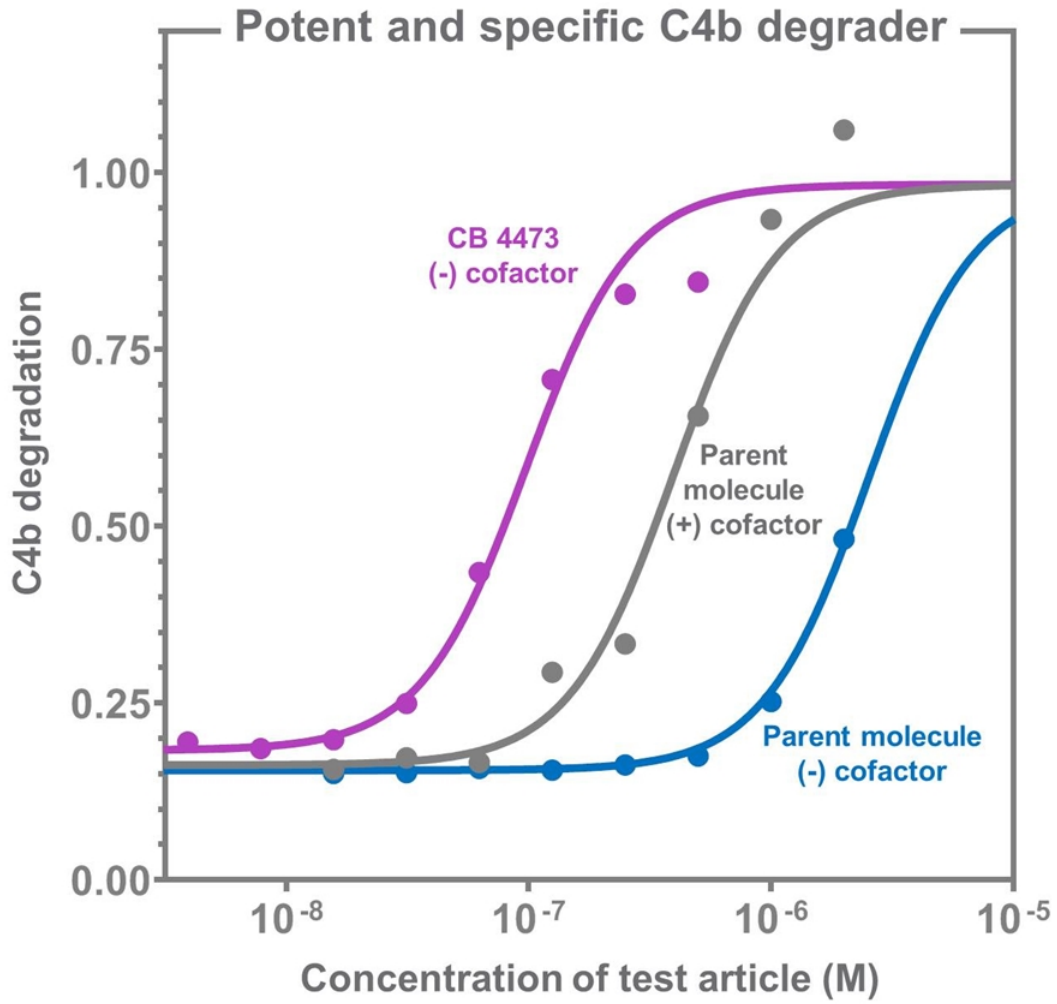
Hematology

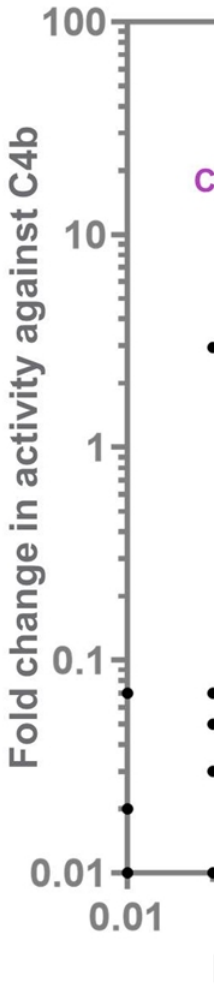
Neurology



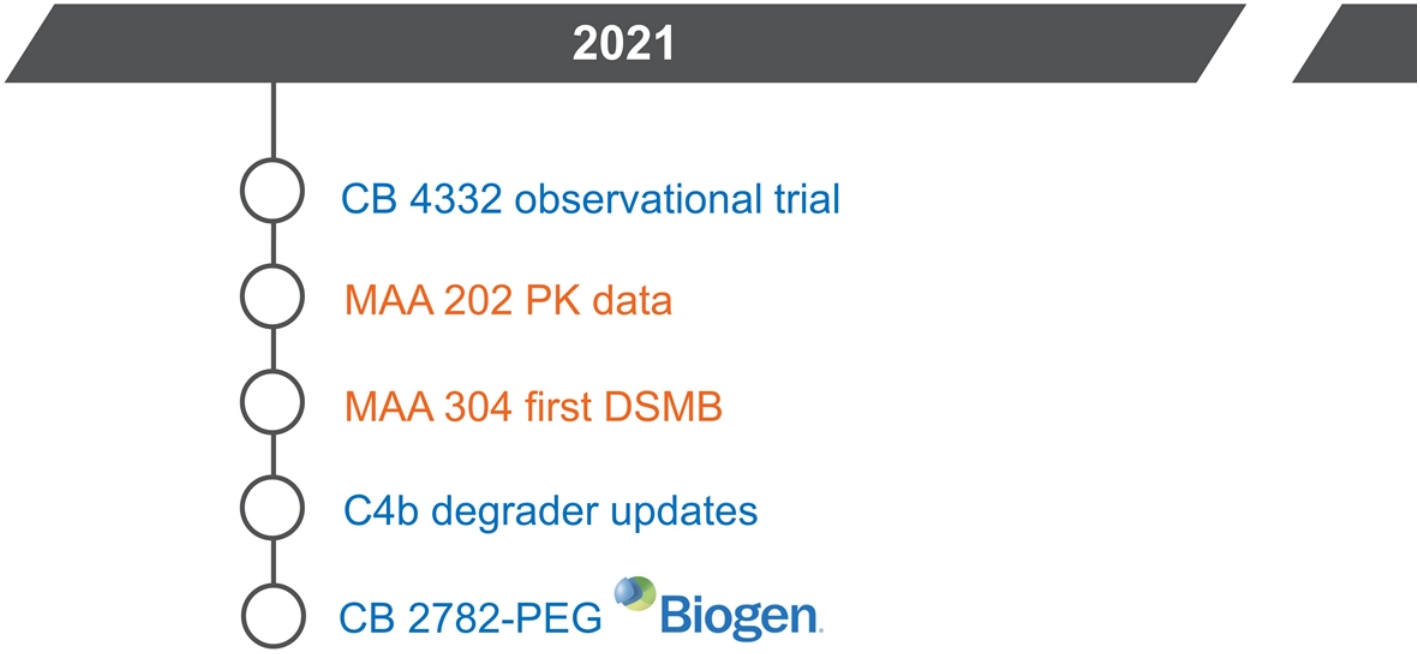
Note: ALS = Amyotrophic lateral sclerosis, GBS = Guillain-Barré syndrome, gMG = Generalized Myasthenia Gravis, MMN = multifocal motor neuropathy, CAD = Cold agglutinin disease, wAIHA = warm Autoimmune hemolytic anemia, SLE = Systemic lupus erythematosus, LN = Lupus Nephritis, References: Data on file

CB 4473 demonstrates engineered C4b pc





Milestones



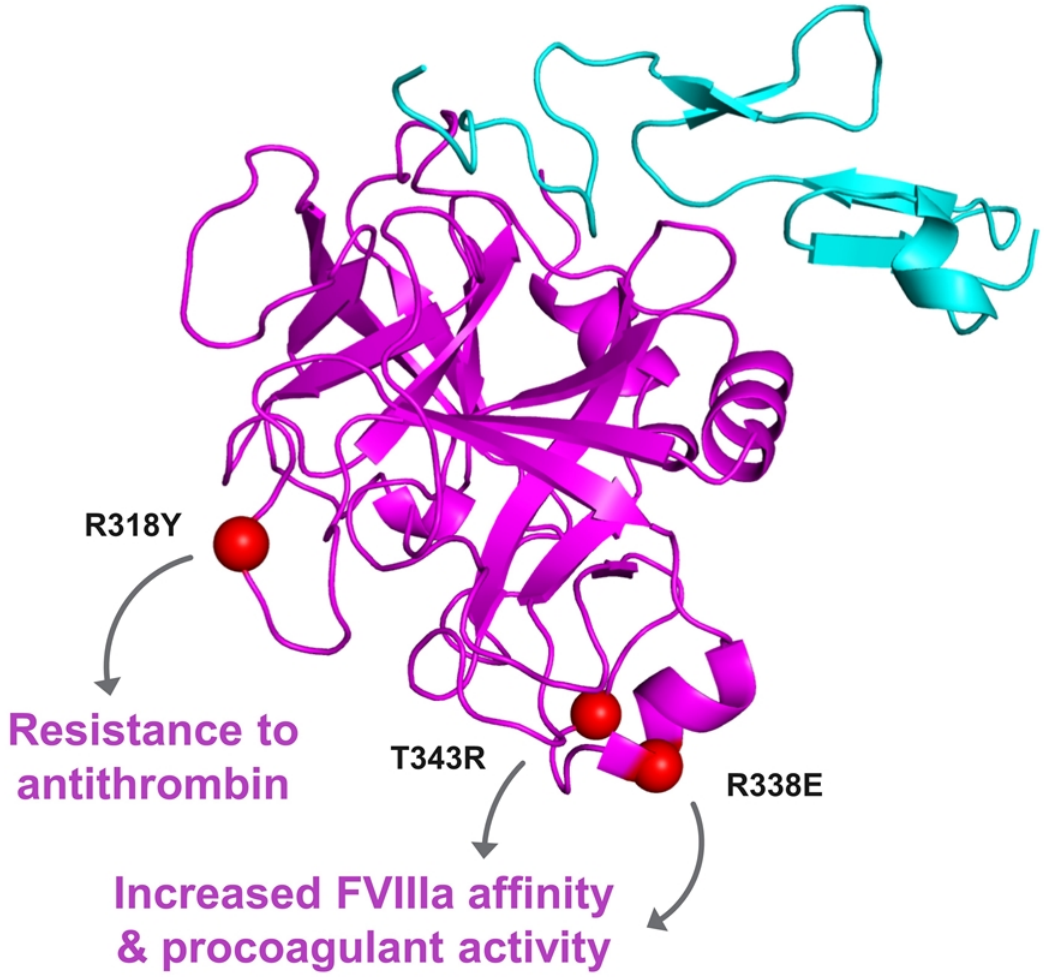
MarzAA (FVIIa) **CB 2782-PEG** (dAMD)

THANK YOU

Nasdaq: CBIO

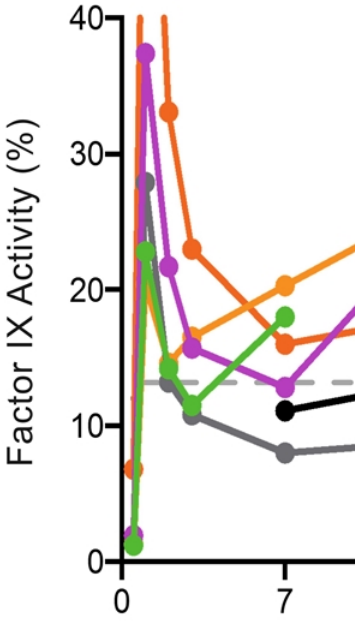
CatalystBiosciences.com

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

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