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): August 5, 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 August 5, 2021, Catalyst Biosciences, Inc., (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 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 August 5, 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 August 5, 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: August 5, 2021

/s/ Clinton Musil
Clinton Musil
Chief Financial Officer

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

SOUTH SAN FRANCISCO, Calif. – August 5, 2021 – Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced its operating and financial results for the second quarter ended June 30, 2021, and provided a corporate update.

"We continue to make progress in our complement and hemostasis programs. In complement, we are advancing the development of our SQ enhanced CFI development candidate, CB 4332, where we screened the first patient in our natural history study for CFI deficiency ("ConFIrm"). We also recently disclosed new proteases from our ProTUNE™; C3b-C4b degrader and ImmunoTUNE™; C3a-C5a degrader platforms designed to target specific disorders of the complement or inflammatory pathways," said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. "With the initiation of the ConFIrm study and our plans to enter the clinic with CB 4332 in 2022 on track, we are building a robust pipeline in complement. We also continue to make progress in our Crimson 1 Phase 3 registrational study of MarzAA, in hemophilia A or B with inhibitors as well as in our Phase 1/2 trial in other rare bleeding disorders."

Recent Milestones

Marzeptacog alfa (activated) – MarzAA

- The Food and Drug Administration (FDA) has granted Fast Track Designation for MarzAA for treatment of episodic bleeding in subjects with Factor FVII deficiency in June 2021. The FDA granted the Fast Track Designation for the treatment of episodic bleeding in subjects with Hemophilia A or B with inhibitors in December 2020.
- Presented four posters at the International Society for Thrombosis and Haemostasis (ISTH) 2021 Virtual Congress in July 2021. The data presented support the Company's ongoing trials of MarzAA in hemostasis.

Systemic Complement Program

- Launched the ConFIrm study with the screening of the first patient in its CFI-deficiency study in the CB 4332 program, Catalyst's wholly-owned, first-in-class, enhanced Complement Factor I (CFI), intended for prophylactic subcutaneous (SQ) administration in individuals with CFI deficiency. The ConFIrm screening study will measure CFI levels and activity in patients who have diseases related to a CFI deficiency and who may potentially benefit from CB 4332 treatment.
- Hosted a research and development day on its protease medicines platform focusing on the regulation of complement, including CB 4332. The event featured a presentation by Filomeen Haerynck, M.D., Ph.D., University of Ghent, Belgium, who discussed the clinical phenotype, current treatment landscape and unmet medical need in treating patients with complement factor I (CFI) deficiency and other complement system disorders. Members of the Catalyst management team also discussed the proteases from the Company's degrader platforms, designed to target specific disorders of the complement and other inflammatory pathways as well as other complement programs in development.

Corporate

- Catalyst announced that it has promoted Grant Blouse, Ph.D., to chief scientific officer and Tom Knudsen, DVM, Ph.D., to senior vice president, corporate development. Howard Levy, M.B.B.Ch, Ph.D., M.M.M., chief medical officer, announced his plan to retire and transition to a senior clinical advisor role to Catalyst.

Expected Milestones

Systemic Complement Program

- Advance CB 2782-PEG, the C3 degrader for the potential treatment of dry AMD in collaboration with Biogen towards the clinic
- Provide additional preclinical data supporting continued development of the C4b degrader program and other complement assets
- Submit an IND and initiate global clinical trial of CB 4332
- Announce development candidates in lead discovery programs
- Present PK and biomarker data for CB 4332

MarzAA

- Continue enrolling the Crimson 1 Phase 3 registrational and the Phase 1/2 trials
- Submit the first Crimson 1 report to the Data and Safety Monitoring Board (DSMB)
- Present PK data from the Phase 1/2 trial

Second Quarter 2021 Results and Financial Highlights

- Cash, cash equivalents and short-term investments, as of June 30, 2021 were $86.5 million.
- Research and development expenses were $15.4 million and $12.9 million during the three months ended June 30, 2021 and 2020, respectively, an increase of $2.5 million, or 19%. The increase was due primarily to an increase of $1.4 million in personnel and facilities costs and an increase of $1.5 million in clinical and manufacturing costs, partially offset by a decrease of $0.4 million in preclinical spending.
- General and administrative expenses were $4.5 million and $4.4 million during the three months ended June 30, 2021 and 2020, respectively, an increase of $0.1 million, or 3%. This increase was due primarily to an increase of $0.3 in personnel-related costs, partially offset by $0.2 million in facilities and overhead costs.
- Interest and other income (expense), net was $0.0 million and $0.1 million during the three months ended June 30, 2021 and 2020, respectively, a decrease of $0.1 million. The decrease was primarily due to a decrease in interest income on investments.
- Net loss attributable to common stockholders for the three-months ended June 30, 2021 was $19.9 million, or ($0.64) per basic and diluted share, compared with $17.2 million, or ($0.96) per basic and diluted share, for the prior year period.
- As of June 30, 2021, the Company had 31,349,740 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 proteases from our ProTUNE™ C3b-C4b degrader and ImmunoTUNE™ C3a-C5a degrader platforms designed to target specific disorders of the complement or inflammatory pathways 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, without limitation, statements about the product candidates of Catalyst Biosciences, Inc. (the "Company") and the benefits of its protease engineering platform; plans to complete the ConFIrm and ConFIdence studies and the expectation that the studies will inform opportunities to develop CB 4332; plans to submit an IND for CB 4332; plans to announce development candidates in lead discovery programs and present PK and biomarker data for CB 4332; plans to continue enrollment of the Phase 3 and Phase 1/2 trials of MarzAA; the potential markets for and advantages of the Company's complement product candidates, including CB 2782-PEG, CB 4332 and complement degraders; plans for the Company's collaboration with Biogen; and plans to start a clinical trial of CB 4332 in 2022.

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, the risk that the ConFIrm and ConFIdence trials will not validate the potential market for CB 4332; the risk Catalyst may elect to terminate or postpone ongoing development programs, including development of MarzAA or any of the Company's complement assets; the risk that the Company will need to raise additional capital, which may not be available on faorable terms if at all; the risk that Biogen will terminate Catalyst's agreement, and other risks described in the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 6, 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)

	June 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 73,621	$ 30,360
Short-term investments	12,902	48,994
Accounts receivable	1,971	3,313
Prepaid and other current assets	8,332	6,843
Total current assets	96,826	89,510
Long-term investments	—	2,543
Other assets, noncurrent	1,169	528
Right-of-use assets	3,107	1,832
Property and equipment, net	684	433
Total assets	$ 101,786	$ 94,846
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,834	$ 5,931
Accrued compensation	2,516	2,476
Deferred revenue	2,038	1,983
Other accrued liabilities	7,366	6,743
Operating lease liability	1,814	663
Total current liabilities	15,568	17,796
Operating lease liability, noncurrent	1,054	981
Total liabilities	16,622	18,777
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; 31,349,740 and 22,097,820 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	31	22
Additional paid-in capital	442,258	390,803
Accumulated other comprehensive income	2	5
Accumulated deficit	(357,127)	(314,761)
Total stockholders' equity	85,164	76,069
Total liabilities and stockholders' equity	$ 101,786	$ 94,846

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
License	$ —	$ 23	$ —	$ 15,068
Collaboration	1,132	1,635	2,599	2,956
License and collaboration revenue	1,132	1,658	2,599	18,024
Operating expenses:				
Cost of license	—	23	—	3,070
Cost of collaboration	1,139	1,719	2,619	3,151
Research and development	15,389	12,906	32,402	26,170
General and administrative	4,518	4,371	9,930	8,062
Total operating expenses	21,046	19,019	44,951	40,453
Loss from operations	(19,914)	(17,361)	(42,352)	(22,429)
Interest and other income (expense), net	(14)	113	(14)	1,128
Net loss	$ (19,928)	$ (17,248)	$ (42,366)	$ (21,301)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.64)	$ (0.96)	$ (1.42)	$ (1.31)
Shares used to compute net loss per share attributable to common stockholders, basic and diluted	31,348,602	17,891,475	29,875,202	16,241,963

CATALYST BIOSCIENCES

Corporate Overview

5 August 2021

CatalystBiosciences.com

Forward looking statements

Certain information contained in this presentation and statements made orally during this presentatic substantial risks and uncertainties. All statements included in this presentation, other than statement looking statements. Forward-looking statements include, without limitation, statements about the pro "Company") and the benefits of its protease engineering platform, potential commercial opportunities potential to treat hemophilia subcutaneously; plans to enroll the Crimson 1 Phase 3 registration stud bleed data for this study; plans to enroll the MAA Phase 1/2 study of MarzAA and report PK and trea and advantages of the Company's complement product candidates, including CB 2782-PEG as a pc a potential treatment for CFI deficiency, and complement degraders; plans for the Company's collab CFI complement product candidates, and plans to enroll the CB 4332 observational trial and to cond

Actual results or events could differ materially from the plans, intentions, expectations and projectior Various important factors could cause actual results or events to differ materially, including, but not li delayed or terminated as a result of COVID-19 and other factors, that trials may not have satisfactor from earlier trials, that the Company will need to raise additional capital, which may not be available develop or manufacture the Company's products will be higher than anticipated, including as a resul from COVID-19 and other factors, the risk that Biogen will terminate its agreement with the Company Factors" section of the Company's Annual Report on Form 10-K filed with the Securities and Exchan filed with the SEC on August 5, 2021, and in other filings with the SEC. The forward-looking stateme of the date of this presentation and the Company does not assume any obligation to update any forv

CATALYST BIOSCIENCES

The Protease Medicines Company

Harnessing the catalytic power of proteases

- Novel differentiated medicines
- Robust complement portfolio
- Clinical-stage assets
- Unique expertise in protease engineering

Catalyst protease platform

Unique expertise enables design of optimized & dif

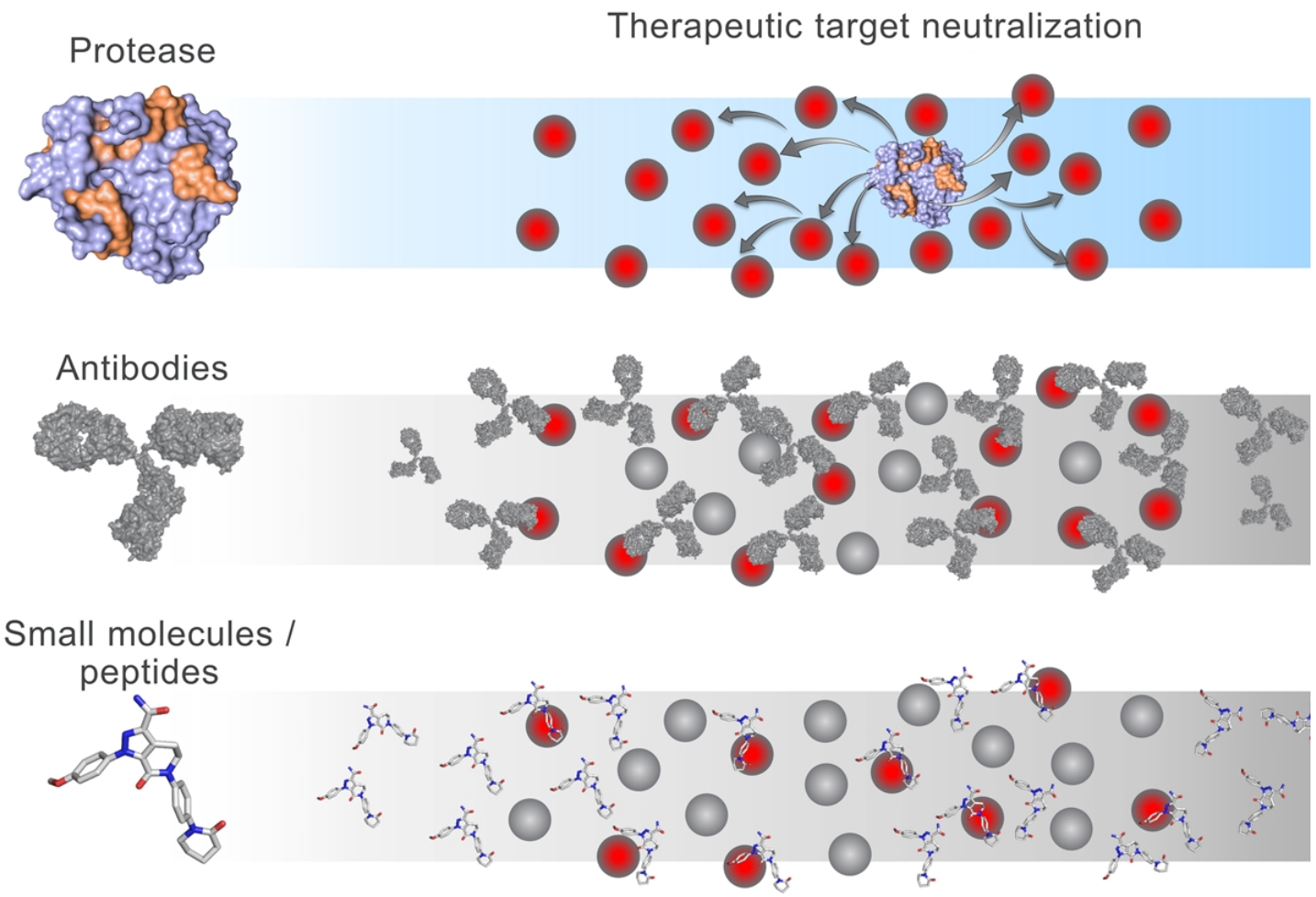
Discovery Platform

Protease
Scaffold

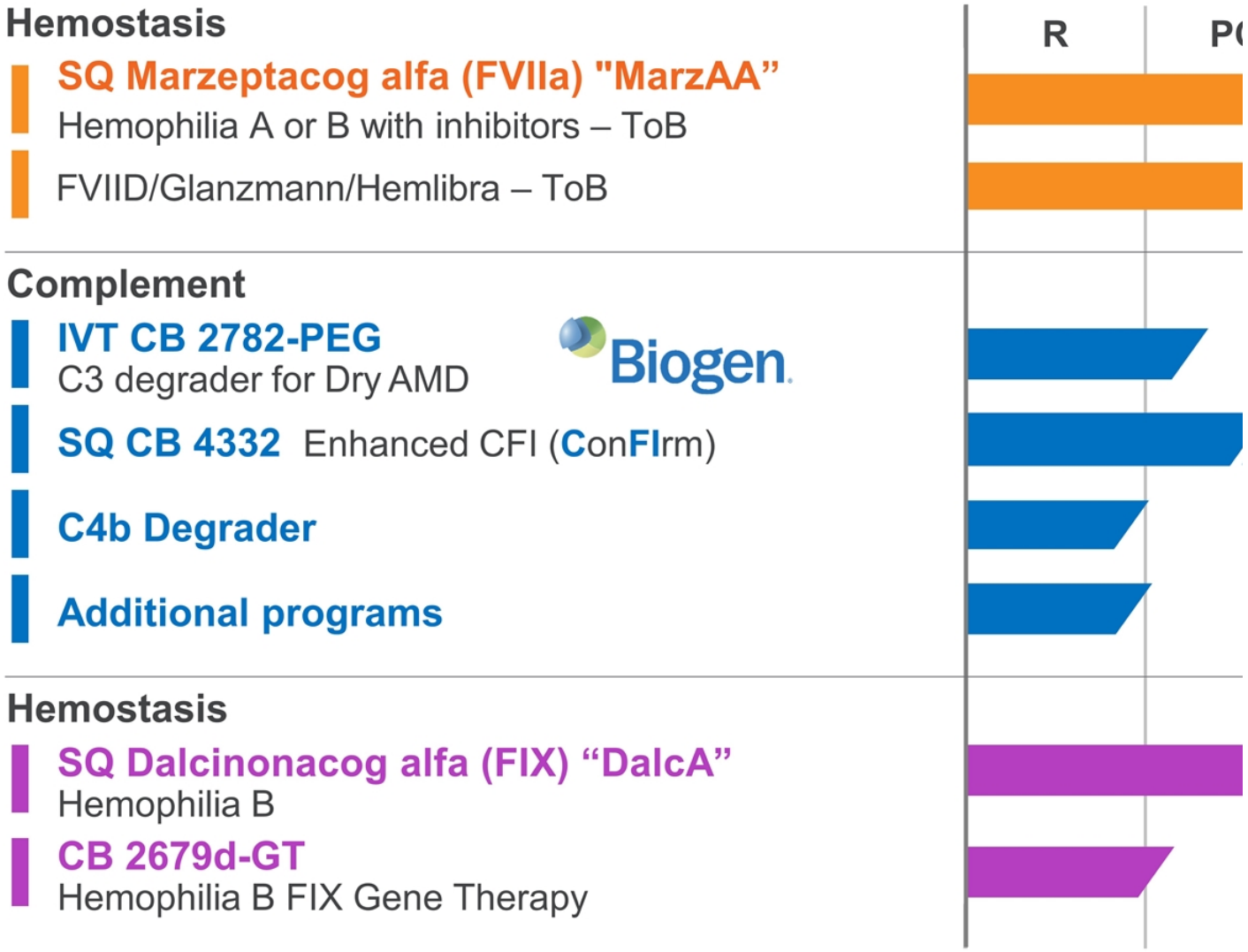
- Structure Guided Design
- Molecular Evolution
- Engineered Regulation
- Pharmacokinetic Impr

Proteases are ideal for high abundancy ta

A better way to regulate biological processes compared



Pipeline

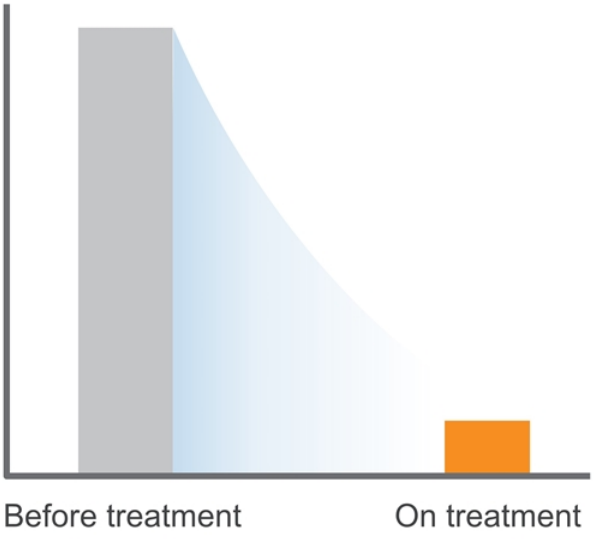


Catalyst protease platform

Validated across three programs

Marzeptacog alfa (activated)

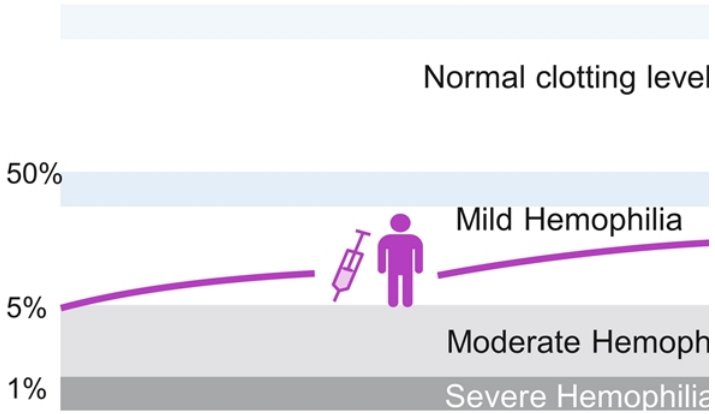
90% reduction in annualized bleed rate



Engineered rFVIIa protease

Dalcinonacog alfa

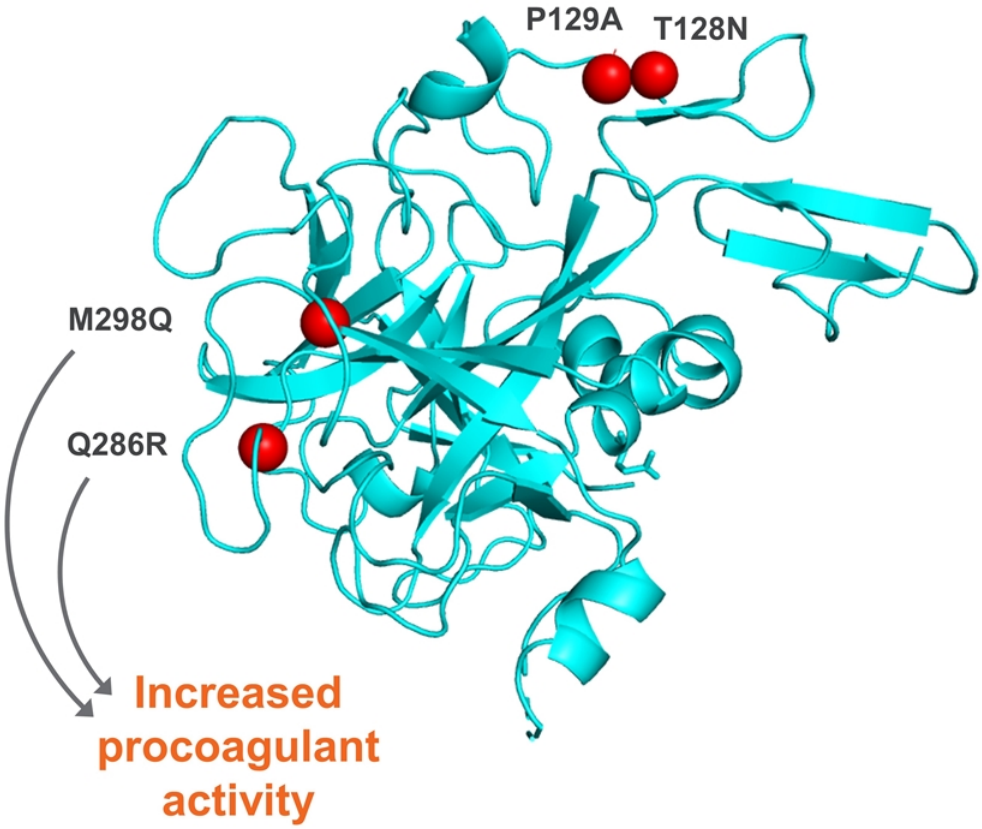
Achieved sustained & high target levels of FIX



Engineered rFIX protease

Marzeptacog alfa (activated) – MarzAA: SC

Designed to address a clear unmet need in hemophilia &



9-fold higher ac

+ Potency allows f
+ NovoSeven RT i

Preclinical effic

+ HA mouse after

P2 proof of con with inhibitors -

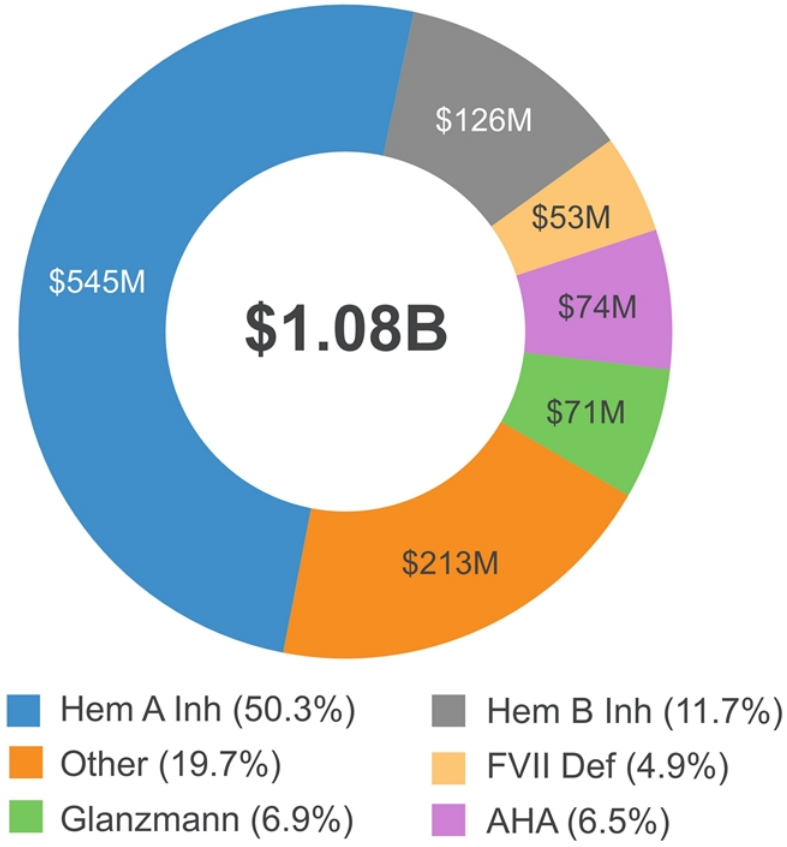
+ 46 patients treat
  3 SQ doses/day,

FDA Fast Track

+ HA/HB with inhib
+ FVIID, episodic

SQ MarzAA is a large commercial opportu

Global NovoSeven sales breakdown by indication (2020)

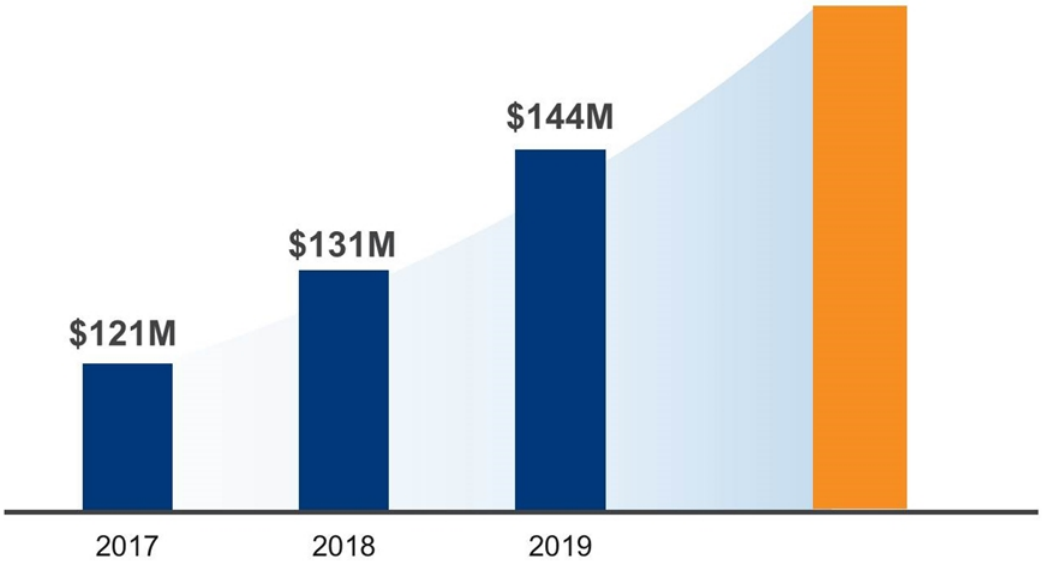


SQ MarzAA

+ SQ is patie
  to fast & e
+ Ideal for p
  access iss
+ Long half-l
  control of b
+ *In vitro* dat
  Hemlibra®
+ Prophylaxi

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

MarzAA could provide SQ prophylaxis for



Global NovoSeven on demand sales Glanzmann Thrombasthenia, FVIID

Unmet need in prophylaxis

Gr
Th
pa

Source: Catalyst Biosciences, Adivo Associates Market Research, Data on file. *Note: 2019 estima patients may have multiple bleeding events per year needing factor treatment

Unmet need for a long-acting SQ episodic tr

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

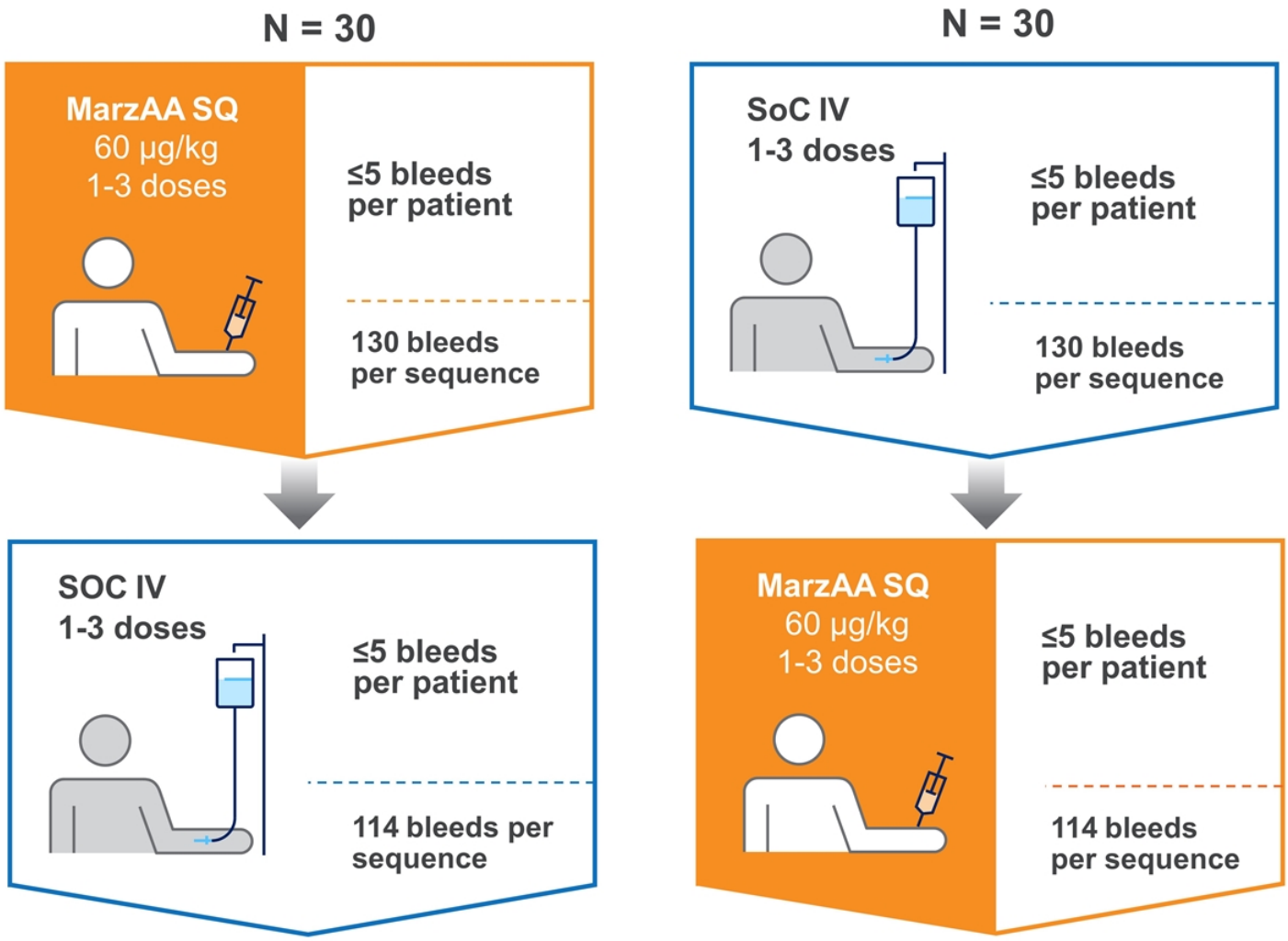
+ MAA-10
  support
+ Target t
  rapidly
+ Target l
  18 hour
  60 µg/k

Clinical Mar

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

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

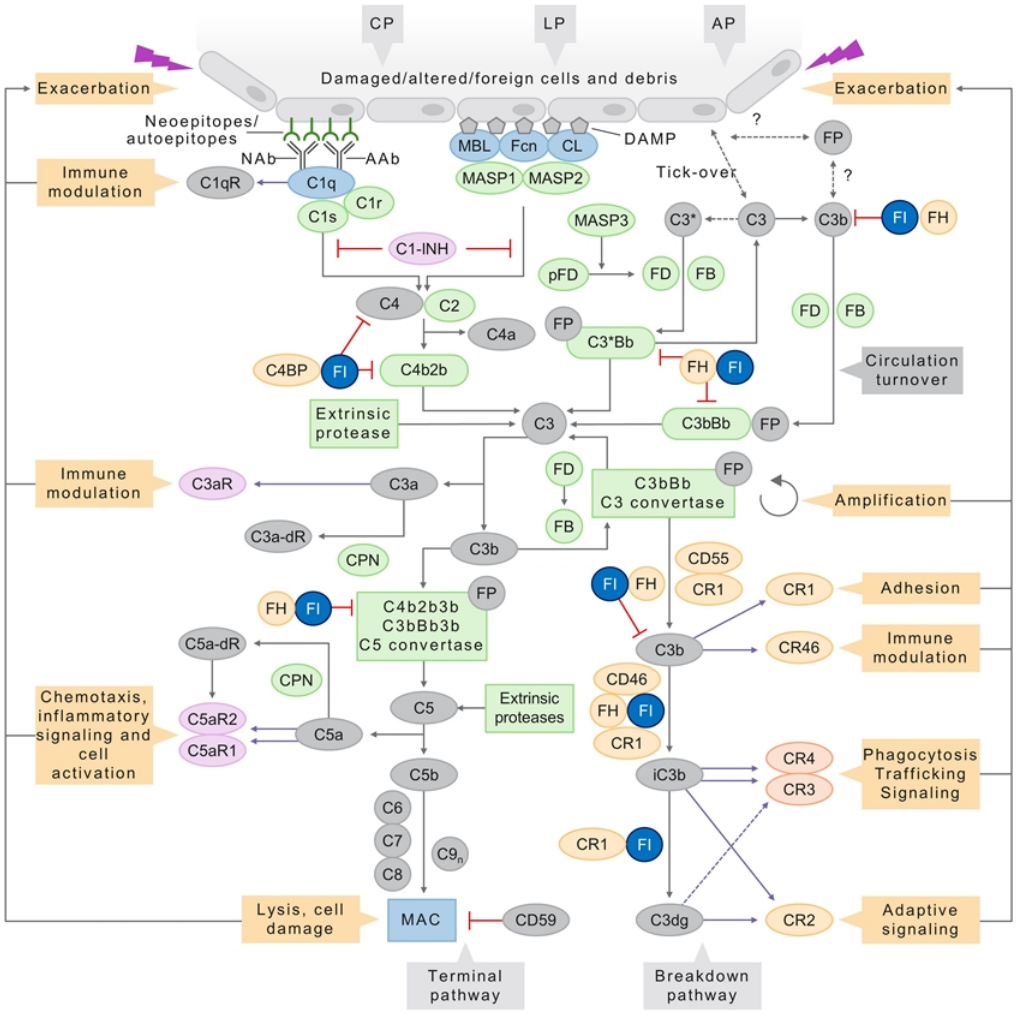
GT ≥30 bleeds

HA ≥15 bleeds

Growing Complement Pathw
Protease Platform

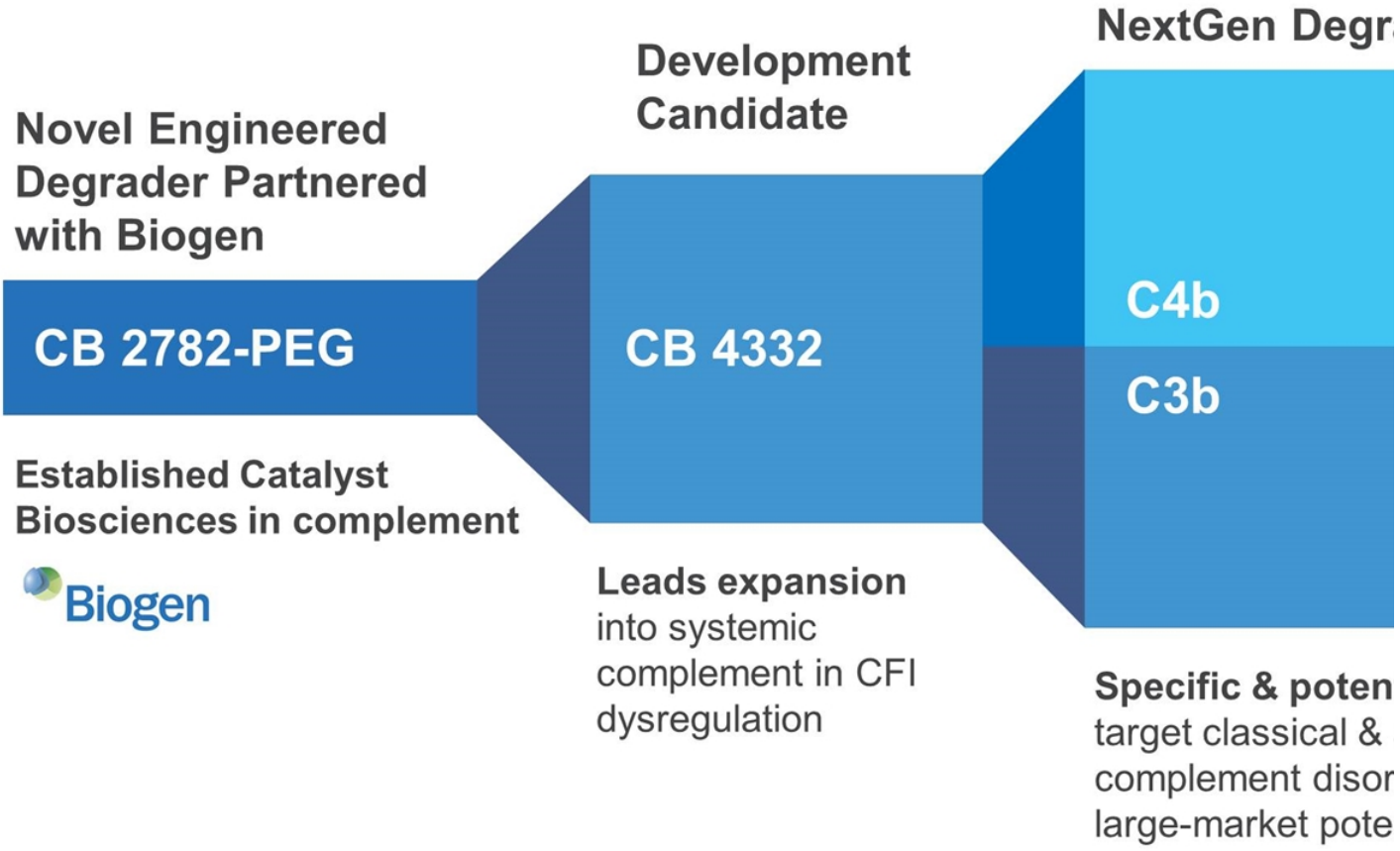
Complement is a perfect fit to develop pro

The complement pathway is driven by a protease ca

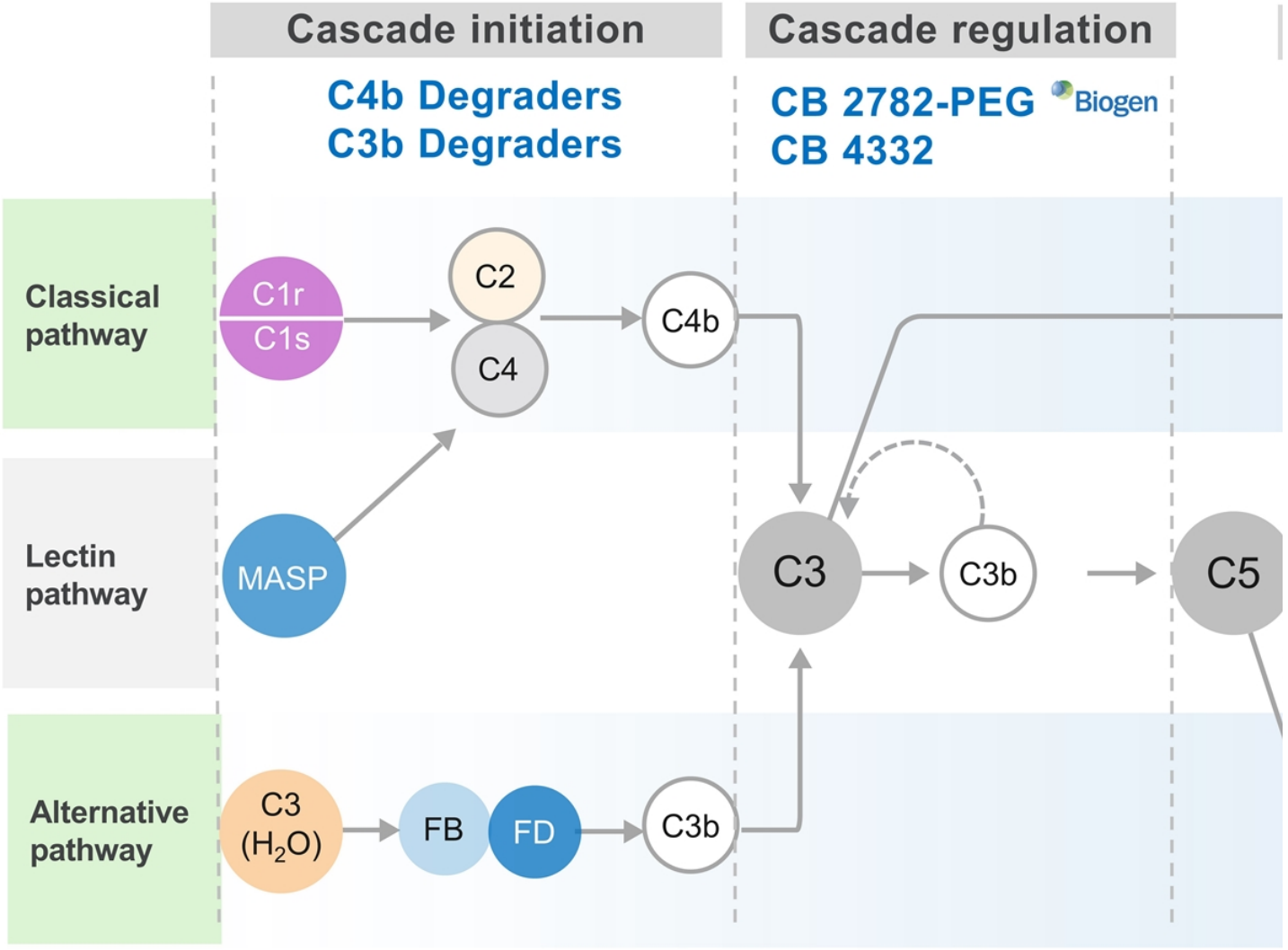


 Source: Figure adapted from Mastellos *et al.*, Clinical promise of next-generation complement ther

Multiple, high-value complement program



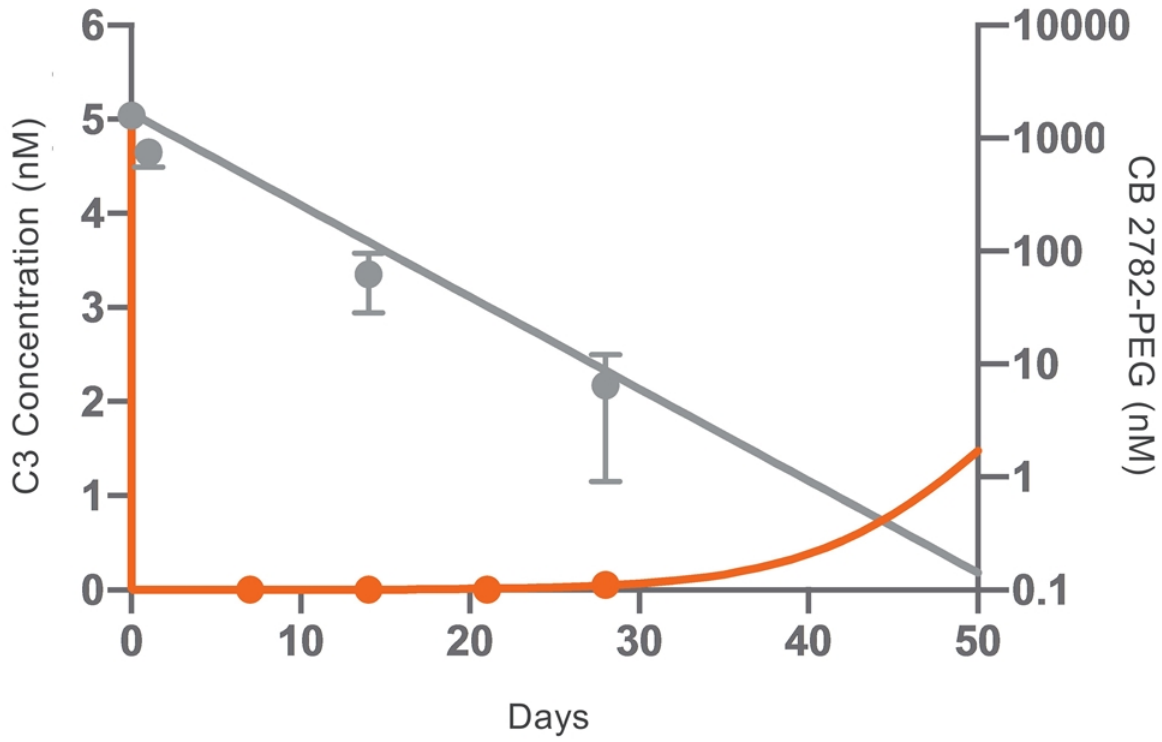
Unique targeted approach to complement



CB 2782-PEG: Best-in-class C3 degrader f

Protease advantage demonstrated *in vivo*

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 proteas

Geographic atrophy is a high unmet need

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

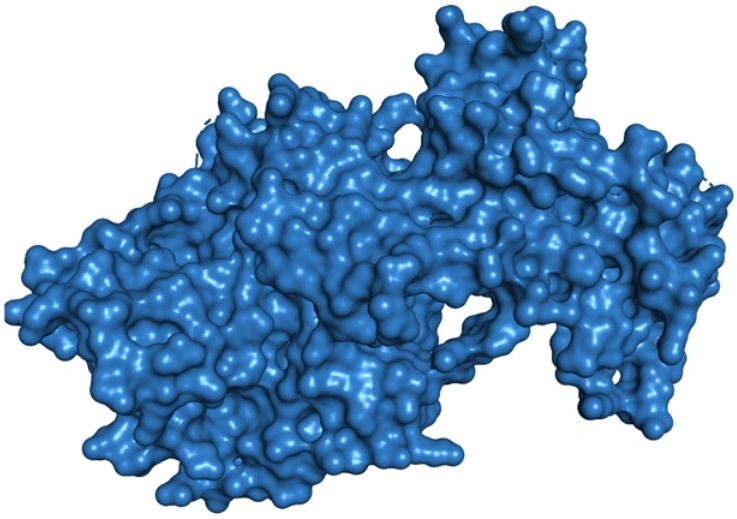
Best-in-class C3 degrader for dry AMD

+ Generated from Catalyst's proprietary **protease engineering platform**
+ Potent, selective & long act degrades C3 into inactive fragments
+ NHP PK & PD data* predic **best-in-class** human intrav **dosing 3 or 4 times a yea**

 *Furfine *et al.* ARVO 2019

CB 4332: SQ Enhanced Complement Facto

Development candidate to restore regulation



+ **Engineered for an extended half-life**
  + Once weekly SQ therapy – no PEG
+ ***In vitro & ex vivo* activity comparable to native CFI**
  + Classical & alternative pathway regulation
+ **High yield production process**

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

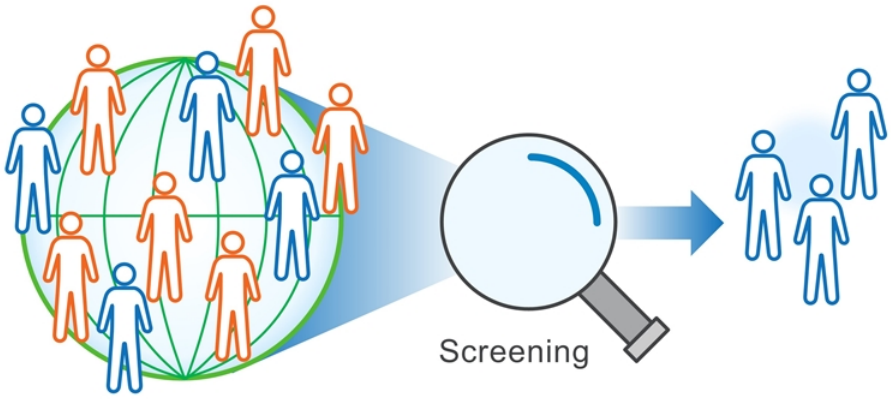
CB 4332: To address CFI deficiency at the

Designed to provide unique advantages

Unmet needs in CFI deficiency
Blocks complement-initiated cell destruction in the circulation
Directly addresses root cause of disease
Addresses extravascular hemolysis
Preserves normal immune functions, *e.g.* to fight off infections
Convenient weekly SQ administration

Screening & natural history of disease stu

ConFIrm & ConFIdence: preparing for Phase 1/2



Identifies Target Popula
Study / Discovers Undia

ConFIrm study

ConFIdence st

Prospective Cli
of CFI-Deficien

- **Identification of CFI-deficient patients & key investigato**
- **Discover undiagnosed disease, create program awaren**

CB 4332: Phase 1/2 - First in human study

Study parts

Single Ascending Doses
(N=up to 12)

Multiple Ascending Doses
(N=up to 9)

Extended treatment to assess proof of concept
(N=up to 15)

Study design

+ Phase 1 open-label, s
  & extended duration p
+ Population: CFI-defici

Proposed starting d

+ 0.5 mg/Kg

Goals

+ Safety & tolerability
+ PK characterization
+ Assessment of compl
  Bb/FB ratio, iC3b, C3
+ Establish a Recomme
  the CFI normal range

Diseases with CFI mutations have tremen

US / EU5 market opportunity

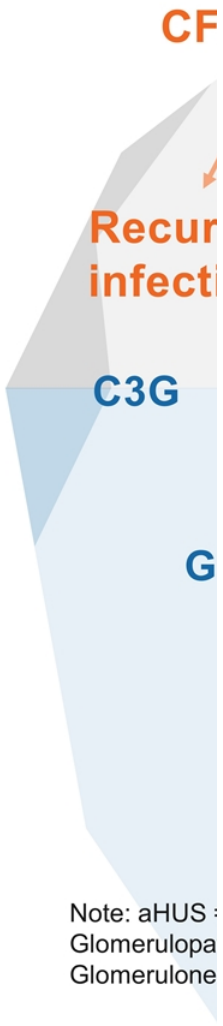
CFI Deficiency
First indication

$500M+
Market opportunity in CFI deficient populations

0 Specific systemic therapies in development for patients with dysregulated CFI

0 Therapies addressing the root cause of disease

0 Approved treatments for C3G, IC-MPGN, CFID

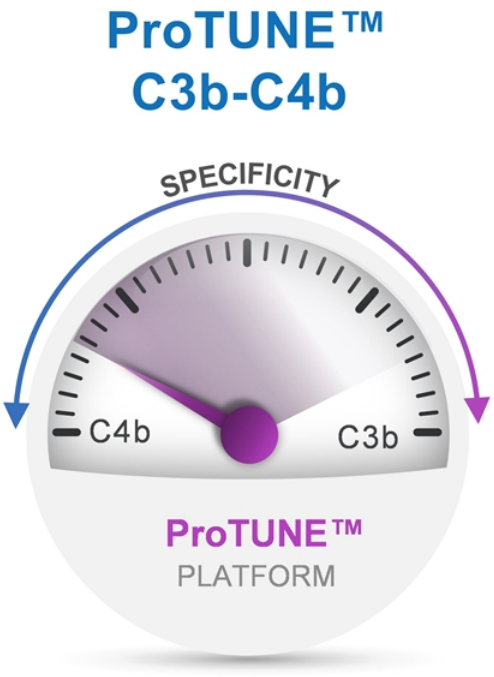


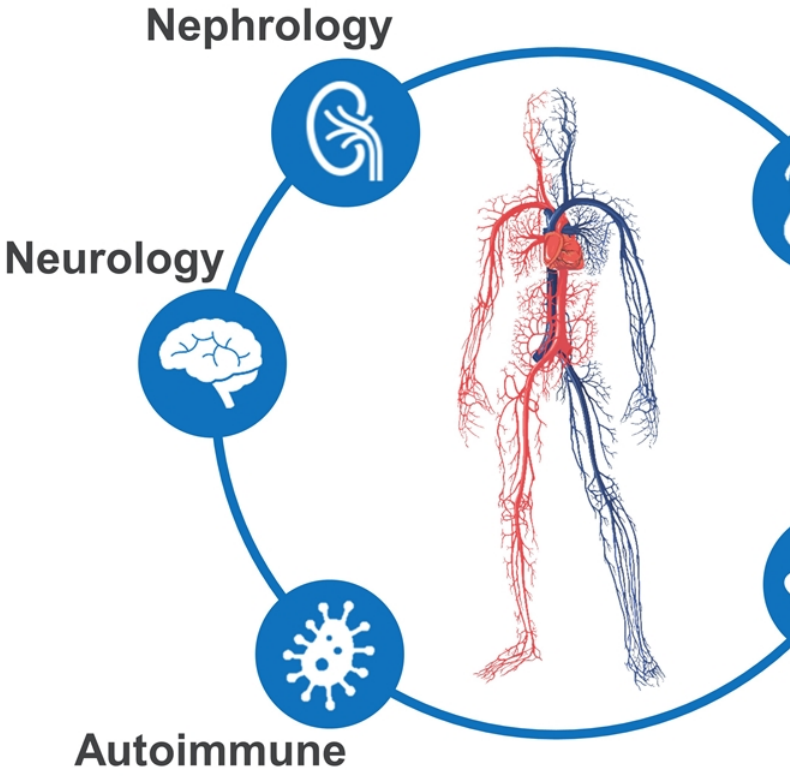
Note: aHUS =
Glomerulopa
Glomerulone

Bresin *et al*. JASN. 2013; Fremeaux-Bacchi *et al*. ASN. 2013; Rui-Ru *et al*. Jour Rare Dis Res. 20
Mol Immunol. 2016; Hou *et al*. Kidney Int. 2014; Alba-Domiguez *et al*. J rare Dis. 2012. El Sissy *e*
Immunol. 2019; Naesens *et al*. Jour Allergy & Clin Immunol. 2020; Yan *et al*. Clin Epi 2020; Smith
Soc Nephrol. 2010; CBIO KOL interviews

Our protease platforms are tailored to spe

Tuning functionality to restore complement homeos

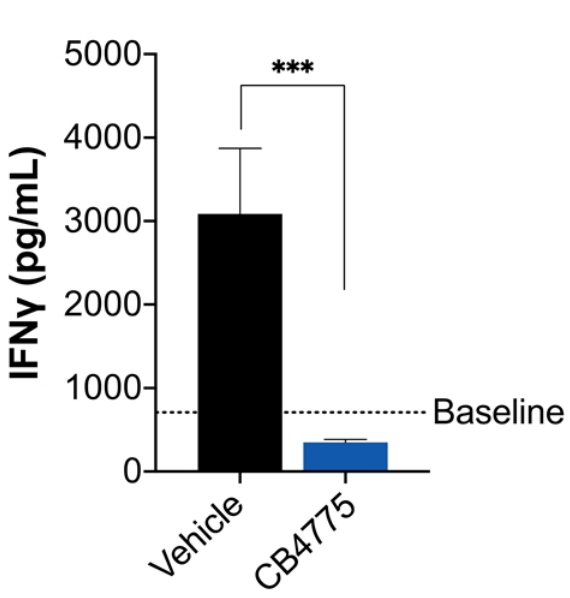


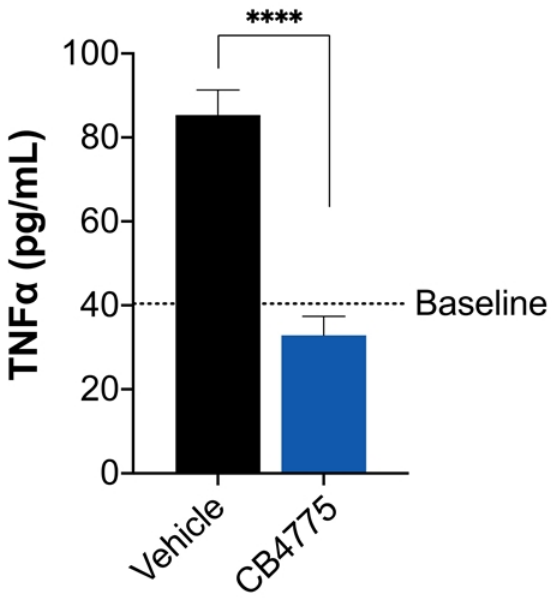


C3b-C4b degraders significantly reduce in

Significantly decrease in inflammatory markers inv

Inflammatory markers in IgA nephropathy





Rat model

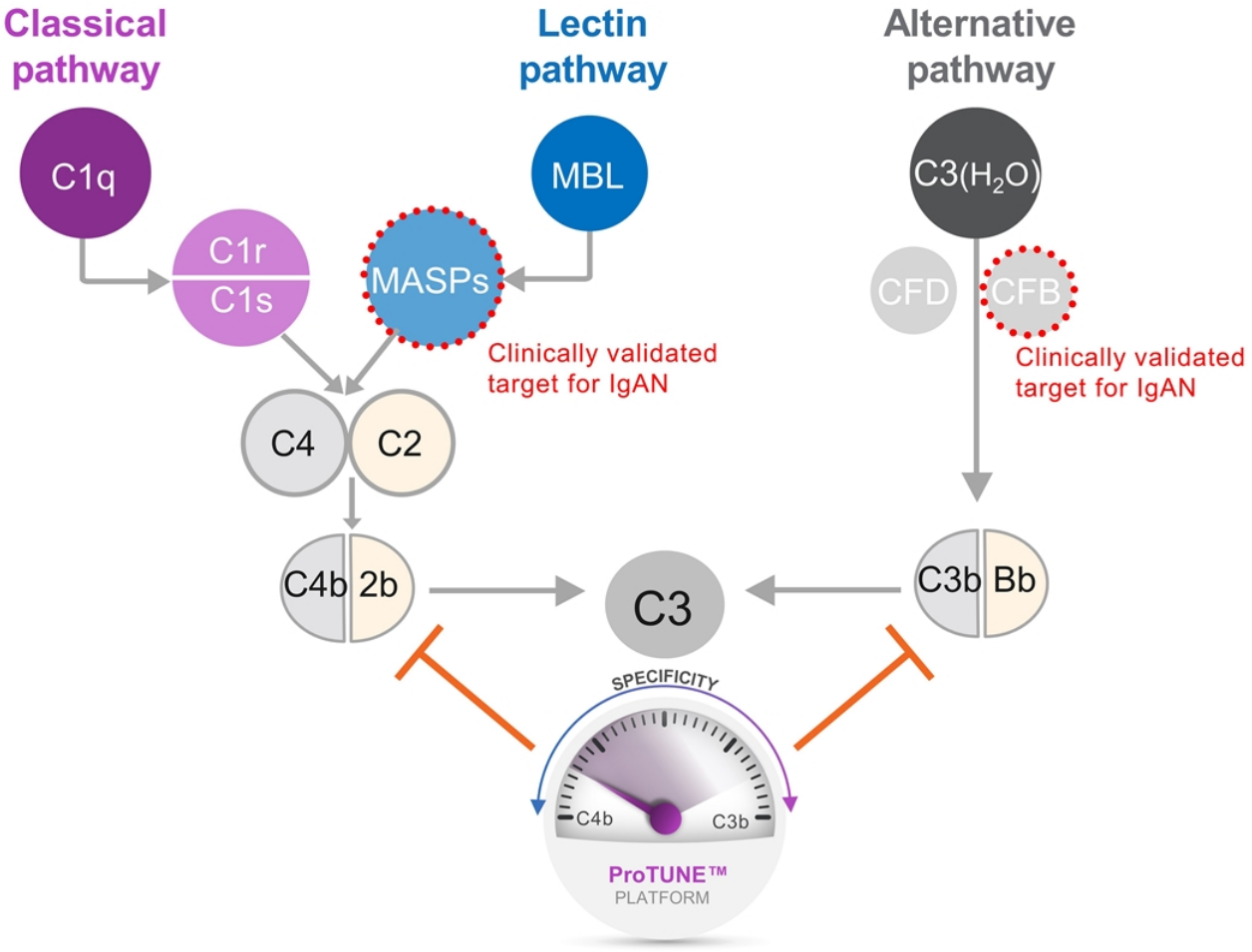
Reduction of **IFNγ & TNFα** involved in kidney damage & prot

1. Yano, N. *et al.* Phenotypic Characterization of Cytokine Expression in Patients With IgA Nephrop Th1/Th2 predominance and proinflammatory cytokines determine the clinicopathological severity o

Values are mean +/- SEM, ***p<0.001 using One Way or Two-way ANOVA.

C3b-C4b degraders for IgA nephropathy p

Dual targeting of alternate & lectin pathways

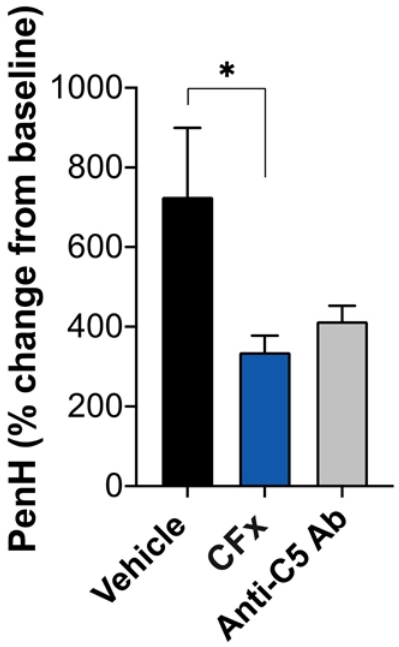


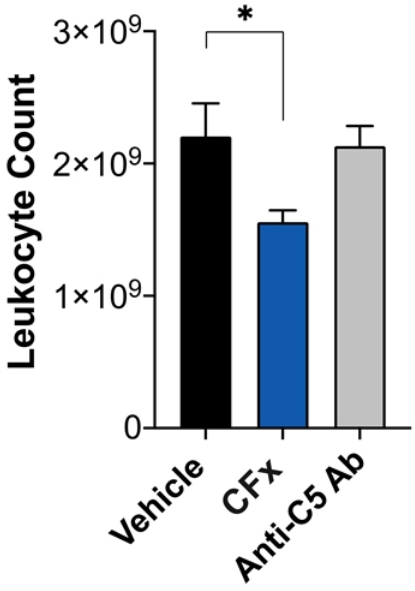
1. Medjeral-Thomas *et al*. Kidney International Reports (2018); 2. Bi *et al*. BMC Nephrology (2019)

C3a-C5a degraders: Efficacy in an acute LP

CFx improves respiratory function & reduces cell in

Respiratory functions & cell infiltration at 24 h



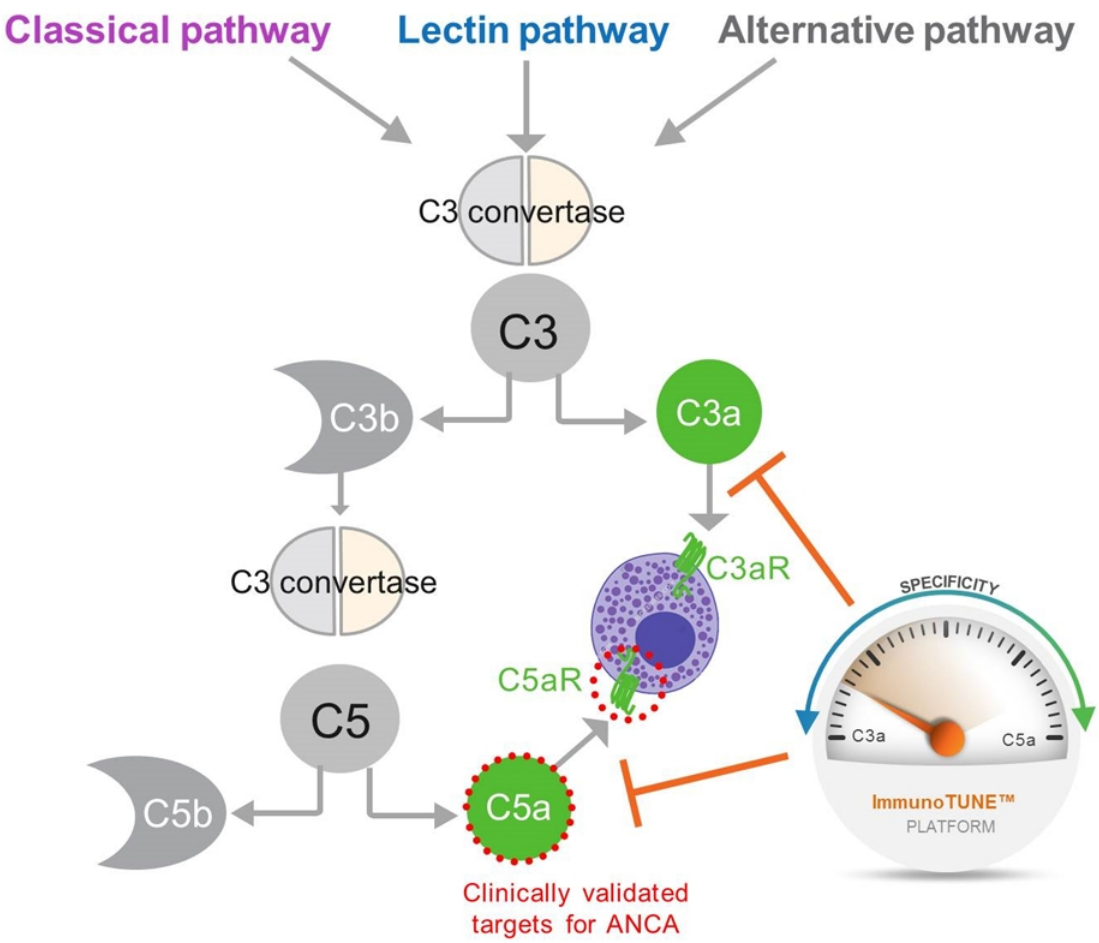


CFx 7-fold lower dose vs. anti-C5

- CFx **outperforms** anti-C5 antibody in reducing inflamma
- CFx **compares well** on respiratory functions with anti-C5

C3a-C5a degraders: Potential for ANCA-A

Dual targeting of both C3a & C5a with one protease



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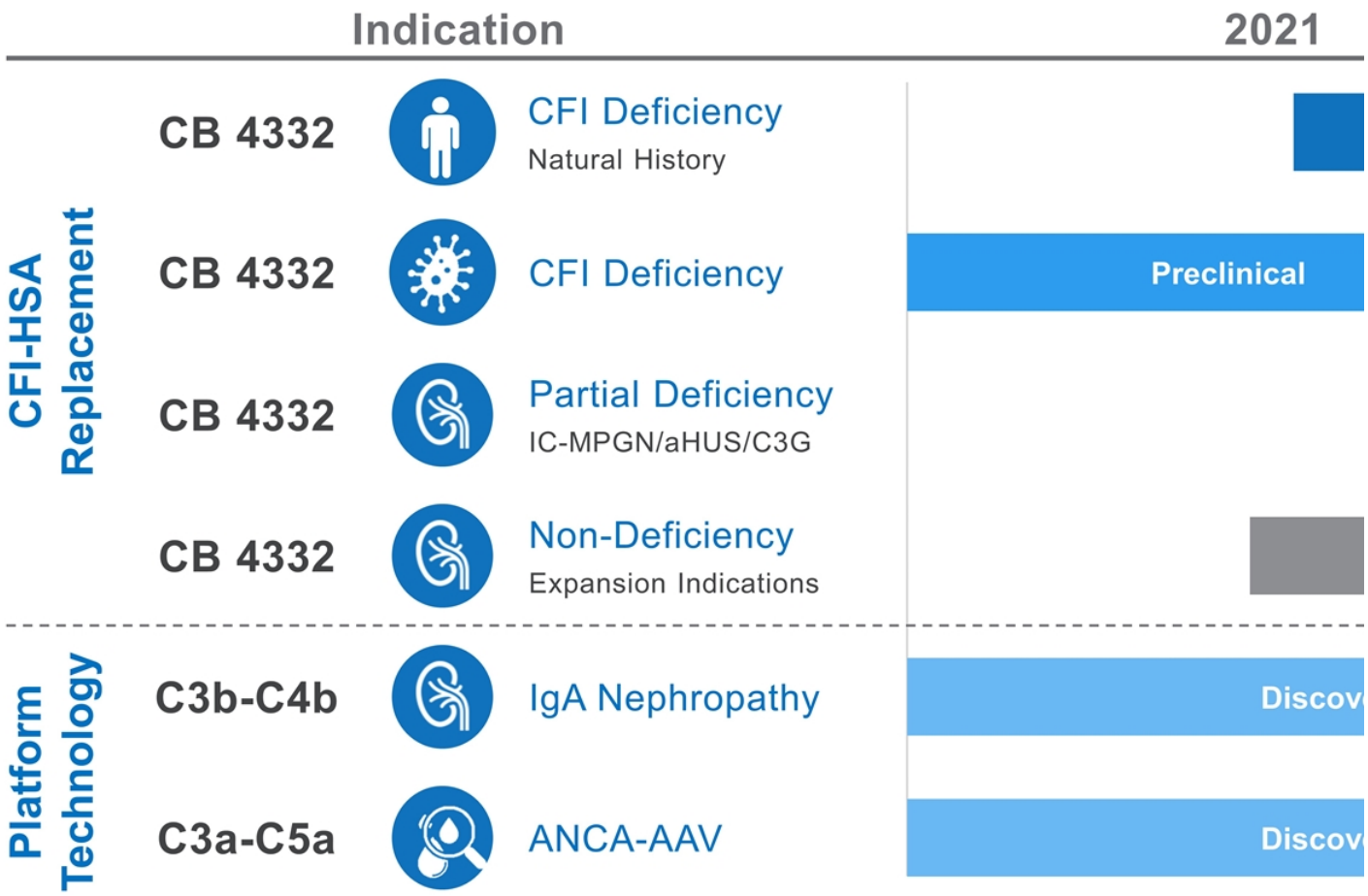
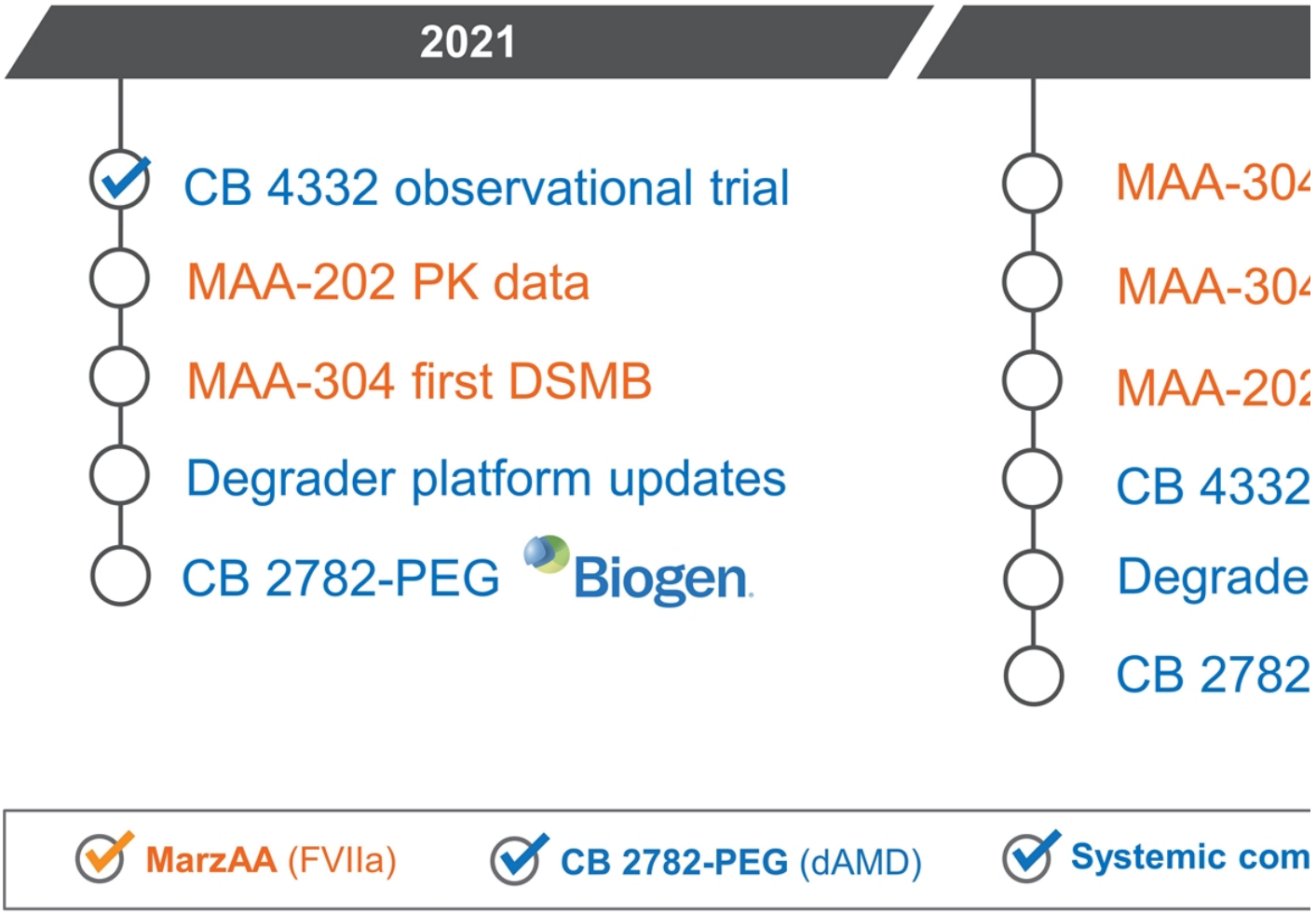
1. S. Moiseev *et al*. British Society for Immunology, Clinical and Experimental Immunology (2020);

CB 4332 spearheads a deep pipeline in co

IND & next development candidate in 2022



Milestones



THANK YOU

Nasdaq: CBIO

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