

---

---

**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): December 24, 2015**

---

**CATALYST BIOSCIENCES, INC.**  
(Exact name of registrant as specified in its charter)

---

**Delaware**  
(State or other jurisdiction  
of incorporation)

**000-51173**  
(Commission  
File Number)

**56-202050**  
(IRS Employer  
Identification No.)

**260 Littlefield Ave.**  
**South San Francisco, California**  
(Address of principal executive offices)

**94080**  
(Zip Code)

**(650) 266-8674**  
**Registrant's telephone number, including area code**

---

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))
- 
-

**Item 7.01. Regulation FD Disclosure.**

Beginning on December 24, 2015, Catalyst Biosciences, Inc. (the “Company”) is making available to financial analysts, current and prospective investors and other interested parties the electronic slide show presentation attached hereto as Exhibit 99.1.

The information in this Current Report on Form 8–K, including Exhibit 99.1, shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability 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, except as we may specifically state in any such filing.

**Safe Harbor Statement**

Statements contained in the slide show presentation that state expectations or predictions about the future are forward-looking statements intended to be covered by the safe harbor provisions of the Securities Act and the Exchange Act. The Company’s actual results could differ materially from those projected in such forward-looking statements. Factors that could affect those results include “Risk Factors” and the other factors appearing in the documents that the Company has filed with the Securities and Exchange Commission.

**Item 9.01. Financial Statements and Exhibits.**

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
99.1	Slide show presentation.

**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: December 24, 2015

/s/ Nassim Usman

---

Nassim Usman, Ph.D.

President and Chief Executive Officer

**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
99.1	Slide show presentation.

# Catalyst Biosciences

Exceptional Science. Essential Medicines.



## Company Overview December 2015

## Forward Looking Statements



This presentation includes forward-looking statements relating to the Catalyst Biosciences, Inc. (the "Company"). Forward-looking statements include statements about the potential markets for the Company's product candidates, the potential advantages of the Company's product candidates, product development plans and timelines, potential safety and efficacy of the Company's product candidates, potential sales of product candidates, if approved, the Company's intellectual property and any statement of belief or assumptions underlying any of the foregoing. These statements reflect the current views of the Company's senior management with respect to future events. Forward-looking statements address matters that involve risks and uncertainties, such as the timing of, costs associated with and outcomes of development, clinical and regulatory activities, risks associated with third-party arrangements, including the risk that Catalyst must negotiate with Pfizer about obtaining manufacturing technology and know-how related to CB 813d, potential adverse effects arising from the testing or use of the Company's drug candidates, risks related to the Company's ability to develop, manufacture and commercialize product candidates, to obtain regulatory approval of product candidates and to obtain marketplace acceptance of product candidates, to avoid infringing patents held by other parties and to secure and defend patents of the Company, and to manage and obtain capital, including through any future financing or the conversion of outstanding convertible promissory notes. Further information regarding these and other risks is included in the Company's Form 10-Q for the quarter ending September 30, 2015 filed with the Securities and Exchange Commission on November 5, 2015, under the heading "Risk Factors."

Exceptional Science.  
Essential Medicines.

Next generation protease therapeutics  
Billion dollar market opportunities

## Hemostasis FVIIa, FIX & FXa

- Current products generate ~\$3.3 billion/year in sales
- Catalyst Next Generation products have potential for multibillion/year in sales from growth in prophylaxis, new markets & new indications

## Complement Anti-C3 IRI and Eye & anti-FB

- Current anti-complement drug (Soliris® - Alexion) generates ~\$2 billion/year in sales
- Catalyst Anti-Complement products have critical advantages in multiple new indications

# Catalyst Biosciences Pipeline



## Next Generation Hemostasis Programs

### FVIIa: CB 813d

Hemophilia A&B w Inhibitors, Surgical Bleeding



### FIX: CB 2679d/ISU 304

Hemophilia B



### FXa

Universal Pro-coagulant



## Anti-Complement Programs

### Anti-C3: CB 2782

Renal Delayed Graft Function, IRI cardiovascular



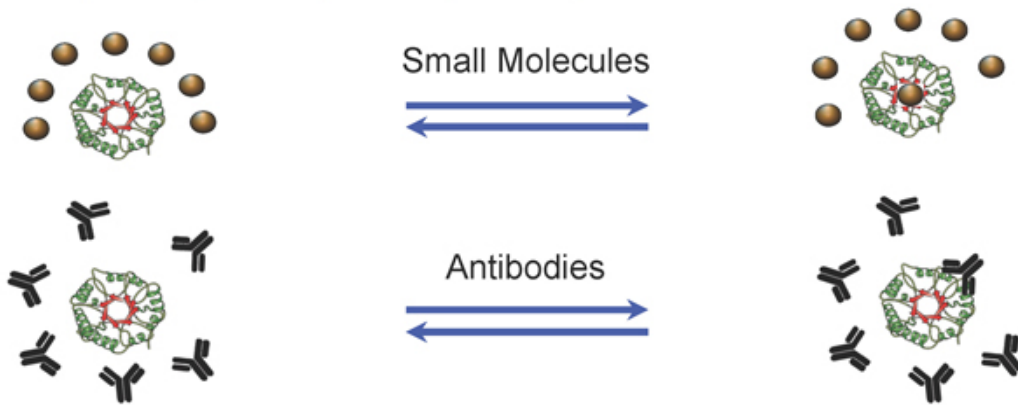
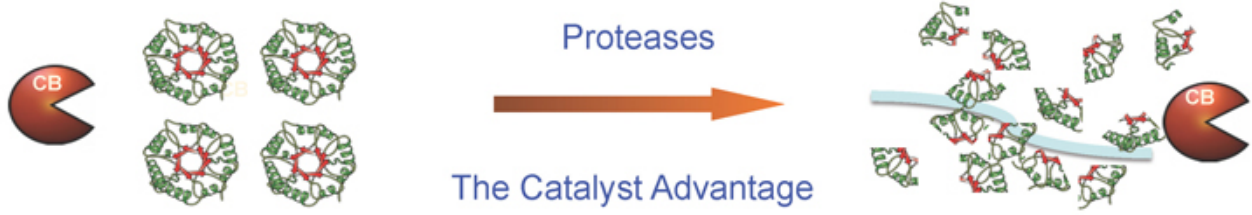
### Anti-C3: Ophthalmic

Dry AMD



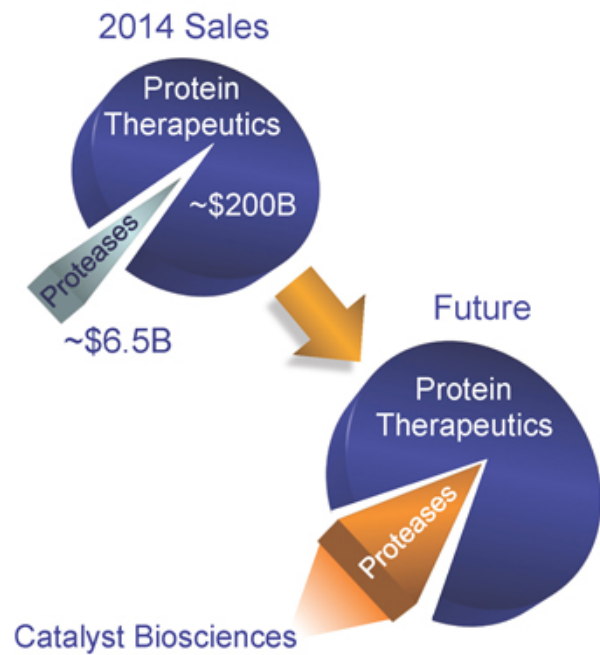


# Proteases – A Unique Mechanism Of Action



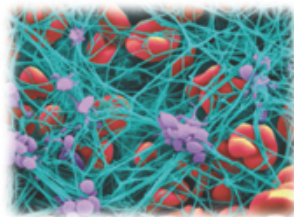
## Currently Approved Proteases

- Microplasmin (Vitreomacular adhesion)
- Botulinum Toxin (Blepharospasm, wrinkles)
- Factor VIIa (Bleeding disorders)
- Factor IX (Hemophilia B)
- t-PA (Myocardial infarction, stroke)
- Thrombin (Bleeding disorders)
- FEIBA (FXa - Bleeding disorders)
- u-PA (Catheter clearing, PAO)
- Zenpep (digestive aid)



## Disease

- Hereditary, chronic condition - orphan disease with a growing population
- Two primary forms: hemophilia A (FVIII) and hemophilia B (FIX), combined ~400,000 patients WW\*
- Patients have complete or severe deficiency of a clotting factor (receive FVIII or FIX) needed to form stable blood clots or have antibodies (inhibitors) against their replacement factor (receive FVIIa or FEIBA)
- Internal bleeding in joints causes substantial pain, inflammation, joint damage, and loss of mobility



\*Bolton-Maggs & Pasi, The Lancet 2003, v361 p1831

## Market Characteristics

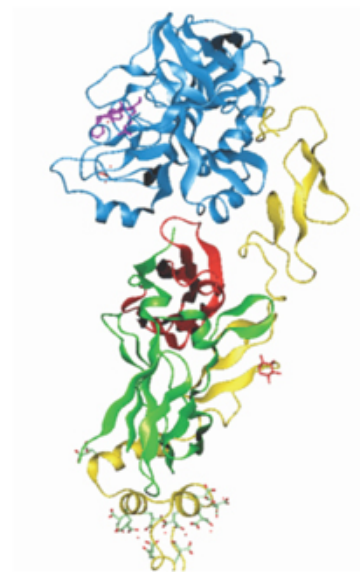
- Recombinant "replacement" factors, FVIII or FIX, or FVIIa/FEIBA are the dominant modes of treatment
- Drugs administered intravenously by patients or caregivers
- P1 trials are in hemophilia patients with PD efficacy endpoints
- Recent registration trials have been single P2/3s
- Small sales force requirement

## Key Unmet Needs

- Products that enable prophylactic treatment, prevent internal joint damage
- Faster-acting and more efficacious products for bleeds

➤ **One product that does both**

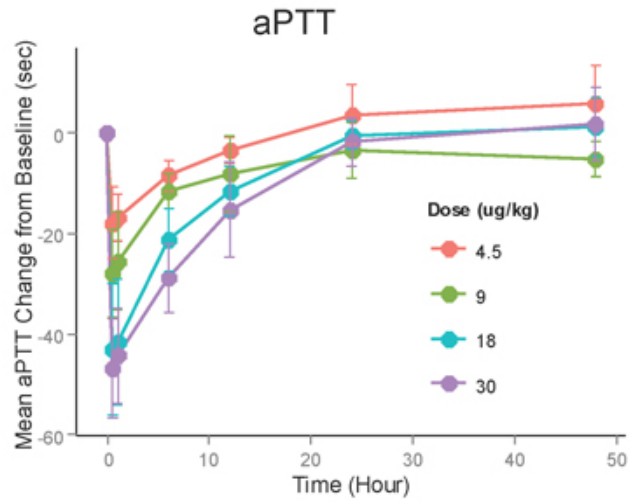
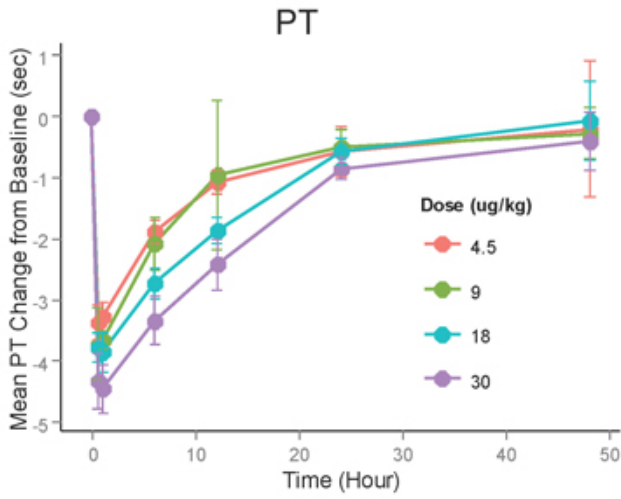
- Current FVIIa market ~\$1.5B (NovoSeven®)
- Leading next-generation FVIIa in the clinic
- Significant improvements (6-9 fold) in potency, duration of effect and an improved therapeutic index vs NovoSeven in multiple pre-clinical animal models
- Phase I *in severe hemophilia patients* ( $\pm$  inhibitors) demonstrated Proof-of-Mechanism (PoM) with excellent safety and tolerability
  - Safe and well tolerated, no serious TEAEs
  - Improved correction of PT and aPTT (vs NovoSeven) for up to 48 h



Activated blood coagulation Factor VII

<http://clinicaltrials.gov/ct2/show/NCT01439971?term=FVIIa&rank=2>

Substantial & dose dependent correction of PT & aPTT at all doses



- Single doses up to 30 µg/kg were very well tolerated when administered to 25 hemophilia A and B patients in the non-bleeding state
- There were no instances of thrombosis or bleeding
- Evidence of pharmacologic activity was observed with dose-dependent changes of PT, aPTT, PF1+2, and TGA for up to 48 hours
- The terminal half-life of CB 813d was approximately 3.5 hours and was similar across all dose groups
- The results for safety and pharmacologic activity support further clinical development of CB 813d for treatment of individuals with hemophilia and inhibitors to FVIII or FIX
- Phase 2/3 trial anticipated to begin in Q1 2017

# Factor VIIa: CB 813d Advantages & Competition

Catalyst vs Commercial Products	Product	Indication(s)	2013 Annual Sales	Overall Control of Bleeding	Avg. Doses to Control Bleed	Prophylactic Dosing Frequency	Safety
	NovoSeven <sup>®</sup> RT <small>Recombinant Factor VIIa (Recombinant)</small>	Hemophilia with Inhibitors	~\$1.5 billion*	Good	2-3	Daily	Good
CB 813d	Hemophilia with Inhibitors	N/A	Excellent	1	2-3x/week	Excellent	

Pipeline Products	Product (Company)	Molecule; Mechanism	Stage	Notes / Competitive Attributes
	BAX 817 (Baxter)	rhFVIIa	Phase 3	Biosimilar; will not be differentiated from NovoSeven
LR769 (rEVO Biologics)	rhFVIIa	Phase 3	Biosimilar; only difference from NovoSeven is manufacturing cost	
CSL 689 (CSL Behring)	rhVIIa Albumin fusion	Phase 2/3	rFVIIa-albumin fusion for longer PK; half-life is 6-9 fold greater than NovoSeven in rats but has significantly reduced activity; Phase 2/3 initiated in August 2015	
ACE910 (Roche/Chugai)	Bi-specific antibody to FIXa and FX	Phase 1/2	Unlikely to treat breakthrough bleeding; multiple ADA's (including neutralizing) observed in early trials	
ALN-AT3 (Anylam)	RNAi anti-thrombin inhibitor	Phase 1	Very unlikely to treat breakthrough bleeding. Likely to have narrow therapeutic window and may compromise safety for rescue options	

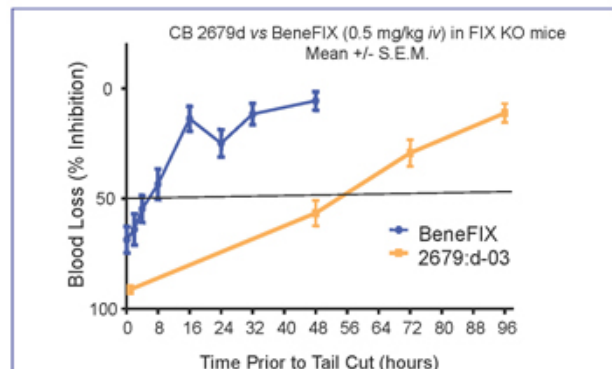
\*NovoNordisk 2014 Annual Report

Gene therapy NOT applicable to FVIIa

## Factor IX: CB 2679d (ISU 304)



- Current FIX market ~\$1B (BeneFIX)
- Designed as best-in-class long-acting recombinant FIX product
- Significantly longer acting and more potent than BeneFIX®, Alprolix® (FIX-Fc) & FIX-GP
- Development Alliance with ISU Abxis, a Korean biopharmaceutical company (Cerezyme & ReoPro)
- Preclinical IND-enabling development initiated
- Phase 1 in 2016



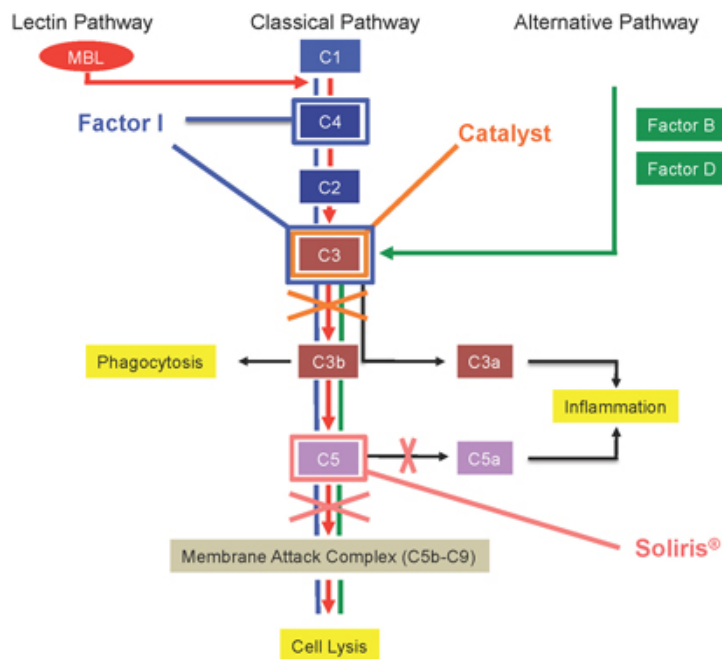
### Catalyst-ISU Alliance Terms

- Upfront & milestone payments to Catalyst
- ISU Abxis responsible for all costs through proof-of-concept Phase 1
- **Catalyst controls global development & commercialization post Phase 1 (ex-Korea)**
- Profit sharing on products worldwide



- Complement targets are biologically & clinically validated
  - KO mice studies
  - Human genetics
  - Approved drug (Soliris®) for PNH & aHUS;
  - Positive P2 data for Dry Age-Related Macular Degeneration (AMD) – Geographic Atrophy (GA)
- Multiple acute indications mediated by complement driven ischemia reperfusion injury
  - Transplant rejection: Initial indication – anti-C3 to prevent Renal Delayed Graft Function (DGF)
  - Cardiovascular: CABG, MI & Stroke (label expansion potential for a DGF drug)
- Chronic indications
  - Ocular: Initial indication – anti-C3 (ocular) to slow the progression of GA in Dry AMD
  - Asthma
  - Autoimmune

# Complement Cascade: Ideal Application for Catalyst's Protease Platform



## Competitive advantages

- Fundamentally better approach than antibodies or small molecules
- Mimics nature's solution
- Efficiently inactivates cascade amplification
- 1 protease drug molecule can efficiently inactivate several hundred target molecules/hour
- Anti-C3 prevents release of pro-inflammatory mediators (C3b) and anaphylotoxins (C3a) – anti-C5 cannot
- Potential to inactivate any target (especially high concentration ones)

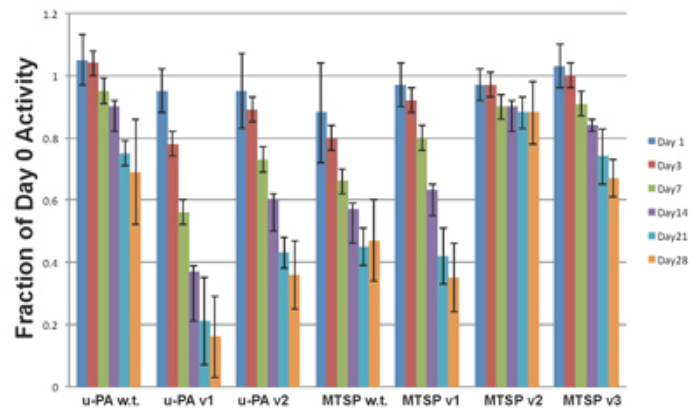
- Advanced dry AMD, or geographic atrophy (GA), leads to loss of RPE photoreceptors, blindness
- No approved drugs
- Global wet AMD market is >\$4 billion annually
- GA prevalence is equivalent to wet AMD
- Strong genetic evidence for complement in pathogenesis of dry AMD\*
- Complement is the only validated anti-GA target
  - Roche anti-Factor D antibody @ 10 mg/eye intravitreal injection showed 20-44% inhibition of GA progression with monthly dosing; dosing every 2 months failed
- C3 is the "best target" in the complement cascade
  - Targeting either individual pathways, e.g., alternative (Factor D) or C5 appears to be "leaky", consequently limiting efficacy
- Efficient inactivation of C3 expected to provide greater efficacy compared with competing anti-Factor D or anti-C5 strategies
- Catalytic turn-over of target expected to support efficacious dosing every 2 months or less frequently
- Less than 40% inhibition of GA progression over 18 months would be acceptable if dosing was less frequent than monthly

\**Science*, April 2005; *JAMA*, July 2006; *NEJM*, July, 2007; and others

# C3 Inactivation & Stability in Vitreous Humor

- Catalyst anti-C3 AMD protease candidates have been optimized for the ocular environment
- 1 anti-C3 AMD protease molecule can efficiently inactivate several hundred target molecules/hour in non-human primate vitreous humor
- Current leads are stable in human and primate vitreous for >4 weeks
- Strong potential for less frequent than 1x/month administration
- Undergoing safety & PK/PD testing in primates
  - Current lead's NOAEL higher than for the approved protease ocular drug, Jetrea®

Anti-C3 Protease Stability in Cynomolgus Vitreous Humor



# Anti-C3 for Renal Delayed Graft Function (DGF)

- High unmet medical need: DGF in 20-30% of all cadaveric allograft recipients
- Multiple animal studies have established key role for complement in ischemia reperfusion injury
- Fast, straightforward development:
  - P1 in normal volunteers as a bridge to P2
  - P2 Endpoint: dialysis within 1 week of transplant
- Patient and payer benefits:
  - Reduced dialysis, shorter hospital stays
  - Reduced acute rejection, extended graft life
- DGF annual market opportunity of >\$500M/year\*
- Gateway to billion \$ MI, CABG & stroke markets

\*Health Advances Market Evaluation 2010

## Anti-C3 Proteases in Non-human Primate Model

Variant	Scaff old	C3 Destruction ED <sub>50</sub> (mg/kg)	Top Non-Toxic Dose (mg/kg)	Single Bolus T.I.
CB 2470	MTSP	0.2	≥2	~10
CB 2561	MTSP	0.1	≥2	~20
CB 2558	MTSP	0.2	≥4	~20
CB 2750	MTSP	0.06	≥1	~17
CB 2782	MTSP	0.07	≥4	>57
CB 3064	MTSP	0.04	≥2	>50
CB 2963	u-PA	0.3	≥4	>13

Comprehensive protection of all programs & protease engineering technologies

- **Factor VIIa:** Worldwide patents encompassing clinical candidate(s) and uses thereof, granted and pending, providing coverage through 2029-2031
- **Factor IX:** Worldwide patents (including composition of matter) granted and pending providing coverage through 2031
- **Factor Xa:** Worldwide patents (including composition of matter) filed and pending providing coverage through 2033
- **Anti-complement programs:** Current granted and pending worldwide, patents (including composition of matter) providing coverage through 2025, with new material >2035
- **Technology platform:** Worldwide issued and pending patents covering multiple novel protease screening and discovery technologies with through 2026

- 2016
  - Receive ISU FIX milestones
  - Publish data from the FVIIa, FIX, and anti-complement programs
  - Initiate CB 2679d FIX Phase 1 in hemophilia B patients
  - Demonstrate bi-monthly dosing feasibility in the Dry AMD program
  - Manufacture CB 813d FVIIa for P2/3 trial
  - Report initial Phase 1 proof-of-mechanism efficacy and safety data for CB 2679d FIX in hemophilia B patients
- 2017
  - Initiate CB 813d FVIIa P2/3 trial in hemophilia A + B inhibitor patients
  - Complete CB 2679d FIX Phase 1 in hemophilia B patients
  - Report on-demand efficacy and multi-dose safety in CB 813d FVIIa trial

- Clinical Stage Public Protease-Based Hemostasis and Anti-Complement Company
  - Design of improved, second generation proteases: FVIIa & FIX
  - Proprietary platform that creates novel proteases: Anti-complement
- Leading next generation, long-acting Factor VIIa for hemophilia A/B inhibitor patients in ~\$1.5B market with significant growth potential
  - Proof of mechanism, safety & tolerability demonstrated in hemophilia patients
  - Phase 1 Clinical Data presented at ISTH in June 2015
  - Phase 2/3 trial to initiate in Q1 2017
- Best-in-class Factor IX in hemophilia B; fully-funded to clinical Proof of Mechanism in late 2016
- Three additional programs
  - Highly differentiated, clinically-validated anti-complement approach to multibillion dollar Dry AMD market
  - Novel, anti-complement orphan program (renal delayed graft function) ready for IND-enabling studies
  - Best-in-class Factor Xa for hemophilia and surgical bleeding with strong pre-clinical efficacy



# Catalyst Biosciences

Exceptional Science. Essential Medicines.



[www.catalystbiosciences.com](http://www.catalystbiosciences.com)