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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2015

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 000-51173

Catalyst Biosciences, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**56-2020050**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
260 Littlefield Ave. South San Francisco, California	**94080**
(Address of Principal Executive Offices)	**(Zip Code)**

(650) 266-8674
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common stock, par value $0.001 per share	**The NASDAQ Capital Market**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act). Yes ☐ No ☒

The number of shares outstanding of the registrant's common stock as of March 1, 2016 was 11,430,104. The aggregate market value of the voting stock held by non-affiliates of the registrant as of June 30, 2015, was approximately $63,198,734. There is no non-voting stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the registrant's Proxy Statement for the registrant's 2016 Annual Meeting of Stockholders will be filed with the Commission within 120 days after the close of the registrant's 2015 fiscal year and are incorporated by reference in Part III.

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CATALYST BIOSCIENCES, INC.
Annual Report on Form 10-K
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PART I

Forward-Looking Statements and Market Data

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"), as amended. These forward-looking statements should not be relied upon as predictions of future events as we cannot assure you that the events or circumstances reflected in these statements will be achieved or will occur. Forward-looking statements are identified by words such as "believes," "expects," "may," "will," "should," "seeks," "intends," "plans," "pro forma," "estimates," or "anticipates" or the negative of these words and phrases or other variations of these words and phrases or comparable terminology. Such forward-looking statements are based on current expectations.

You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. For example, forward-looking statements include any statements regarding:

- the strategies, prospects, plans, expectations or objectives of management for future operations;
- the progress, scope or duration of the development of product candidates or programs;
- the benefits that may be derived from product candidates or the commercial or market opportunity in any target indication;
- our ability to protect intellectual property rights;
- our anticipated operations, financial position, revenues, costs or expenses, statements regarding future economic conditions or performance;
- potential regulatory filings for or approval of any of our product candidates;
- the progress of our third-party collaborations, including estimated milestones;
- our intention to seek, and the ability to enter into strategic alliances and collaborations;
- the responsibilities of our collaborators, including the responsibility to make cost reimbursement, milestone, royalty and other payments to us, and our expectations regarding our collaborators' plans with respect to our products;
- our responsibilities to our collaborators, including our responsibilities to conduct research and development, clinical trials and manufacture products;
- the results and timing of clinical trials and the possible commencement of future clinical trials;
- conditions for obtaining regulatory approval of our product candidates;
- submission and timing of applications for regulatory approval;
- the impact of U.S. Food and Drug Administration (FDA) and other government regulations on our business,
- uncertainties associated with obtaining and protecting patents and other intellectual property rights, as well as avoiding the intellectual property rights of others;
- products and companies that will compete with the products we license to third-party collaborators;
- the possibility we may commercialize our own products and build up our commercial, sales and marketing capabilities and other required infrastructure;
- our employees, including the number of employees and the continued service of key management, technical and scientific personnel;
- our future performance and our expectations regarding our ability to achieve profitability;

- requirements for us to purchase supplies and raw materials from third parties, and the ability of third parties to provide us with required supplies and raw materials;
- sufficiency of our cash resources, anticipated capital requirements and capital expenditures and our need for additional financing;
- the composition of future revenues;
- accounting policies and estimates, including revenue recognition policies; and
- statements of belief and any statement of assumptions underlying any of the foregoing.

These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this report in Part II, Item 1A — “Risk Factors,” and elsewhere in this report. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. We caution investors that our business and financial performance are subject to substantial risks and uncertainties and they should carefully consider the factors set forth in other reports or documents that we file from time to time with the Securities and Exchange Commission.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for certain drugs, including data regarding the estimated size of those markets, their projected growth rates and the incidence of certain medical conditions. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

Unless the context requires otherwise, in this Annual Report on Form 10-K the terms “Catalyst,” the “Company,” “we,” “us” and “our” refer to Catalyst Biosciences, Inc., together with its subsidiary, Catalyst Bio, Inc. See “Item 1 - Business - Business Overview.”

ITEM 1. BUSINESS.

Overview

We are a clinical-stage biopharmaceutical company focused on creating and developing novel medicines to address serious medical conditions. To date, we have focused our product development efforts in the fields of hemostasis, including the treatment of hemophilia and surgical bleeding, and inflammation, including prevention of delayed graft function ("DGF") in renal transplants and the treatment of dry age-related macular degeneration ("Dry AMD"), a condition that can cause visual impairment or blindness for which there are no approved treatments. Our most advanced program is an improved next-generation coagulation Factor VIIa variant, CB 813d, that has successfully completed a Phase 1 clinical trial in severe hemophilia A and B patients. In addition to our lead Factor VIIa program, we have two other next-generation coagulation factors, a Factor IX variant, CB 2679d/ISU 304, that is in advanced preclinical development, and a Factor Xa variant, that has reached the advanced lead preclinical stage of development. Proteases regulate several complex biological cascades, or sequenced biochemical reactions, including the coagulation cascade that controls bleeding (hemostasis) in hemophilia and non-hemophilia settings and the complement cascade that causes inflammation and tissue damage in certain diseases.

Proteases constitute an established and prominent class of drugs, with more than ten on the market, which we estimate, based on our research, generated over $6.3 billion worldwide annual sales in 2014. Our most advanced program is an improved next-generation coagulation Factor VIIa variant, CB 813d, that has completed a Phase 1 clinical trial evaluating safety and tolerability as well as pharmacokinetics, pharmacodynamics and coagulation activity in severe hemophilia A and B patients. Based on our research, we estimate annual worldwide sales in 2014 for FDA-approved Factor VIIa products were approximately $1.6 billion. In addition to our lead Factor VIIa program, we have a Factor IX variant, CB 2679d/ISU 304, that is in advanced preclinical development and several Factor Xa variants that have demonstrated efficacy and safety in preclinical animal models. Based on our research, we estimate annual worldwide sales in 2014 for FDA-approved Factor IX and Factor Xa-containing products were approximately $1.8 billion. We believe that these three coagulation factors could form the basis of a hemostasis franchise.

We are also developing novel proteases that inhibit inflammation and tissue damage by cleaving certain components of the complement cascade, initially focused on C3. We have created and characterized the development candidate CB 2782 for the treatment of DGF in kidney transplants. We have created and discovered lead candidates for the potential treatment of dry AMD.

We have delayed initiating preclinical IND-enabling studies for our Factor Xa variants and our anti-C3 protease for the prevention of DGF so that we can focus our efforts and resources on advancing CB 813d, our next generation Factor VIIa and CB 2679d, our next-generation FIX through Phase 2/3 and Phase 1/2 clinical trials respectively.

We are applying our substantial expertise in protease engineering and its proprietary product discovery platform to create, engineer, and characterize protease drug candidates. Our protease discovery platform allows us to improve the biochemical and pharmacological properties of currently marketed protease drugs, such as Factor VIIa and Factor IX and to create completely novel proteases that cleave disease-causing proteins, such as C3.

With drug candidates in clinical and advanced preclinical development across a range of diseases, we are a leader in the field of engineered protease biopharmaceuticals. We have assembled an experienced management team, scientists and advisors with subject matter expertise, a strategic collaborator, an enabling technology platform, and a leading intellectual property position in the fields of protease therapeutics and protease technologies to advance our clinical and preclinical pipeline.

Business Organization

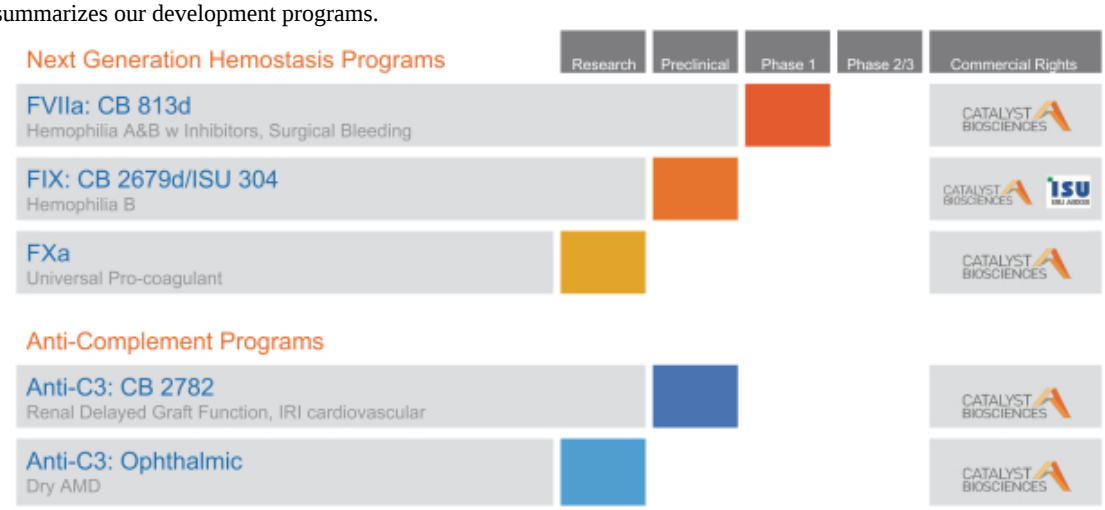
We commenced operations in 2002 and are a Delaware corporation. On August 20, 2015, the Company completed its business combination with Targacept, Inc., which was incorporated in Delaware in 1997. Following the completion of the merger, the business conducted by the Company became primarily the business conducted by Old Catalyst. We refer in this Annual Report on Form 10-K to the business combination as the "merger," to the Company prior to the merger as "Targacept" and to our subsidiary as "Old Catalyst," and discussions of historical results reflect the results of Old Catalyst prior to the completion of the merger and do not include the historical results of Targacept prior to the completion of the merger.

Our corporate headquarters are located in South San Francisco, California 94080. We report segment information using the "management approach." Under this approach, operating segments are identified in substantially the same manner as they are reported internally and used by us for purposes of evaluating performance and allocating resources. Based on this approach, we have one reportable business segment. Our management reporting process is based on our internal operating structure, which is subject to change and is not necessarily similar to that of other comparable companies. See Note 1 to our consolidated financial statements included in this Annual Report on Form 10-K. For financial information regarding our business, see *"Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations"* and our consolidated financial statements and related notes.

Our Product Candidate Pipeline

Our drug research activities are currently devoted to the creation and clinical development of improved, next-generation pro-coagulant proteases Factor VIIa and Factor IX, and novel proteases that cleave complement factor C3 in the complement cascade to treat inflammatory diseases and dry AMD.

The following table summarizes our development programs.



Hemostasis & Hemophilia

Hemophilia is a rare but serious bleeding disorder that results from a genetic or an acquired deficiency of a protein required for normal blood coagulation. There are two major types of hemophilia, A and B, that are caused by alterations in Factor VIII or Factor IX genes, respectively, with a corresponding deficiency in the affected proteins. The disease is X chromosome-linked, meaning that most people who inherit the disorder and suffer from symptoms are male. However, female carriers of mutations in Factor VIII or Factor IX can also have difficulty making clotting factors. Hemophilia A occurs in approximately 1 in 10,000 male births, and

hemophilia B in 1 in 30,000 male births. The prevalence of hemophilia A and B in the United States is estimated to be around 20,000 people, with more than 400,000 cases worldwide. Hemophilia patients suffer from spontaneous bleeding episodes as well as substantially prolonged bleeding times upon injury. In cases of severe hemophilia, spontaneous bleeding into muscles or joints is frequent and often results in permanent, disabling joint damage and can become life threatening.

Currently there is no cure for hemophilia. Treatment usually involves management of acute bleeding episodes or prophylactic treatment through factor replacement therapy by infusion of patients' missing Factor VIII or IX.

Based on our research, we estimate worldwide sales of all Factor IX replacement products for the treatment of hemophilia B in 2014 were approximately $1.1 billion, including approximately $0.9 billion as reported by Pfizer, Inc. ("Pfizer") for its BeneFIX ® product.

A complication for hemophilia patients receiving factor replacement therapy is the production of antibodies against the replacement factor, also called inhibitors. The overall prevalence of inhibitor formation is up to 30% in patients with hemophilia A and up to 5% in patients with hemophilia B. Inhibitor patients are treated with what are known as bypassing agents that initiate coagulation by a pathway that is independent of Factor VIII or Factor IX, the proteins that are deficient in hemophilia A and B patients respectively. Currently available bypassing agents include recombinant Factor VIIa, NovoSeven® RT produced by Novo Nordisk and activated prothrombin complex concentrates, marketed as FEIBA by Baxter. NovoSeven® was first approved in 1999 and is indicated for treatment of bleeding episodes, prevention of bleeding during surgeries in patients with hemophilia A or B with inhibitors, and patients with congenital Factor VII deficiency. In 2006, it was approved for the treatment of acquired hemophilia. NovoSeven ® RT, was approved in 2014 and is indicated for treatment of Glanzmann's thrombasthenia. Sales of NovoSeven RT in 2014 were $1.6 billion, as reported by Novo Nordisk. FEIBA is approved for use in hemophilia A and B patients with inhibitors, which we estimate, based on our research, had 2014 sales of $0.7 billion.

Hemophilia Inhibitor Patients—Clinical Stage Factor VIIa Program

Our most advanced product candidate is CB 813d, a next-generation Factor VIIa that was the subject of a Phase 1 clinical trial completed in February 2015 that evaluated the safety and tolerability, pharmacokinetics, pharmacodynamics and coagulation activity in severe hemophilia A and B with and without inhibitors. CB 813d is initially being developed for the on-demand and prophylactic treatment of severe hemophilia A and B patients with inhibitors. Pfizer had filed the Investigational New Drug Application (IND) with the FDA for this trial in August 2011 for adult males with hemophilia A or B, with or without inhibitors to Factor VIII or Factor IX. We plan to initiate a clinical efficacy trial in 2017.

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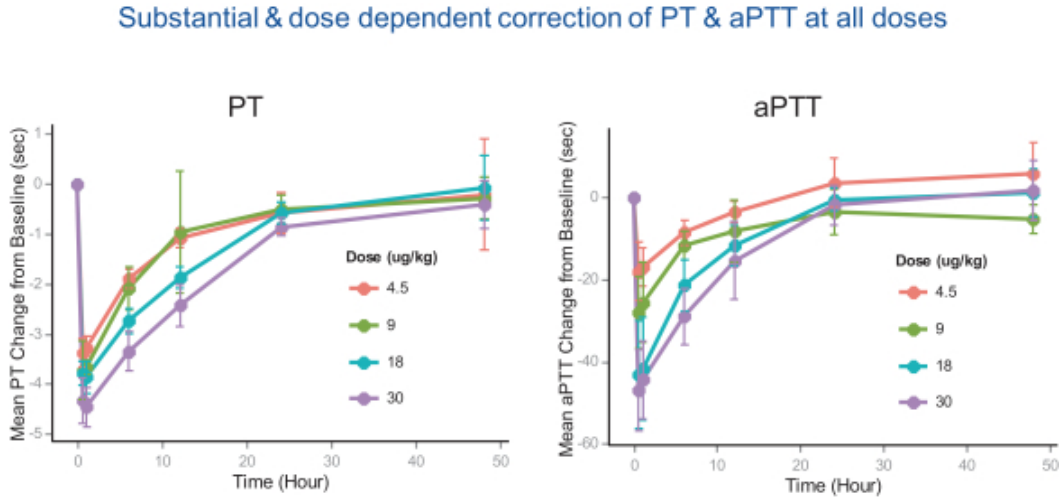
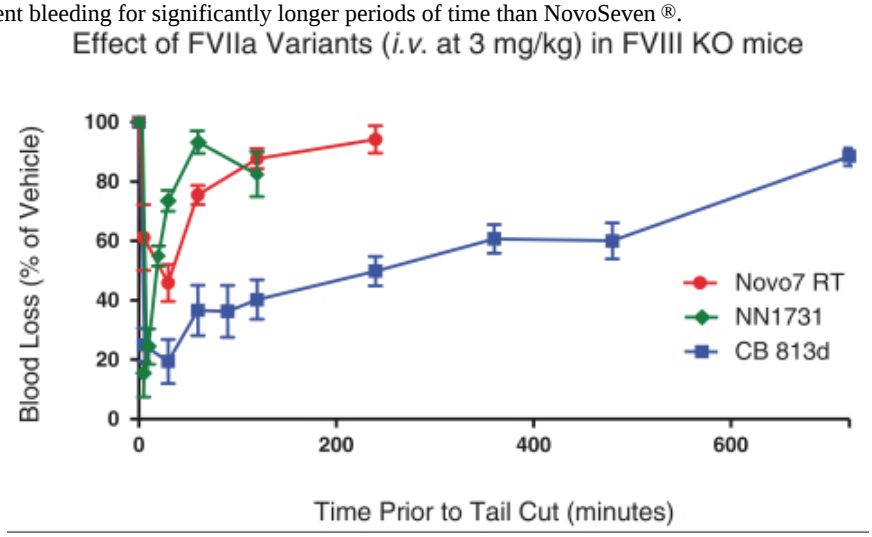
In the Phase 1 clinical trial of CB 813d, 25 severe hemophilia A and B patients with and without inhibitors were enrolled and treated. The clinical trial design was a single ascending dose-escalation study with 1 patient treated at 0.5 µg/kg followed by 4 cohorts of 6 patients each at doses of 4.5, 9.0, 18.0, and 30.0 µg/kg. Clinical endpoints included safety, tolerability, pharmacokinetics and clot-forming activity, such as prothrombin time, or PT, activated partial thromboplastin time, or aPTT, thrombin-antithrombin activity and others. Results showed that single doses of CB 813d were well tolerated when administered to hemophilia A and B patients, and there were no instances of bleeding or thrombosis. As shown in the graph below, CB 813d demonstrated pharmacological efficacy as measured by significant shortening of aPTT (activated partial thromboplastin time) and PT (prothrombin time) for up to 48 hours post dosing. The results were presented in a poster session at the International Society on Thrombosis and Haemostasis (ISTH) Meeting held in Toronto, Canada from June 20 to 25, 2015.



We designed CB 813d to combine higher clot-generating activity at the site of bleeding and improved duration of action *in vivo*. We anticipate that this product candidate could be used to treat acute bleeding episodes with both lower and fewer doses and decreased treatment time compared with existing products and other therapies in development. It was designed to allow for the effective, long-term, prophylactic management of hemophilia A and B inhibitor patients. To test this hypothesis, we compared CB 813d with NovoSeven ® RT in a preclinical murine tail clip model of bleeding. In this model, different groups of mice lacking the ability to produce Factor VIII (referred to as Factor VIII knockout mice) were either treated with Factor VIIa test articles or a saline control. The groups of mice were subjected to a tail clip at increasing time points after receiving either drug or saline. At each time point the amount of bleeding in the groups of mice treated with Factor VIIa test articles was compared with the groups of mice treated with the saline control, with 100% blood loss indicating that the mice treated with Factor VIIa test articles were bleeding at the same rate as if they received saline control. As shown in the graph below, CB 813d was able to prevent bleeding for significantly longer periods of time than NovoSeven ®.



We have also identified treatment of surgical bleeding in both hemophilia inhibitor patients and non-hemophilia patients as attractive secondary indications for CB 813d. CB 813d has received orphan drug designation from the FDA.

Hemophilia B Patients—Factor IX

Our next most advanced product candidate is CB 2679d/ISU 304, a next-generation Factor IX drug for the on-demand and prophylactic treatment of patients with hemophilia B, a chronic disease caused by a genetic deficiency in coagulation Factor IX. The National Hemophilia Foundation has recommended chronic, prophylactic treatment as the optimal therapy for patients with severe hemophilia B. CB 2679d/ISU 304 is currently in IND-enabling preclinical studies, and we intend to enter Phase 1/2 clinical development with our collaborator ISU Abxis in 2016. We entered into a co-development agreement with ISU Abxis in 2013. ISU Abxis is responsible for preclinical development activities and clinical development through a proof-of-concept Phase 1/2 study in hemophilia B patients. We retain rights for worldwide development of the product outside South Korea.

CB 2679d/ISU 304 has demonstrated duration of action *in vivo* in preclinical models of bleeding and coagulation correction approximately 8 times longer than BeneFIX ®, the currently marketed Factor IX therapeutic, and 2-3 times longer than Alprolix, Biogen Idec's approved Factor IX-Fc fusion protein.

The Complement Cascade as a Target for Inflammatory Disease

The complement cascade is a series of naturally occurring molecular processes that plays a central role in the body's inflammatory and immune responses. It helps to localize particular immune system cells at the site of infection or inflammation, to rupture the membranes of pathogens, and to mediate various specific responses to antigens through effects on both B- and T-cells. Consequently, drugs that target the complement cascade could potentially be used in a variety of indications, including prevention of transplant rejection, dry age-related macular degeneration, cardiovascular disease, asthma, and autoimmune disease. Many key targets within the complement cascade are found at such high concentrations that it is likely to be difficult or impractical to block their action with antibodies or small molecules because extremely high drug concentrations would be required for efficacy. We believe that the enzymatic properties of an engineered novel protease could overcome some of the challenges of inhibiting the complement cascade.

Complement in Ischemia-Reperfusion Injury

Our lead anti-C3 inflammation development candidate, CB 2782, is a novel protease for the prevention of delayed graft function (DGF) following kidney transplant driven by ischemia-reperfusion injury. This novel protease variant is directed against complement factor C3, a target present at concentrations that may be too high to address effectively with a therapeutic antibody or small molecule but which we believe is amenable to treatment using a protease. We have delayed initiating preclinical IND-enabling studies for our anti-C3 protease for the prevention of DGF so that we can focus our efforts and resources on advancing CB 813d, our next generation Factor VIIa and CB 2679d, our next-generation FIX through Phase 2/3 and Phase 1/2 clinical trials respectively.

Ischemia, the interruption of the blood supply to a part of the body, commonly results in ischemia-reperfusion injury, or IRI. Injury caused by the initial loss of oxygen from the ischemia is well known. However, the sudden restoration of blood flow to ischemic tissue (called reperfusion) activates the complement cascade, leading to the production of potent pro-inflammatory mediators that cause additional cell and tissue injury, or IRI. Mice lacking the ability to activate the complement cascade due to genetic inability to produce C3, referred to as C3 knockout mice, have been shown to experience reduced IRI in a variety of model systems relevant to IRI indications.

In kidney transplant procedures IRI is a major contributor to DGF. Patients with DGF require dialysis and extended hospitalization that is costly and damages the transplanted kidney. Approximately 18,000 kidney transplants are performed in the United States each year, with between 20-30% of patients experiencing complications with the transplanted kidney, including DGF. The occurrence of DGF is very costly because it requires the initiation of dialysis therapy, prolongs hospitalization, and can lead to transplant failure. Many kidneys are discarded pre-transplant because of fear of DGF post-transplant. Market research conducted for us on the use of novel proteases to pretreat kidney transplant recipients to prevent DGF projected a potential global annual revenue opportunity of approximately $0.6 billion.

We selected CB 2782 as a development candidate from a group of specific novel proteases that cleave C3 and block activation of the complement cascade, preventing local tissue injury after reperfusion. Studies in non-human primates have demonstrated that our novel anti-C3 proteases display potent activity, completely removing C3 from the circulation, and appear to be well tolerated.

In addition to DGF, a protease that effectively inhibits C3 could potentially have broader clinical applications in other indications such as the prevention of reperfusion injury in coronary artery bypass grafting, myocardial infarction, and stroke.

Complement in Dry Age-Related Macular Degeneration

Dry age-related macular degeneration, or dry AMD, is the leading cause of blindness in the elderly worldwide and according to Nature, a scientific journal, affects approximately 20 million people in the United States and EU

combined, with the potential size of the dry AMD market worldwide estimated at $30 billion. The disease is a chronic condition characterized by a progressive loss of central vision due mostly to degenerative changes and/or the formation of microvascular networks in the center of the eye's visual field, called the macula. There are two forms of AMD, wet and dry. Wet AMD is the more severe form of the disease and represents approximately 10% of all AMD patients. Dry AMD is the most common form of early to intermediate stage AMD and occurs in approximately 90% of patients with the condition. While there have been recent improvements in the treatment of wet AMD, dry AMD treatment remains an unmet medical need.

Recent studies from several independent investigators have demonstrated that over 70% of the risk of developing AMD (both dry and wet forms) corresponds to mutations in human complement genes, particularly the factor H gene whose product is required for proper regulation of the complement cascade. Also recently, Roche/Genentech's Anti-Factor D antibody fragment demonstrated an approximately 20-40% reduction of lesion size growth after 18 monthly injections in a Phase 1/2 clinical trial for geographic atrophy, or GA, an advanced form of dry AMD. This clinical study suggests that inhibition of the complement cascade can have a significant effect on the progression of GA.

We are developing an anti-C3 novel protease that is being optimized for chronic administration in the eye. These molecules should have an advantage over antibodies because, while they should exhibit a similar rate of clearance from the eye as antibodies, their catalytic activity will allow them to effectively cleave C3 at protease concentrations that are far lower than the C3 target concentration. This, in turn, could be expected to allow less frequent dosing, a critical consideration for drugs injected into the eye. We expect to demonstrate bi-monthly dosing feasibility in the dry AMD program during 2016.

Protease Product Discovery Platform

Among our scientific team, management, and advisors are leading experts in protease engineering, biology, and drug discovery. We have leveraged this expertise to develop a proprietary, industrialized protease product discovery engine composed of the following important components.

Rational Design of Improved Proteases*:* We are able to leverage our scientific team's expertise in protease structure and function and in predictive modeling to create protease variants using a rational design strategy. In this process a small number of amino acids in a given protease are substituted in an iterative fashion with other amino acids to improve the molecule's biological properties. We believe that this approach can provide us with important differentiated advantages, including:

- Increasing a protease's catalytic activity (speed in cleaving targets);
- Modulating cofactor dependence, the ability to form complexes, with other proteins to facilitate the cleavage of the target;
- Modulating inhibitor resistance to disrupt natural regulatory interactions that can reduce efficacy; and
- Adjusting pharmacokinetics, the duration of circulation through the body and presence in tissues.

We have used this technology to create our next-generation Factor VIIa, Factor IX, and Factor Xa variants.

Creation and Selection of Novel Proteases: We have optimized a propriety method to create novel proteases that cleave a disease-causing protein target. First, it constructs a large library of proteases containing more than ten billion variants of a starting protease. Our most commonly used starting protease scaffolds are membrane type serine protease 1, or MTSP-1, and urokinase plasminogen activator, or uPA. From these libraries, we use a patent-protected process to select lead proteases that preferentially cleave the target of interest. The field of leads can be narrowed by repeating the selection process or by counter-selecting the library to reduce cleavage of non-target proteins. Many parts of this core technology have been automated, facilitating rapid identification of novel

engineered proteases with new substrate specificities not previously contemplated as potential therapeutics. We believe that this approach can provide us with important differentiated advantages including:

- Evolving the specificity and activity of a starting protease scaffold towards a desired target;
- Reducing the activity of a protease towards other targets; and
- Increasing resistance to naturally occurring protease inhibitors.

This technology was used to select novel MTSP-1 and uPA-based variants that cleave complement factor C3, leading to the selection of our anti-complement drug candidates.

Confirmation of Activity and Selectivity Through In Vitro Assays*:* We have developed our own and uses highly specialized *in vitro* assays that measure the properties of our proteases to ensure that they cleave the correct target in the desired manner.

Protease Expression and Purification: We use both mammalian and bacterial systems to manufacture protease developmental leads and product candidates for preclinical testing. The production and purification of these proteases are highly specialized processes in which we have considerable expertise and know-how. For example, our next-generation coagulation Factor VIIa, Factor IX, and Factor Xa product candidates require specialized mammalian cells that correctly modify the desired factor to maintain its activity *in vivo*.

Our Strategy

Our goal is to use our transformative protease platform to become a leading company in the discovery, development, and commercialization of products based on engineered human proteases. Key elements of our strategy to achieve this goal are to:

- ***Advance the Clinical Development of our Lead Product Candidates:*** Our most advanced drug candidate, CB 813d, for the treatment of hemophilia and surgical bleeding, recently completed a Phase 1 clinical trial evaluating safety and tolerability as well as pharmacokinetics, pharmacodynamics and coagulation activity. We expect that we will advance CB 813d into a clinical efficacy trial in hemophilia A and hemophilia B inhibitor patients in the first quarter of 2017. In addition, we expect that our collaborator ISU Abxis will initiate a Phase 1/2 clinical trial of CB 2679d/ISU 304, a next-generation Factor IX drug candidate for the treatment of patients with hemophilia B, in 2016.
- ***Leverage Existing Strategic Factor IX Collaboration:*** We have established a strategic collaboration with ISU Abxis for its CB 2679d/ISU 304 program. We are entitled to up front and milestone payments of up to $5 million and have retained worldwide commercialization rights, except for ISU Abxis' right of first refusal for commercialization rights in South Korea, and subject to a future profit sharing arrangement. We believe our Factor IX collaboration contributes to our ability to advance our Factor IX product candidate to the clinical stage.
- ***Build a Hemostasis Franchise:*** We intend to build on our recent clinical and preclinical success in Factor VIIa and Factor IX by advancing its Factor VIIa program into a clinical efficacy trial in 2017. The combination of a Factor VIIa product entering into a clinical efficacy trial and two additional wholly owned (except for CB 2679d/ISU 304 in South Korea) coagulation factors could allow us to build a strong hemostasis franchise.
- ***Build an Anti-complement Franchise.*** Our novel protease approach to regulating the complement cascade has the potential to create several highly differentiated drug candidates that address diseases with significant unmet medical needs, including DGF and dry AMD.

Collaborations

Pfizer

On June 29, 2009 we entered into a research and license agreement with Wyeth Pharmaceuticals, Inc., subsequently acquired by Pfizer, whereby we and Pfizer collaborated on the development of novel human Factor VIIa products and we granted Pfizer the exclusive rights to develop and commercialize the licensed products on a worldwide basis. As a result of this agreement, Pfizer paid us an up-front non-refundable signing fee of $21.0 million, which was initially recognized as revenue ratably over the term of our continuing involvement in the research and development of products with Pfizer. The term was determined to be five years (covering the initial two-year research term plus potential extensions permitted under the applicable agreement).

During the initial two years of the collaboration period Pfizer reimbursed us for certain costs incurred in the development of the licensed products including FTE-based research payments. Following the conclusion of the initial collaboration, without extension by Pfizer, we had no further substantive performance obligations to Pfizer under the agreement and we recognized the remaining $12.6 million of deferred revenue related to the up-front fee in June 2011. Subsequently, in August 2013, we entered into an amendment to the Pfizer agreement, in accordance with which Pfizer made two $1.5 million non-refundable annual license maintenance payments to us in August 2013 and August 2014 and we agreed to certain performance obligations to Pfizer for the period starting from the effective date of the amendment. Pfizer was also obligated to pay to us contingent milestone-based payments upon the occurrence of certain defined development, commercialization, and sales-based milestones.

On April 2, 2015 Pfizer notified us that it was exercising its right to terminate the research and license agreement effective June 1, 2015. Accordingly we revised the expected period of performance to end on June 1, 2015 and the deferred revenue balance was fully amortized as of that date. We are currently negotiating with Pfizer regarding rights to use certain manufacturing technology and materials.

ISU Abxis

On September 16, 2013 we entered into a License and Collaboration Agreement with ISU Abxis, as subsequently amended on October 31, 2014, or the ISU Abxis Agreement. Under the ISU Abxis Agreement, we licensed our proprietary human Factor IX products to ISU Abxis for initial development in South Korea. ISU Abxis is responsible for development and manufacturing of the licensed products through Phase 1/2 clinical trials. Until the completion of Phase 1 development ISU Abxis also has a right of first refusal with respect to commercialization rights for the licensed products in South Korea. We have the sole rights and responsibility for worldwide development, manufacture, and commercialization of Factor IX products after Phase 1/2 development unless ISU Abxis has exercised its right of first refusal regarding commercialization rights in South Korea in which case our rights are throughout the entire world excluding South Korea. ISU Abxis’s development and manufacturing rights (but not its right of first refusal) will also terminate in the event that we enter into a license agreement with another party to develop, manufacture, and commercialize Factor IX products in at least two major market territories.

Prior to completion of Phase 1/2 clinical studies, ISU Abxis is responsible for and will fund the clinical development and manufacture of the licensed products. ISU Abxis will also reimburse us for a portion of our costs relating to intellectual property filings and maintenance thereof on products. We have established a joint steering committee with ISU Abxis to, among other things, coordinate and assist in planning and execution of development activities and review the product development plan.

ISU Abxis paid us a non-refundable upfront signing fee of $1.75 million. ISU Abxis is also obligated to make contingent cash payments to us of up to $3.25 million payable based upon the achievement of predefined development milestones (none of which have been achieved as of December 31, 2015 and through the date of this filing). In addition, we are required to pay ISU Abxis a royalty of between a quarter and a third of our net

profits determined on a country-by-country basis until the expiration of the last valid claim in such country or fifteen years after the first commercial sale of a product in such country, whichever is sooner, after which time we will have a perpetual, irrevocable and non-exclusive license to the applicable technology with respect to such country. However, if the Phase 1/2 clinical study of the Factor IX products is not completed by a specified date and we continue the development of Factor IX products using cell lines created by ISU Abxis or in a manner that otherwise would be covered by a patent held by ISU Abxis or if the Phase 1/2 clinical trial is not successful and we continue to develop the Factor IX products, we will be obligated to pay ISU Abxis a low single-digit royalty on net product sales, in addition to up to $2.0 million in potential milestone payments to ISU Abxis. Either party may terminate the ISU Abxis Agreement in its entirety upon written notice of a material uncured breach or upon the other party's bankruptcy and we may terminate the agreement upon prior notice if the Phase 1 clinical study is not completed by a certain date. As of December 31, 2015, the cumulative aggregate payments received and recognized by us under this agreement were $1.0 million, and we had made no payments to ISU Abxis.

Intellectual Property

We have established a broad intellectual property portfolio including patents and patent applications covering the identification, selection, optimization, and manufacture of human proteases, the composition of matter and methods of use of our product candidates and related technology, and other inventions that are important to our business.

We strive to protect the proprietary technologies that we believe are important to our business by seeking, maintaining and defending patent rights, whether developed internally or in conjunction with or in-licensed from third parties. We also rely on trade secrets relating to our proprietary technology platform and on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in the field of human protease engineering.

As more fully described below, as of February 29, 2016, our patent portfolio included approximately 105 patents; including 13 issued and allowed U.S. patents and 92 foreign granted and accepted patents, and 3 U.S. patent applications, plus an additional 86 pending foreign patent applications. We also rely on trade secrets and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will depend significantly on our ability to:

- Obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business;
- Defend and enforce our patents;
- Maintain our licenses to use intellectual property owned by third parties; and
- Preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties.

Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets.

In addition, a third-party may hold intellectual property, including patent rights that are important or necessary to the development of our products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. For example, certain of the methods for screening our novel proteases, our non-complement proteases modified to cleave a

complement protein such as C2 or C3, or for using proteases as scaffolds, are covered by patents held by third parties. Although we have obtained exclusive licenses to these patents from these third parties on what we believe are commercially reasonable terms, if we were not able to obtain a license on similar technology, or were not able to obtain a license on commercially reasonable terms, our business could be harmed, possibly materially. In addition, we are aware of a patent that has been issued in Europe (with counterparts in Australia, China, Japan, Poland and South Korea) and includes a claim that may read on CB 813d. An opposition proceeding with respect to this patent sustained this patent, and we are considering whether to appeal. There can also be no assurance whether or not the claims of such patent would be found to read on CB 813d even if a claim survives the opposition. There may be third-party patents or patent applications with claims to compositions of matter, materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe.

The patent positions of biopharmaceutical companies like us are generally uncertain and involve complex legal, scientific, and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by enforceable patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented, or invalidated by third parties.

Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office, or USPTO, or a foreign patent office to determine priority of invention or in post-grant challenge proceedings, such as oppositions, that challenge priority of invention or other features of patentability. Such proceedings could result in substantial cost, even if the eventual outcome is favorable to us.

All of our patents and applications were internally developed and assigned to us, except for one pending South Korean patent application that is co-owned. In addition, members of the 4902 family directed to screening methods (14 patents, including 2 issued U.S. patents) are jointly owned with the Torrey Pines Institute for Molecular Studies, which licensed its interest to us. We are currently reviewing our patent portfolio and may choose to abandon certain patents that do not appear to have significant value. Our current patents and patent applications include:

- 56 patents, including 1 issued U.S. patent, and 34 patent applications, including 1 U.S. patent application, covering modified Factor VII polypeptides, such as our lead product candidate, CB 813d, and methods of production of modified Factor VII polypeptides. The U.S. patent, with patent term adjustment, and patent application, if granted, expires or is expected to expire, in 2031 and 2030. The foreign patents and patent applications, if granted, expire, or are expected to expire, respectively, in 2028-2029.
- 5 patents, including 3 issued and allowed U.S. patents and 17 patent applications, covering modified Factor IX polypeptides, such as our clinical candidate CB 2679d/ISU 304. The issued and allowed U.S. patents, including patent term adjustment, expire, or are expected to expire, respectively, in 2030-2032 and the foreign patents and patent applications, if granted, expire, or are expected to expire, respectively, in 2031.
- 27 patents, including 4 issued and allowed U.S. patents, and 22 patent applications, including 1 U.S. patent applications, covering novel proteases. The U.S. patents, and patent applications, if granted, including patent term adjustment, expire or are expected to expire, respectively, in 2025-2029, and the foreign patents and foreign patent applications, if granted, expire, or are expected to expire, in 2025-2027.

- 1 issued U.S. patent and 16 patent applications, including 1 U.S. patent applications, covering improved Factor Xa variants and methods of production of improved Factor Xa variants. The issued patent and patent applications, if granted, including patent term adjustment, expire, or are expected to expire in 2033.
- 14 patents, including 2 issued U.S. patents, covering methods for identifying proteases that cleave or inactivate a protein target. The U.S. patents, including patent term adjustment, expire in 2027-2030, and the foreign patents expire in 2027.
- 2 issued U.S. patents covering the MTSP-1 protease scaffold used for our novel proteases, which expire in 2019.

The term for individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is 20 years from the earliest claimed filing date of a non-provisional patent application in that country or the international filing date. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date.

The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration date of a U.S. patent as partial compensation for the length of time the drug is under regulatory review while the patent is in force. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent applicable to each regulatory review period may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar provisions are available in the European Union and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug.

In the future, to the extent our product candidates including CB 813d, CB 2679d/ISU 304, and novel anti-C3 proteases receive approval by the FDA or foreign regulatory authorities, we expect to apply for patent term extensions on issued patents covering those products, depending upon the length of the clinical trials for each drug and other factors.

In addition to the above intellectual property owned by Catalyst, we obtained the intellectual property related to the neural nicotinic receptor (NNR) portfolio from Targacept in the reverse merger. We are currently in the process of out-licensing, selling off and terminating the remaining NNR portfolio obtained from Targacept and expect this process to be completed by the end of 2016.

Manufacturing

We do not have any manufacturing facilities. We currently rely, and expects to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for the commercial manufacture of our product candidates that receive marketing approval. Pfizer has historically been responsible for manufacturing CB 813d for clinical trials pursuant to our license and collaboration agreement with Pfizer, but we will need to transition such activities from Pfizer as a result of Pfizer's termination of the agreement effective June 1, 2015. We have begun the transfer of manufacturing technology from Pfizer to a third-party contract manufacturer, and we are in discussions with Pfizer about obtaining manufacturing technology, materials and know-how related to CB 813d, although there can be no assurance that we will agree to the terms with Pfizer, or that any such technology and know-how transfer will be successful. ISU Abxis is responsible for manufacturing CB 2679d/ISU 304, our next-generation Factor IX drug candidate, through the completion of Phase 1 clinical trials, after which point we will be responsible for manufacturing this product candidate. We intend to identify and qualify third-party manufacturers for this product candidate.

Commercialization

We have not yet established a sales, marketing, or product distribution infrastructure for our other product candidates, which are still in preclinical or early clinical development. Except for ISU Abxis' potential rights to commercialize CB 2679d/ISU 304 in South Korea, we generally expect to retain commercial rights for the company's product candidates. We believe that it will be possible to access the United States hemophilia market through a focused, specialized sales force. We have not yet developed a commercial strategy outside of the United States.

Subject to receiving marketing approvals, we expect to commence commercialization activities by building a focused sales and marketing organization in the United States to sell our products. We believe that such an organization will be able to address the community of hematologists who are the key specialists in treating hemophilia patients for which our product candidates are being developed.

Competition

Some of our proposed products will face competition from approved therapeutics. Competition for our pipeline products comes primarily from large, well-established pharmaceutical companies, who have greater financial resources and expertise in research and development, manufacturing, conducting clinical trials, and marketing approved products. Mergers and acquisitions within the pharmaceutical and biotechnology industries may further concentrate competitors' resources. We are not only competing with these companies in terms of technology, but also in recruiting and retaining qualified scientists and management personnel, in establishing partnerships with clinical trial sites, and in registering patients into clinical trials.

In addition to current standard of care for patients, clinical trials are being pursued by a number of parties in the field of biologics and in our lead indications. These products in development may provide efficacy, safety, convenience, and other benefits that are not provided by currently marketed therapies. As a result, they may provide significant competition for any of our product candidates for which we obtain marketing approval. Based on publically available information, the following are some of the products being developed by competitors in indications overlapping with those of our programs.

- ***Factor VIIa Competition***: Novo Nordisk's NovoSeven is a recombinant Factor VIIa indicated for treatment of bleeding episodes. NovoSeven was FDA approved in 1999 for use in the treatment of hemophilia A or B patients with inhibitors to Factor VIII or Factor IX. The treatment has since been approved for use in patients with Factor VII deficiency and Glanzmann's thrombasthenia. Several other companies have competing products under development, including companies developing biosimilars of NovoSeven, such as Baxalta's BAX 817, that was filed for approval in late 2015, and rEVO Biologics, whose product is in a Phase 3 clinical trial, as well as Roche, whose biospecific Factor VIII-Factor IX monoclonal antibody has recently completed a Phase 1/2 clinical trial, and Alnylam, whose investigational RNAi therapeutic targeting antithrombin for the treatment of hemophilia is in a Phase 1 clinical trial.
- ***Factor IX Competition:*** BeneFIX, a recombinant Factor IX indicated for treatment of hemophilia B patients, was approved in 1997 and is marketed by Pfizer, which reported 2014 revenues of $0.9 billion, according to Pfizer's Annual Report on Form 10-K. In addition, Alprolix, a Factor IX-Fc product approved in 2014, is marketed by Biogen Idec and Swedish Orphan Biovitrum (SOBI - in Europe, Russia, North Africa and the Middle East) with 2014 revenues of $0.1 billion, and Rixubis, a recombinant Factor IX biosimilar approved in 2013, is marketed by Baxalta, with 2014 revenues of $0.2 billion, which we estimate, based on our research. CSL Behring announced they were approved a biologics license application (BLA) on their Idelvion (rFIX) product by the FDA on March 4, 2016 and Novo Nordisk has announced plans to file a BLA during the first half of 2016 for its glyco-pegylated-FIX product.

- ***Delayed Graft Function Competition:*** While there are no currently approved treatments for DGF that we believe would pose competitive risk, several companies are developing antibody and small molecule-based product candidates currently in Phase 2 & 3 studies.
- ***Dry AMD Competition:*** While there are no currently approved treatments for dry AMD that we believe would pose competitive risk, several companies, including Genentech and Novartis, are developing antibody-based product candidates for treatment of dry AMD currently in Phase 2 or Phase 3 studies, and Ophthotech is developing its commercially available product, Zimura, for indications in both dry and wet AMD.

Our commercial opportunity in different indications could be reduced or eliminated if our competitors develop and market products that are more convenient to use, more effective, less expensive, and safer to use than our products. Furthermore, if competitors gain FDA approval faster than we do, we may be unable to establish a strong market presence or to gain market share. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition, and the availability of reimbursement from government and other third-party payors.

Government Regulation

As a clinical-stage biopharmaceutical company that operates in the United States, we are subject to extensive regulation. Our engineered human protease products will be regulated as biological products. Biological products, including engineered human proteases, are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, and the Public Health Service Act, or PHS Act, and other federal, state, local, and foreign statutes and regulations. The FD&C Act and the PHS Act and their implementing regulations govern, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biological products. FDA approval must be obtained before clinical testing of a biological product begins and before the marketing of biological products. The process of obtaining regulatory approvals and the subsequent compliance with federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development, the approval process, or after product approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

U.S. Biological Products Development Process

The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an investigational new drug application or IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations, commonly referred to as good clinical practices, or GCPs, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- submission to the FDA of a biologics license application or BLA for marketing approval that includes substantive evidence of safety, purity and potency from results of nonclinical testing and clinical trials;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with good manufacturing practices or GMP, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current good tissue practices, or GTPs, for the use of human cellular and tissue products;
- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure, of the BLA.

Before testing any biological product candidate, including an engineered human protease, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs.

The clinical trial sponsor must submit the results of the preclinical tests, together with the manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after an IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical study on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research patients provide informed consent. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Clinical trials also must be reviewed by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1.* The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients, particularly where the drug may be too inherently toxic to administer ethically to healthy subjects.

- *Phase 2*. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- *Phase 3*. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

Engineered protease biopharmaceuticals are a relatively new class of therapeutics. Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the trial period, the number of patients the FDA will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of the engineered protease products, or that the data generated in these trials will be acceptable to the FDA to support marketing approval.

Concurrently with clinical trials, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with GMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The FDA may grant deferrals for submission of data or full or partial waivers. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual product fee for biological products and an annual establishment fee on facilities used to manufacture prescription biological products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the

proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with GMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure GMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than how we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a REMS, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

The FDA has agreed to certain review goals under PDUFA, and aims to complete its review of 90% of standard BLAs within ten months from filing and 90% of priority BLAs within six months from filing. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs and its review goals are subject to change from time to time. The review process and the PDUFA goal date may be extended by three months if the FDA requests, or the BLA sponsor otherwise provides, additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Fast Track Designation, Accelerated Approval, Priority Review and Breakthrough Therapy Programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biological product may request the FDA to designate the drug or biological product as a Fast Track product at any time during the clinical development of the product. Under a Fast Track designation, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Other types of FDA programs intended to expedite development and review, such as priority review, accelerated approval and Breakthrough Therapy designation, also exist. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval, pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

A product may also be eligible for receipt of a Breakthrough Therapy designation. The Breakthrough Therapy designation is intended to expedite the FDA's review of a potential new drug for serious or life-threatening diseases where "preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development." The designation of a drug as a Breakthrough Therapy provides the same benefits as are available under the Fast Track program, as well as intensive FDA guidance on the product's development program. Fast Track designation, priority review, accelerated approval and Breakthrough Therapy designation do not change the standards for approval, but may expedite the development or approval process.

Post-approval Requirements

Maintaining substantial compliance with applicable federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to GMP. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the GMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements applicable to biological products include reporting of GMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product

before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency and effectiveness of biological products.

We also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Biological product manufacturers and other entities involved in the manufacturing and distribution of approved biological products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with GMPs and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain GMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan drug designation subsequently receives FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, for seven years. These circumstances are an inability to supply the drug in sufficient quantities or a situation in which a new formulation of the drug has shown superior safety or efficacy or a major contribution to patient care. This exclusivity, however, could also block the approval of our product for seven years if a competitor obtains earlier approval of the same drug for the same indication.

U.S. Patent Term Restoration and Marketing Exclusivity

The Biologics Price Competition and Innovation Act, or BPCIA, amended the PHS Act to authorize the FDA to approve similar versions of innovative biologics, commonly known as biosimilars. A competitor seeking approval of a biosimilar must file an application to establish its molecule as highly similar to an approved

innovator biologic, among other requirements. The BPCIA, however, bars the FDA from accepting biosimilar applications for 4 years after an innovator biological product receives initial marketing approval and from approving biosimilar applications for 12 years after an innovator biological product receives initial marketing approval. As innovative biological products, we believe that our products would receive this data protection if the FDA approves them for marketing.

Pediatric exclusivity is another type of regulatory market exclusivity that may apply to biological products approved in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods, include the 4- and 12-year periods discussed. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents, if granted, may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years, as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws, each as amended.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (discussed below).

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the U.S. government. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies’ marketing of the product for unapproved, and thus non-reimbursable, uses.

HIPAA created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of, or payment for healthcare benefits, items or services.

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA’s privacy and security standards directly applicable to business associates independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act within the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states,

manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private “qui tam” actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to that third-party payors provide coverage, and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, or also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor’s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor’s determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on healthcare pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern the use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on its business. We cannot predict, however, how changes in these laws may affect its future operations.

Government Regulation Outside of the United States

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval of a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the EU, for example, a clinical trial application must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the clinical trial application is approved in accordance with a country's requirements, clinical trial development may proceed. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug or biological product under EU regulatory systems, we must submit a marketing authorization application. The application used to file the BLA in the United States is similar to that required in the EU, with the exception of, among other things, country-specific document requirements.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we or our potential collaborators fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Research and Development

Our research and development costs were $6.0 million, $5.3 million and $6.6 million for the years ended December 31, 2015, 2014 and 2013, respectively. See "*Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations*" for additional details regarding our research and development activities.

Employees

As of December 31, 2015, we had 19 full-time employees, 9 of whom have Ph.D. or M.D. degrees. Of these full-time employees, 13 employees are engaged in research and development activities and 6 employees are engaged in finance, legal, human resources, facilities and general management. We have no collective bargaining agreements with our employees and we have not experienced any work stoppages. We consider our relations with our employees to be good.

Available Information

We file electronically with the Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Exchange Act. We make available on our website at www.catalystbiosciences.com, free of charge, copies of these reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

The public may read or copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street NE, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is www.sec.gov.

The information in or accessible through the websites referred to above are not incorporated into, and are not considered part of, this filing. Further, our references to the URLs for these websites are intended to be inactive textual references only.

Item 1A. RISK FACTORS

The following section includes the most significant factors that may adversely affect our business and operations. You should carefully consider the risks and uncertainties described below and all information contained in this Annual Report on Form 10-K before deciding to invest in our common stock. If any of the following risks actually occur, our business, financial condition, results of operations and growth prospects may be materially and adversely affected. In that event, the trading price of our common stock could decline, and you could lose all or part of your investment.

Risks related to our financial condition and capital requirements

We have incurred significant losses since our inception, and are expected to continue to incur significant losses for the foreseeable future.

We are a clinical-stage biotechnology company, and we have not yet generated significant revenues. We have incurred net losses in each year since our inception in August 2002, including net losses of $14.8 million, $6.6 million and $10.0 million for the years ended December 31, 2015, 2014 and 2013, respectively. As of December 31, 2015, we had an accumulated deficit of $131.0 million.

We are still in the early stages of development of our product candidates, and have no products approved for commercial sale. To date, we have financed our operations primarily from private placements of convertible preferred stock, payments under collaboration agreements, and to a lesser extent through issuances of shares of common stock. In addition, due to Pfizer's termination of its research and license agreement with us, our ability to use payments from collaboration agreements to finance our operations will be significantly reduced, and additionally, we may enter into agreements with Pfizer in which development milestones and royalties may be due to Pfizer in the future for certain manufacturing technology.

We have devoted most of our financial resources to research and development, including our preclinical development activities. We expect to continue to incur significant expenses and operating losses over the next several years. Our operating losses may fluctuate significantly from quarter to quarter and year to year. We are expected to continue to incur significant expenses and increasing operating losses for at least the next several years, and our expenses will increase substantially if and as we:

- continue clinical development of CB 813d;
- continue research and preclinical and clinical development of our other product candidates, including dry AMD and CB 2679d/ISU 304;
- initiate additional preclinical, clinical or other studies for our product candidates;
- further develop the manufacturing process for our product candidates;
- change or add additional manufacturers or suppliers to complete the technology transfer from Pfizer;
- attract and retain skilled personnel;
- seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical studies;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to identify and validate additional product candidates;
- acquire or in-licenses other product candidates and technologies;
- make milestone or other payments under collaboration agreements, or any in-license agreements;
- maintain, protect and expand our intellectual property portfolio;

- create additional infrastructure to support operations as a public company and our product development and planned future commercialization efforts; and
- experience any delays or other issues with any of the above.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which regulatory approval is obtained. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, we may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Failure to become and remain profitable would depress the value of the company and could impair our ability to raise capital, expand our business, maintain research and development efforts, diversify product offerings or even continue operations. A decline in the value of the Company could also cause you to lose all or part of your investment.

We will need additional capital. If we are unable to raise sufficient capital, we will be forced to delay, reduce or eliminate product development programs.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our research and development expenses to increase in connection with our ongoing activities, particularly activities related to the continued clinical development of CB 813d, including a clinical efficacy trial and, if Phase 1 clinical trials of CB 2679d/ISU 304 are successful, an efficacy trial for this compound. We will also incur additional expenses if our product candidates for age-related macular degeneration enter Phase 1 clinical trials. Expenses are also likely to increase as we continue to work on our research programs. We believe that our available cash is sufficient to fund our operations at least through the first quarter of 2017. However, we will need to raise substantial additional capital to complete the development and commercialization of CB 813d, CB 2679d/ISU 304 and our other product candidates, and depending on the availability of capital, may need to delay development of some of our product candidates.

In August 2015, we issued $37.0 million in aggregate principal amount of redeemable convertible notes to former Targacept stockholders as part of a dividend immediately prior to the completion of the Merger (the “Pre-Closing Dividend”), with an amount equal to the total principal deposited in an escrow account for the benefit of the noteholders. The notes may be redeemed for cash or repaid upon maturity, holders may also elect to convert any principal amount of the notes into shares of common stock at a price of $9.19 per share on or before February 19, 2018. As of December 31, 2015, $3.0 million in aggregate principal has been redeemed and $0.3 million had been converted to common stock. Except for this arrangement, we have no commitments or arrangements for any additional financing to fund our research and development programs. There can be no assurance regarding the amount of the notes that will be redeemed or the portion of the remaining $33.7 million in capital that will become available to us.

Until we can generate a sufficient amount of revenue from our product candidates, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings, corporate collaborations and/or licensing arrangements. Additional funds may not be available when we need them on terms that are acceptable, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs.

Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds required to complete research and development and commercialize our products under development. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of clinical trials for our product candidates in hemophilia, including CB 813d and CB 2679d/ISU 304;
- the timing, costs and results of preclinical studies for our other potential product candidates;
- the number and characteristics of product candidates that we pursue;
- the terms and timing of any future collaboration, licensing or other arrangements that we may establish;
- the outcome, timing and cost of regulatory approvals;
- the cost of obtaining, maintaining, defending and enforcing intellectual property rights, including patent rights;
- the effect of competing technological and market developments;
- the cost and timing of completing outsourced manufacturing activities;
- market acceptance of any product candidates for which we may receive regulatory approval;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval; and
- the extent to which we acquire, license or invest in businesses, products or technologies.

Raising additional funds by issuing securities or through licensing arrangements may cause dilution to stockholders, restrict our operations or require us to relinquish proprietary rights.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing, if available at all, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates or future revenue streams or grant licenses on terms that are not favorable to us. We may also seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. There can be no assurance that we will be able to obtain additional funding if and when necessary. If we are unable to obtain adequate financing on a timely basis, we could be required to delay, curtail or eliminate one or more, or all, of our development programs or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We have no history of clinical development or commercialization of pharmaceutical products, which may make it difficult to evaluate the prospects for the company's future viability.

We began operations in August 2002. Our operations to date have been limited to financing and staffing the company, developing our technology and product candidates and establishing collaborations. We have not yet demonstrated an ability to successfully conduct a clinical trial, obtain marketing approvals, manufacture a product for clinical trials or at commercial scale, or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about the company's future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

Risks related to the discovery, development and commercialization of our product candidates

We are substantially dependent upon the success of CB 813d, which is our only product candidate that has completed a Phase 1 clinical trial.

The failure of CB 813d to achieve successful clinical trial endpoints, delays in clinical trial enrollment or in the clinical development of CB 813d generally, unanticipated adverse side effects related to CB 813d or any other adverse developments or information related to CB 813d would significantly harm our business, its prospects and the value of the company's common stock. We expect to advance CB 813d into a clinical efficacy trial in hemophilia A and hemophilia B inhibitor patients. There is no guarantee that the results of this clinical trial, if it occurs, will be positive or will not generate unanticipated safety concerns. The Phase 1 clinical trial of CB 813d was a single-dose escalation trial that would not, compared to multi-dose trials, be expected to exclude the possibility of an immunological response to CB 813d in patients who received the product candidate. After completion of the dosing portion of the Phase 1 clinical trial, Pfizer observed a positive result in an assay for a potential non-neutralizing anti-drug antibody in a single patient at a time point 60 days post-dosing that was not confirmed by testing of a subsequent, follow-up blood draw. Additional confirmatory testing is planned to investigate further whether the initial observation was due to a false positive assay result, a pre-existing, non-neutralizing antibody against NovoSeven, or a non-neutralizing, anti-CB 813d/PF-05280602 antibody.

If subsequent multi-dose trials demonstrate a treatment-related neutralizing immunological response in patients, development of CB 813d could be halted. Even if the next trials of CB 813d are positive, CB 813d may require substantial additional trials and other testing before approving CB 813d for marketing.

Even if the FDA or other regulatory agency approves CB 813d, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product and may impose ongoing commitments or requirements for post-approval studies, including additional research and development and clinical trials. The FDA and other agencies also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval. Regulatory approval from authorities in foreign countries will be needed to market CB 813d in those countries. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. If we fail to obtain approvals from foreign jurisdictions, the geographic market for CB 813d would be limited.

CB 813d is not expected to be commercially available in the near term, if at all. Further, the commercial success of CB 813d will depend upon its acceptance by physicians, patients, third-party payors and other key decision-makers as a therapeutic and cost effective alternative to currently available products. If we are unable to successfully develop, obtain regulatory approval for and commercialize CB 813d, our ability to generate revenue from product sales will be significantly delayed and our business will be materially and adversely affected, and we may not be able to earn sufficient revenues to continue as a going concern.

We must transition manufacturing and clinical activities related to CB 813d from Pfizer and fully optimize the manufacturing process. This process will be lengthy and its outcome uncertain.

Pfizer conducted the Phase 1 clinical trial of CB 813d pursuant to a research and license agreement. Pfizer terminated this agreement effective June 1, 2015, and to our knowledge such termination was the result of an internal review of products in development at Pfizer. Under this license agreement, we and Pfizer collaborated on the development of CB 813d, and Pfizer was responsible for product manufacturing and clinical trials. To continue development of CB 813d, we must successfully transition manufacturing and clinical development activities from Pfizer. We are in discussions with Pfizer to obtain manufacturing technology and know-how related to CB 813d, although there can be no assurance that we and Pfizer will agree to terms satisfactory to us; or that the mechanism for manufacturing technology transfer, and know-how transfer will be successful. If we are unable to agree to terms with Pfizer, successfully transfer manufacturing technology and know-how from Pfizer related to CB 813d, and/or optimize the manufacturing process, clinical development of this product candidate could be significantly delayed.

On November 30, 2015, we entered into a Letter of Agreement ("LoA") with a third-party manufacturer concerning the transfer of manufacturing technology from Pfizer for the further development and manufacturing of CB 813d. In addition, if technical issues arise or negotiations falter, the project might take longer, clinical trials may be delayed, and project costs could increase. Even if the transfer of manufacturing technology is successful, we may need to further optimize the manufacturing process of CB 813d in order to manufacture clinical supplies for additional clinical trials.

The biological basis of our product candidates exposes them to risk of adverse immunological response, which could result in the failure of a product to advance further in clinical trials or, with respect to approved products, result in its removal from the market.

All of our product candidates are modified versions of human proteases. As a result they have the potential to elicit an immunological response that eliminates or neutralizes the product, severely inhibiting its efficacy. This in turn could result in the failure of any of our product candidates to advance into further clinical trials, or for any approved products, in the removal of the product from the market if adverse immunological responses are identified after approval.

We are very early in our development efforts and have only one product candidate that has completed a Phase 1 clinical trial. All of our other product candidates are still in preclinical development. If we are unable to commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

We are very early in our development efforts and have only one product candidate that has completed a Phase 1 clinical trial, CB 813d. All of our other product candidates are still in preclinical development. We expect to advance CB 813d into a clinical efficacy trial in hemophilia A and hemophilia B inhibitor patients. In addition, we expect that our collaborator ISU Abxis will initiate a Phase 1 clinical trial of CB 2679d/ISU 304, our next-generation Factor IX drug candidate for the treatment of patients with hemophilia B, in 2016. We have delayed initiating preclinical IND-enabling studies for our anti-C3 protease for the prevention of DGF and Factor Xa, so that we can focus our efforts and resources on advancing CB 813d, our next generation Factor VIIa and CB 2679d, our next-generation FIX through Phase 2/3 and Phase 1/2 clinical trials respectively. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of these and other product candidates. The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical studies and clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities;
- launching commercial sales of the products, if and when approved, whether alone or in collaboration with others;
- acceptance of the products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement;
- protecting our rights in our intellectual property portfolio; and
- maintaining a continued acceptable safety profile of the products following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome. Results from our successful Phase 1 trials may not be confirmed in later trials, and if serious adverse or unacceptable side effects are identified during the development of our product candidates, we may need to abandon or limit our development of some of our product candidates.

Clinical testing is expensive, time-consuming and uncertain as to outcome. We cannot guarantee that any preclinical studies and clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of our product candidates is susceptible to the risk of failure at any stage of drug development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of severe or medically or commercially unacceptable adverse events, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or any comparable foreign regulatory authority that a drug product is not approvable. It is possible that even if one or more of our product candidates has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of or intolerability caused by our product candidates, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case.

In addition, the outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials. For example, the Phase 1 clinical trial of CB 813d was a single dose trial, and adverse immunological reactions such as the development of a neutralizing anti-drug antibody would not be likely to appear until patients received multiple doses in later trials.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we may face similar setbacks. The design of a clinical trial can determine whether our results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. Any Phase 2, Phase 3 or other clinical trials that we may conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates.

If our product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon development or limit development of the product candidate to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We or our collaborators may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate, enroll and maintain enrolment of a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In particular, there are a relatively small number of hemophilia patients, which may cause delays in enrollment of clinical trials of CB 813d in hemophilia A and B patients with inhibitors or CB 2679d/ISU 304 in hemophilia B patients. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials will result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in clinical trials conducted by us may also result in increased development costs for our product candidates, which would cause the value of the company to decline and limit our ability to obtain additional financing.

We may not be successful in our efforts to use and expand our protease platform to discover and develop drugs that lead to marketable products.

A key element of our strategy is to use our protease platform to build a hemostasis franchise and an anti-compliment franchise, which include several highly differentiated drug candidates that address diseases with high unmet medical needs, including delayed graft function, or DGF, and dry age-related macular degeneration, or dry AMD. The discovery of biopharmaceutical products based on the creation of novel proteases is an emerging field, and the scientific discoveries that form the basis for our efforts to discover and develop product candidates using this technology are relatively new. Although modified human protease drugs have been developed, no drugs have been developed premised on novel engineered proteases with new substrate specificities that preferentially cleave the target of interest. Furthermore, no drugs directly targeting complement factor C3 have been approved.

Accordingly, we do not know if our approach of using proteases to regulate coagulation and complement cascades will successfully result in the development of additional product candidates for target indications that are safe and effective and/or commercially differentiated from competitor molecules. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be product candidates that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our technological approach, we will not be able to obtain product revenues in future periods, which likely would result in significant harm to our financial position and adversely affect the company's stock price.

Risks related to our reliance on third parties

We depend on our collaborative relationship with ISU Abxis for the Phase 1 development of CB 2679d/ISU 304.

We have a collaboration agreement with ISU Abxis for preclinical and Phase 1/2 development of an improved, next-generation Factor IX product, CB 2679d/ISU 304, to enable an investigational new drug application, which requires ISU Abxis to obtain approval from South Korean regulatory authorities to conduct trials. Under this agreement, ISU Abxis is responsible for manufacturing and Phase 1/2 clinical trials of this product candidate, and we depend on ISU Abxis to complete these activities.

Our ability to generate revenues from this arrangement will depend on the ability of ISU Abxis to successfully perform the functions assigned to it in this arrangement, and accordingly, any failure by ISU Abxis to develop this product candidate could adversely affect our cash flows. Further, this collaboration agreement may not lead to development or commercialization of this product candidate in the most efficient manner or at all, and ISU Abxis has the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms. We are subject to a number of risks associated with our dependence on ISU Abxis:

- We are not able to control any decisions by ISU Abxis regarding the amount and timing of resource expenditures for the development or commercialization of CB 2679d/ISU 304, and may have limited or no ability to control such decisions with respect to other product candidates subject to collaboration agreements;
- ISU Abxis may have difficulty manufacturing CB 2679d/ISU 304 for clinical trials, or may experience delays doing so;
- ISU Abxis may delay clinical trials, provide insufficient funding, or manufacture insufficient amounts or quality of product, for a clinical trial, stop a clinical trial or abandon products, repeat or conduct new clinical trials or require a new formulation of products for clinical testing;
- ISU Abxis may not perform its obligations as expected;
- Adverse regulatory determinations or other legal action may interfere with the ability of ISU Abxis to conduct clinical trials or other development activity, such as any failure by ISU Abxis to obtain approvals from South Korean regulatory authorities to conduct Phase 1/2 clinical trials of CB 2679d/ISU 304;
- ISU Abxis may be subject to regulatory or legal action resulting from the failure to meet healthcare industry compliance requirements in the conduct of clinical trials or the promotion and sale of products;
- Our relationship with ISU Abxis could be adversely impacted by changes in their key management personnel and other personnel that are administering collaboration agreements; and
- The collaboration with ISU Abxis may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of CB 2679d/ISU 304.

We expect to seek to establish additional collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. Accordingly, we may seek one or more additional collaborators for the development and commercialization of one or more of our product candidates. For example, we may seek a new collaborator to develop CB 813d and might also seek collaborators for CB 2689d/ISU 304 or our earlier stage programs. In addition, full development efforts on the use of our novel proteases for the treatment of DGF or dry AMD will likely involve significant cost, and we expect that we may conduct any such efforts in collaboration with one or more partners.

We face significant competition in seeking appropriate collaborators. Whether we can reach a definitive agreement with a collaborator will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of preclinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us. There can also be no assurance that any collaboration agreements will be on favorable terms.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, and increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

We contract with third parties for the manufacture of our product candidates for preclinical testing and expect to continue to do so for clinical testing and commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We currently have no internal capabilities to manufacture our product candidates for clinical use or for preclinical trials following good manufacturing practices, or GMP, or good laboratory practices, or GLP. We expect to rely on one or more third-party contractors to manufacture, package, label and distribute clinical supplies and commercial quantities of any product candidate that we commercialize following approval for marketing by applicable regulatory authorities. We also expect to rely on one or more third-party contractors to manufacture our product candidates for use in our clinical trials. Reliance on such third-party contractors entails risks, including:

- our inability to identify and negotiate manufacturing and supply agreements with suitable manufacturers;
- manufacturing delays if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the possible termination or nonrenewal of agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the possible breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and

- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

We may incur delays in product development resulting from the need to identify or qualify manufacturers for our product candidates. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We and our contract manufacturers will be subject to significant regulation with respect to manufacturing our products. The manufacturing facilities on which we will rely may not continue to meet regulatory requirements and have limited capacity.

All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including any contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with GMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a Biologics License Application on a timely basis and must adhere to the FDA's good laboratory practices, or GLP, and GMP regulations enforced by the FDA through its facilities inspection program. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA approval of the products will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third-party to implement and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. An alternative manufacturer would need to be qualified through a Biologics License Application supplement which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause the delay of clinical studies, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable

to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed or we could lose potential revenue.

We expect to rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We expect to rely on third parties such as contract research organizations, or CROs, medical institutions and clinical investigators to enroll qualified patients and conduct, supervise and monitor clinical trials. Our reliance on these third parties for clinical development activities will reduce our control over these activities. Our reliance on these third parties, however, will not relieve us of our regulatory responsibilities, including ensuring that our clinical studies are conducted in accordance with good clinical practices, or GCP, and the investigational plan and protocols contained in the relevant regulatory application, such as an investigational new drug application, or IND. In addition, the CROs with whom we contract may not complete activities on schedule, or may not conduct our preclinical studies or clinical studies in accordance with regulatory requirements or our clinical study design. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, our efforts to obtain regulatory approvals for, and to commercialize, our product candidates may be delayed or prevented.

Risks related to employee matters, managing growth and our business operations

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management and scientific personnel, including our President and Chief Executive Officer, Dr. Usman, our Chief Scientific Officer, Dr. Madison, and our Chief Financial Officer, Fletcher Payne. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. In addition, we will need to add personnel to achieve our business objectives. The loss of the services of any of our executive officers, other key employees, and our inability to find suitable replacements, or our inability to hire new clinical development and manufacturing personnel, could result in delays in product development and harm our business.

We conduct operations at our facility in the San Francisco Bay Area. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at Catalyst, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in the company’s stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of management and scientific and development teams may terminate their employment with the company on short notice. Our employees are under at-will employment arrangements, which means that any of our employees can leave employment with Catalyst at any time, with or without notice. Failure to retain, replace or recruit personnel could harm our business.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and collaborators. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply

with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies that, could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We will continue to incur significant increased costs as a result of operating as a public company, and our new management is required to devote substantial time to compliance initiatives, particularly after the completion of a one-year transition period to full compliance.

In connection with the completion of the merger between Targacept and Catalyst, the employment of the teams that historically operated the business of Targacept and its financial reporting was terminated, and substantially all of our current employees, including our finance staff, were the employees of Old Catalyst or are new hires. Accordingly, prior to the merger, we had never operated our current business as a public company. As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting and corporate governance requirements, in order to comply with the rules and regulations imposed by the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection, or the Dodd-Frank Act, as well as rules implemented by the SEC and Nasdaq. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways that are not currently anticipated. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives, and it is likely that we will need to hire additional staff in the areas of investor relations, legal and accounting to continue to operate as a public company. In addition, these rules and regulations make it difficult and expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain our current levels of such coverage. We expect that we will annually incur significant additional expenses to comply with the requirements imposed on us as a public company.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls over financial reporting and disclosure controls and procedures. In particular, as a public company, we are required to perform system and process evaluations and testing of our internal control over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. However, our independent registered public accounting firm will not be required to report on the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act for the year ended December 31, 2015, based on the SEC's response to our request for temporary relief from this provision. In addition, our testing, or the subsequent testing in the future by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that may be deemed to be material weaknesses. Our compliance with Section 404 will require that we incur substantial accounting expense and management time on compliance-related issues. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, we could lose investor confidence in the accuracy and completeness of our financial reports, which could cause our stock price to decline.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans that, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Risks related to our intellectual property

If we are unable to obtain, protect or enforce intellectual property rights related to our product candidates, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. Third parties may challenge the validity, enforceability or scope of our patents that, may result in those patents being narrowed or invalidated. The patent applications that we own may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Certain of our patents also cover processes, for which enforcement can be difficult. Any of these outcomes could impair our ability to prevent competition from third parties that, may have an adverse impact on our business.

If the patents or patent applications we hold or have in-licensed for our programs or product candidates are invalidated or fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could threaten our ability to commercialize future products. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Once the patent life has expired for a product, we may be open to competition from generic medications.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent and other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information

or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information.

Further, filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Third-party claims of intellectual property infringement or challenging the inventorship or ownership of our patents may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and *inter parties* reexamination proceedings before the U.S. Patent and Trademark Office, or U.S. PTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that the manufacture, use or sale of our product candidates infringes patents held by such third parties, or that we are employing their proprietary technology without authorization. For example, we are aware of a patent that has been issued in Europe (with counterparts in Australia, China, Japan, Poland, and South Korea) and includes a claim that may read on CB 813d. An opposition proceeding with respect to this patent sustained this patent, and we are considering whether to appeal. There can also be no assurance whether or not the claims of such patent would be found to read on CB 813d even if a claim survives the opposition. There may be third-party patents or patent applications with claims to compositions of matter, materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe.

In addition, we have received confidential and proprietary information from third parties, and we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims.

Parties making claims against us may obtain injunctive or other equitable relief that, could effectively block our ability to further develop and commercialize one or more of our product candidates unless we redesigned infringing products (which may be impossible) or obtained a license under the applicable patents (which may not be available on commercially reasonable terms or at all), or until such patents expire.

We may be involved in lawsuits to protect or enforce our patents.

Competitors may infringe our patents. To counter infringement or unauthorized use, we or our collaborators may be required to file infringement claims that, can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one of our patents is not valid, is unenforceable and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims, regardless of their merit, would cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, in addition to paying royalties, redesign infringing products or obtain one or more licenses from third parties that, may be impossible or require substantial time and monetary expenditure. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third-party may hold intellectual property, including patent rights that are important or necessary to the development of our products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, and changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The U.S. PTO is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, were enacted March 16, 2013. However, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. Further, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Risks related to regulatory approval of our product candidates and other legal compliance matters

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

While we have multiple drug candidates in clinical and advanced preclinical development for a range of diseases, we have not yet submitted biologics license applications, or BLAs, for our engineered human proteases to the FDA, or similar approval filings to comparable foreign authorities. Submission of a BLA requires extensive preclinical and clinical data and supporting information that demonstrates the product candidate's safety, purity, and potency, also known as safety and effectiveness, for each desired indication. A BLA must also include significant information regarding the chemistry, manufacturing and controls for the product. One of our product candidates, CB 813d, has completed a Phase 1 clinical trial. However, failure of one or more clinical trials can occur at any stage in the clinical trial process. Accordingly, the regulatory pathway for our product candidates is still uncertain, complex, and lengthy, and ultimately approval may not be obtained.

We may experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- the availability of financial resources to commence and complete the planned trials;
- inability to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an independent institutional review board, or IRB;
- recruiting suitable patients to participate in trials;
- having patients complete a trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; and
- manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a subject by subject basis for use in clinical trials.

We could also experience delays in obtaining approval if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles given the serious nature of the diseases for the core indications for our product candidates. Additionally, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which the trials are being conducted, the Data Monitoring Committee for the trial, or

by the FDA or other regulatory authorities for a number of reasons, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues, or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, our ability to commercialize our product candidates will be harmed and our ability to generate revenue will be materially impaired. Additionally, delays in completing trials will increase costs, slow down our product development and approval process, and impair our ability to commence product sales and generate revenue. Many of the factors that could create or lead to a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval for our product candidates.

The FDA may disagree with our regulatory plan and we may fail to obtain regulatory approval of our product candidates.

The results of clinical trials we conduct may not support regulatory approval of our product candidates. Our product candidates could ultimately fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- We may be unable to demonstrate to the satisfaction of the FDA or comparable foreign authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- We may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we would market, sell and distribute our products. As a pharmaceutical company, even though we do not and may not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. These regulations include:

- the Federal Healthcare Anti-Kickback Statute that, prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid, and which will constrain our marketing practices and the marketing practices of our licensees, educational programs, pricing policies, and relationships with healthcare providers or other entities;
- the federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients to providers of "designated health services" with whom the physician or a member of the physician's immediate family has an ownership interest or compensation arrangement, unless a statutory or regulatory exception applies;
- federal false claims laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other government reimbursement programs that are false or fraudulent, and which may expose entities that provide coding and billing advice to customers to potential criminal and civil penalties, including through civil whistleblower or qui tam actions, and including as a result of claims presented in violation of the Federal Healthcare Anti-Kickback Statute, the Stark Law or other healthcare-related laws, including laws enforced by the FDA;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services that, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- federal physician sunshine requirements under the Affordable Care Act, which requires manufacturers of drugs, devices, biologics and medical supplies to report annually to the U.S. Department of Health and Human Services or HHS, information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;
- the Federal Food, Drug, and Cosmetic Act, which, among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state laws requiring pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and which may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state and foreign laws governing the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws such as HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable

fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices for our product candidates.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

More recently, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the PPACA of importance to our potential product candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report financial arrangements with physicians and teaching hospitals;

- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding.

We expect that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we or our collaborators may receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts that, could adversely affect our business, financial condition, results of operations or prospects. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use of our product candidates harms patients, or is perceived to harm patients even when such harm is unrelated to our product candidates, regulatory approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. There is a risk that our product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

We carry product liability insurance of $10,000,000 per occurrence and $10,000,000 aggregate limit. We believe our product liability insurance coverage is sufficient in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed insurance coverage, could adversely affect our results of operations and business.

Patients with the diseases targeted by our product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process in other countries, or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

Risks related to commercialization of our product candidates

Even if any of our product candidates receives marketing approval, we may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our product candidates receives marketing approval, we may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current hemophilia treatments like NovoSeven are well established in the medical community, and doctors may continue to rely on these treatments. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared with alternative treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared with alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

If we are unable to establish sales, marketing and distribution capabilities, we may not be successful in commercializing our product candidates if and when they are approved.

We have not yet established a sales, marketing or product distribution infrastructure for our other product candidates, which are still in preclinical or early clinical development. Except for ISU Abxis' potential rights to commercialize CB 2679d/ISU 304 in South Korea, we generally expect to retain commercial rights for the company's hemophilia product candidates. We believe that it will be possible to access the United States hemophilia market through a focused, specialized sales force. However, we have not yet developed a commercial strategy for hemophilia products outside of the United States, or for any other of our product candidates. To achieve commercial success for any product for which we obtain marketing approval, we will need to establish a sales and marketing organization within the United States, and develop a strategy for sales outside of the United States.

There are risks involved with establishing internal sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. If we are unable to establish our sales, marketing and distribution capabilities and enter into additional arrangements with third parties to perform these services, our product revenues and profitability, if any, are likely to be lower than if we were to market, sell and distribute any products that we develop ourselves.

We face substantial competition that, may result in others discovering, developing or commercializing products before or more successfully than we do.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. We face potential competition from many different

sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies, and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Specifically, there are a large number of companies developing or marketing treatments for hemophilia, including many major pharmaceutical and biotechnology companies, including Novo Nordisk, which has developed NovoSeven, a human recombinant coagulation Factor VIIa indicated for treatment of bleeding episodes that has been approved for use in treatment of hemophilia A or B patients with inhibitors to Factor VIII or Factor IX and in patients with Factor VII deficiency and Glanzmann's thrombasthenia, Baxter, which has developed BAX 817, a biosimilar of NovoSeven that recently completed a Phase 3 clinical trial and has been filed for marketing approval, Roche, which is developing a biospecific Factor VIII-Factor IX monoclonal antibody, and Alnylam, which is developing an investigational RNAi therapeutic targeting antithrombin for the treatment of hemophilia.

Our commercial opportunity in different indications could be reduced or eliminated if competitors develop and market products that are more convenient to use, more effective, less expensive, and safer to use than our products. Furthermore, if competitors gain FDA approval faster than we do, we may be unable to establish a strong market presence or to gain market share. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition, and the availability of reimbursement from government and other third-party payors.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives that, would harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we may obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide

which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we or our collaborators commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate that receives marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, ability to raise capital needed to commercialize products and overall financial condition.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

If the market opportunities for our product candidates are smaller than expected, our revenues may be adversely affected and our business may suffer.

We focus our research and product development on hemostasis and inflammation treatment. Our projections of both the number of people who suffer from related conditions, as well as the subset of people with these conditions who have the potential to benefit from treatment with our product candidates, are based on estimates. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of these diseases. The number of patients in the United States, Europe and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

Risks Related to Our Common Stock

Our capital stock ownership is concentrated with our executive officers and directors, and their respective affiliates, which limits your ability to influence corporate matters.

Our significant stockholders, acting together, have the ability to affect matters submitted to our stockholders for approval, including the approval of significant transactions. This concentration of ownership may have the effect of delaying, deferring or preventing a strategic transaction, even if such a transaction would benefit other stockholders. As a result, the market price of our common stock could be adversely affected.

The market price of our common stock has historically been highly volatile.

The trading price of our common stock has historically been highly volatile and the volume of common shares traded has been relatively low. Additionally, the stock market in general has experienced extreme price and volume fluctuations. The market prices of securities of pharmaceutical, biopharmaceutical and biotechnology companies in particular have been extremely volatile and have experienced fluctuations that have often been unrelated or disproportionate to operating performance. Factors giving rise to this volatility may include:

- regulatory or political developments in both the United States and abroad;
- developments concerning proprietary rights, including patents and litigation matters;
- disclosure of new collaborations or other strategic transactions;
- public concern about the safety or efficacy of product candidates or technology, their components, or related technology or new technologies generally;
- public announcements by competitors or others regarding new products or new product candidates; and
- general market conditions and comments by securities analysts and investors.

Fluctuations in operating results could adversely affect the price of our common stock.

Our operating results are likely to fluctuate significantly from quarter to quarter and year to year. These fluctuations could cause our stock price to decline. Some of the factors that may cause operating results to fluctuate on a period-to-period basis include the scope, progress, duration results and costs of preclinical and clinical development programs, as well as non-clinical studies and assessments of product candidates and programs, restructuring costs, implementation or termination of collaboration, licensing, manufacturing or other material agreements with third parties, non-recurring revenue or expenses under any such agreement, the cost, timing and outcomes of regulatory compliance, approvals or other regulatory actions and general and industry-specific economic conditions, particularly as affects the pharmaceutical, biopharmaceutical or biotechnology industries in the United States. Period-to-period comparisons of our historical and future financial results may not be meaningful, and investors should not rely on them as an indication of future performance. Fluctuating losses may fail to meet the expectations of securities analysts or investors. Failure to meet these expectations may cause the price of our common stock to decline.

If our stockholders sell a substantial number of shares of our common stock in the public market, our stock price may decline.

Our current trading volumes are modest, and sales of a substantial number of shares of our common stock in the public market, or the perception that these sales could occur, could cause the market price to decline. Such sales also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. As part of the Pre-Closing Dividend, we issued $37.0 million in aggregate principal amount of redeemable convertible notes. At the option of the note holders, those notes will be redeemable at any time on or before February 19, 2018 or convertible into shares of the Company at a conversion rate of $9.19 per share. As of December 31, 2015 the balance of these redeemable convertible note was $33.7 million, convertible into approximately 3.7 million shares of our common stock. In addition, we have also registered all of the shares of common stock that we may issue under outstanding stock options and employee stock incentive plans, and as of December 31, 2015, approximately 2.2 million shares of common stock were issuable upon the exercise of outstanding stock options at a weighted average exercise price of $9.84 per share, approximately 0.1 million additional shares of common stock were reserved for issuance under our stock option plan, and approximately 0.2 million shares of common stock were issuable upon the exercise of warrants outstanding with a weighted average exercise price of $9.70 per share. Conversion or exercise of these securities into shares of our common stock will cause dilution to the other holders of our common stock, and all such stock may be sold in the public market after conversion or exercise, subject to restrictions under the securities laws, which may lead to a decline in the market price of our common stock.

Anti-takeover provisions in our charter documents and provisions of Delaware law may make an acquisition more difficult and could result in the entrenchment of management.

We are incorporated in Delaware. Anti-takeover provisions of Delaware law and our charter documents may make a change in control or efforts to remove management more difficult. Also, under Delaware law, our board of directors may adopt additional anti-takeover measures. The existence of the following provisions of Delaware law and our restated certificate of incorporation and amended and restated bylaws could limit the price that investors might be willing to pay in the future for shares of our common stock.

Our restated certificate of incorporation authorizes our board of directors to issue up to 5,000,000 shares of preferred stock and to determine the terms of those shares of stock without any further action by our stockholders. If the board of directors exercises this power to issue preferred stock, it could be more difficult for a third-party to acquire a majority of our outstanding voting stock and vote the stock they acquire to remove management or directors.

Our restated certificate also provides staggered terms for the members of our board of directors, and that directors may be removed by stockholders only by vote of the holders of 66 2/3% of voting shares then outstanding. In addition, our amended and restated bylaws do not permit stockholders to call special or annual meetings of stockholders, or to act by written consent without a meeting. These provisions may prevent stockholders from replacing the entire board in a single proxy contest, making it more difficult for a third-party to acquire control without the consent of our board of directors. These provisions could also delay the removal of management by the board of directors with or without cause.

As a Delaware corporation, we are also subject to certain Delaware anti-takeover provisions. Under Delaware law, a publicly-held corporation may not engage in a business combination with any holder of 15% or more of our voting stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Our board of directors could rely on Delaware law to prevent or delay an acquisition.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

Our corporate headquarters are located in South San Francisco, California, where we subleased a portion of a facility which encompasses approximately 12,965 square feet of space. The sublease for this space expires on February 27, 2018. We believe that our existing facilities are adequate for our current needs, as the facilities have sufficient laboratory space to house additional scientists to be hired as we expand. When our lease expires, we may review our options including renewing our lease or looking for additional or alternate space for our operations and we believe that suitable additional or alternative space will be available in the future on commercially reasonable terms.

Item 3. LEGAL PROCEEDINGS

We are not currently a party to any material litigation or other material legal proceedings.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Shares of Targacept common stock were historically listed on the NASDAQ Global Select Market under the symbol "TRGT." After completion of the merger on August 20, 2015, Targacept was renamed "Catalyst Biosciences, Inc." and commenced trading on the NASDAQ Capital Market under the symbol "CBIO." The following table sets forth for the periods indicated the high and low sales price per share of our common stock as reported on The NASDAQ for the quarterly periods indicated. This table has been adjusted to reflect the 7-for-1 reverse stock split of our common stock in connection with, and prior to the completion of the merger:

Year Ended December 31, 2015:	High	Low
First Quarter	$ 3.05	$ 2.50
Second Quarter	2.91	2.26
Third Quarter	11.80	2.21
Fourth Quarter	5.69	2.00

Year Ended December 31, 2014:	High	Low
First Quarter	$ 5.18	$ 4.08
Second Quarter	4.79	3.61
Third Quarter	3.94	2.49
Fourth Quarter	2.78	2.32

Holders of Common Stock

As of March 1, 2016, there were approximately 62 holders of record of our common stock. In addition, a substantially greater number of stockholders may be "street name" or beneficial holders, whose shares are held of record by banks, brokers and other financial institutions.

Securities Authorized for Issuance Under Equity Compensation Plans

The response to this item is incorporated by reference from the discussion responsive thereto under the caption "Stock Based Compensation" in the notes to Financial Statements.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors.

Unregistered Sales of Securities; Use of Proceeds from Registered Securities; Issuer Purchases of Equity Securities

None.

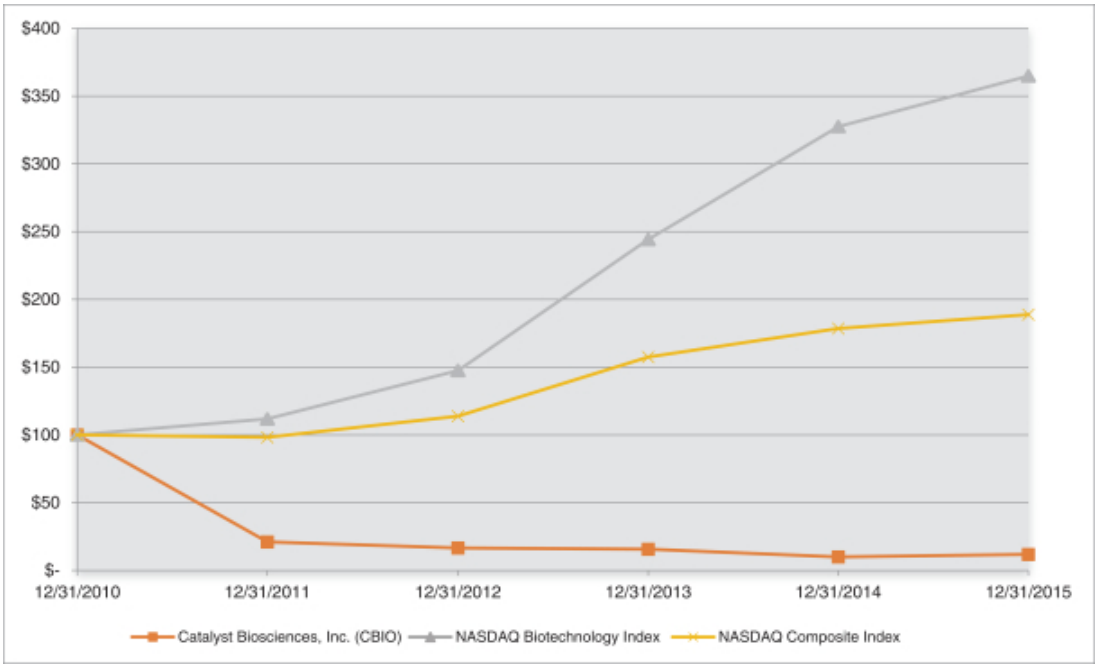
Performance Graph

This graph is not "soliciting material," is not deemed "filed" with the Securities and Exchange Commission, or SEC, and is not to be incorporated by reference into any filing of Catalyst Biosciences, Inc. under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

The following graph shows the total stockholder return for the calendar years ended December 31, 2011, 2012, 2013, 2014, and 2015 of an investment of $100 on December 31, 2010 in (i) our common stock, (ii) the NASDAQ Composite Index (U.S.) and (iii) the NASDAQ Biotechnology Index. Pursuant to applicable SEC rules, all values assume reinvestment of the full amount of all dividends, however no dividends have been declared on our common stock to date. The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

	Ticker	12/31/2010	12/31/2011	12/31/2012	12/31/2013	12/31/2014	12/31/2015
Catalyst Biosciences, Inc.	CBIO	100.00	21.02	16.53	15.66	9.92	11.81
NASDAQ Composite Index	IXIC	100.00	111.81	147.48	244.24	327.52	364.93
NASDAQ Biotechnology Index	NBI	100.00	98.20	113.82	157.44	178.53	188.75

Comparison of Cumulative Five Year Cumulative Return



ITEM 6. SELECTED FINANCIAL DATA.

The selected consolidated statement of operations data for the years ended December 31, 2015, 2014 and 2013 and the selected consolidated balance sheet data as of December 31, 2015 and 2014 are derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The selected consolidated statement of operations data for the years ended December 31, 2012 and 2011 and the selected consolidated balance sheet data as of December 31, 2013, 2012 and 2011 are derived from our audited consolidated financial statements which are not included in this Annual Report on Form 10-K.

The information set forth below for the five years ended December 31, 2015, which reflect the results of Old Catalyst prior to the completion of the merger and do not include the historical results of Targacept prior to the completion of the merger, is not necessarily indicative of results of future operations, and should be read in conjunction with *Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations"* and the consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K (*in thousands, except share and per share data*).

	Year Ended December 31,				
	2015	2014	2013	2012	2011
Consolidated Statement of Operations Data:					
Contract revenue	$ 1,750	$ 1,813	$ 523	$ —	$ 23,279
Operating expenses:					
Research and development	5,958	5,267	6,557	14,176	24,023
General and administrative	9,594	4,055	4,086	4,558	5,124
Total operating expenses	15,552	9,322	10,643	18,734	29,147
Loss from operations	(13,802)	(7,509)	(10,120)	(18,734)	(5,868)
Interest and other income	518	896	154	1	—
Interest expense	(1,478)	—	—	(340)	(14)
Net loss	$ (14,762)	$ (6,613)	$ (9,966)	$ (19,073)	$ (5,882)
Net loss per common share, basic and diluted	$ (3.33)	$ (17.99)	$ (27.29)	$ (56.84)	$ (31.47)
Shares used to compute net loss per common share, basic and diluted	4,429,093	367,586	365,214	335,519	186,874

	As of December 31,				
	2015	2014	2013	2012	2011
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 32,498	$ 1,544	$ 2,828	$ 3,401	$ 9,231
Restricted cash	33,919	50	50	50	—
Working capital	30,942	(266)	1,165	2,715	7,144
Total assets	69,521	2,981	5,274	6,783	13,590
Convertible preferred stock	—	108,877	104,641	98,899	90,178
Accumulated deficit	(131,037)	(116,275)	(109,661)	(99,695)	(80,623)
Total stockholders' equity (deficit)	31,425	(109,352)	(103,008)	(93,340)	(79,274)

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion and analysis should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion may contain forward-looking statements based upon current expectations that involve risks and uncertainties, including those set forth under the heading "Risk Factors" and elsewhere in this Annual Report on Form 10-K. Our actual results and the timing of selected events discussed below could differ materially from those expressed in, or implied by, these forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company focused on creating and developing novel medicines to address serious medical conditions. To date, we have focused our product development efforts in the fields of hemostasis, including the treatment of hemophilia and surgical bleeding, and inflammation, including prevention of delayed graft function ("DGF") in renal transplants and the treatment of dry age-related macular degeneration ("Dry AMD"), a condition that can cause visual impairment or blindness for which there are no approved treatments. Our most advanced program is an improved next-generation coagulation Factor VIIa variant, CB 813d, that has successfully completed a Phase 1 clinical trial in severe hemophilia A and B patients. In addition to our lead Factor VIIa program, we have two other next-generation coagulation factors, a Factor IX variant, CB 2679d/ISU 304, that is in advanced preclinical development, and several Factor Xa variants, that have demonstrated efficacy and safety in preclinical animal models. Proteases regulate several complex biological cascades, or sequenced biochemical reactions, including the coagulation cascade that controls bleeding (hemostasis) in hemophilia and non-hemophilia settings and the complement cascade that causes inflammation and tissue damage in certain diseases.

Our most advanced program is an improved next-generation coagulation Factor VIIa variant, CB 813d, that has completed a Phase 1 clinical trial evaluating safety and tolerability as well as pharmacokinetics, pharmacodynamics and coagulation activity in severe hemophilia A and B patients. Based on our research, we estimate annual worldwide sales in 2014 for FDA-approved Factor VIIa products were approximately $1.6 billion. In addition to our lead Factor VIIa program, we have a Factor IX variant, CB 2679d/ISU 304, that is in advanced preclinical development and several Factor Xa variants which we have delayed initiating further research studies on our Factor Xa variants so that we can focus our efforts and resources on advancing CB 813d, our next generation Factor VIIa and CB 2679d, our next-generation FIX through Phase 2/3 and Phase 1/2 clinical trials respectively. Based on our research, we estimate annual worldwide sales in 2014 for FDA-approved Factor IX and Factor Xa-containing products were approximately $1.8 billion.

On June 29, 2009, we entered into a research and license agreement with Wyeth Pharmaceuticals, Inc., subsequently acquired by Pfizer, whereby we and Pfizer collaborated on the development of novel human Factor VIIa products, and we granted Pfizer the exclusive rights to develop and commercialize the licensed products on a worldwide basis. As a result of this agreement, Pfizer paid us an up-front non-refundable signing fee of $21.0 million, which was initially recognized as revenue ratably over the term of our continuing involvement in the research and development of products with Pfizer, which was determined to be five years (covering the initial two-year research term plus potential extensions permitted under the applicable agreement).

During the initial two-years of the collaboration period, Pfizer reimbursed us for certain costs incurred in the development of the licensed products, including FTE-based research payments. Following the conclusion of the initial collaboration, without extension by Pfizer, we had no further substantive performance obligations to Pfizer under the agreement, and we recognized the remaining $12.6 million of deferred revenue related to the up-front fee in June 2011. Subsequently, in August 2013, we entered into an amendment to the Pfizer agreement, in accordance with which Pfizer made two $1.5 million non-refundable annual license maintenance payments to us in August 2013 and August 2014 and we agreed to certain performance obligations to Pfizer for the period

starting from the effective date of the amendment. Pfizer was also obligated to pay to us contingent milestone-based payments upon the occurrence of certain defined development, commercialization, and sales-based milestones.

Collaboration and license revenue related to the Pfizer agreement during the years ended December 31, 2014 and 2015 was $1.4 million and $1.3 million, respectively, reflecting the amortization of the annual license maintenance payments received over the estimated expected period of our performance obligations which was estimated to conclude in August 2015.

On April 2, 2015, Pfizer notified us that it was exercising its right to terminate the research and license agreement effective June 1, 2015. Accordingly, we revised the expected period of performance to end on June 1, 2015, and the deferred revenue balance was fully amortized as of that date. We are currently negotiating with Pfizer regarding rights to use certain manufacturing materials.

In September 2013, we entered into a license and collaboration agreement with ISU Abxis pursuant to which we licensed our proprietary human Factor IX products to ISU Abxis for initial development in South Korea. Under the agreement, ISU Abxis is responsible for development and manufacturing of the licensed products through Phase 1/2 clinical trials. Until the completion of Phase 1 development, ISU Abxis also has a right of first refusal with respect to commercialization rights for the licensed products in South Korea. ISU Abxis paid us an up-front signing fee of $1.75 million and is obligated to pay to us contingent milestone-based payments on the occurrence of certain defined development events, none of which have been achieved as of December 31, 2015. Collaboration and license revenue related to the ISU Abxis agreement during the years ended December 31, 2014 and 2015 was $0.4 million and $0.4 million, respectively, that reflect the amortization of the up-front fee over the estimated period of our performance obligations, that are estimated to conclude in August 2017. We had a deferred revenue balance of $0.7 million as of December 31, 2015 related to the ISU Abxis collaboration.

On August 20, 2015, we completed the business combination between Old Catalyst and Targacept in accordance with the terms of the Agreement and Plan of Merger, dated as of March 5, 2015, as amended on May 6 and May 13, 2015 (the “Merger Agreement”). Also on August 20, 2015, in connection with, and prior to the completion of, the merger, we effected a 7-for-1 reverse stock split of our common stock (the “Reverse Stock Split”) and changed our name to “Catalyst Biosciences, Inc.”

Immediately prior to and in connection with the merger, each share of Old Catalyst preferred stock outstanding was converted into shares of Old Catalyst common stock at ratios determined in accordance with the Old Catalyst certificate of incorporation then in effect. Under the terms of the Merger Agreement, at the effective time of the merger, we issued shares of our common stock to Old Catalyst stockholders, at an exchange rate of 0.0382 shares of common stock, after taking into account the Reverse Stock Split, in exchange for each share of Old Catalyst common stock outstanding immediately prior to the merger. The exchange rate was calculated by a formula that was determined through arms-length negotiations between Targacept and Old Catalyst. Immediately after the merger, there were 11,416,984 shares of our common stock outstanding, and the former Old Catalyst equity holders beneficially owned approximately 59% of our common stock. The merger was accounted for as a reverse asset acquisition.

We have no products approved for commercial sale and have not generated any revenue from product sales. From inception to December 31, 2015, we have raised net cash proceeds of approximately $217.4 million, primarily from private placements of convertible preferred stock and the proceeds from the merger in addition to issuances of shares of common stock and warrants and payments received under collaboration agreements. The cash proceeds raised do not include the redeemable convertible notes which are held in restricted cash.

We have never been profitable and have incurred significant operating losses in each year since inception. Our net losses were $14.8 million and $6.6 million for years ended December 31, 2015 and 2014, respectively. As of December 31, 2015, we had an accumulated deficit of $131.0 million. Substantially all of our operating losses

resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. Our operating costs have decreased since 2012 due to the termination of the research activities under the Pfizer agreement and other agreements, a restructuring of our operations that included a reduction in work force, and the focusing of our research programs.

We expect to incur significant expenses and increasing operating losses for at least the next several years as we continue the preclinical and clinical development of, and seek regulatory approval for, our drug candidates. In addition, following the merger our expenses have further increased as a result of hiring additional financial personnel, upgrading our financial information systems and incurring costs associated with being a public company. In addition, our operating losses may fluctuate significantly from quarter to quarter and year to year due to timing of preclinical, clinical development programs and regulatory approval.

Financial Operations Overview

Contract Revenue

Our contract revenue was generated by recognizing revenue from the amortization of up-front licensee fees for research and development services under our collaboration agreements with Pfizer and ISU Abxis. Payments made to us under these agreements are recognized over the period of performance for each arrangement. We may also be entitled to receive additional milestone payments and other contingent payments upon the occurrence of specific events. We have not generated any revenue from commercial product sales to date. As of June, 2015, our deferred revenue balance from the Pfizer research and license agreement was fully amortized following the termination by Pfizer of that agreement.

For the years ended December 31, 2015, 2014 and 2013, revenue from Pfizer and ISU Abxis represented the following percentage of our total contract revenue:

	Year ended December 31,		
	2015	2014	2013
Pfizer (Wyeth)	75%	76%	68%
ISU Abxis	25%	24%	32%

Due to the nature of the milestone payments under the remaining collaboration agreement, the termination of the Pfizer agreement and the nonlinearity of the earnings process associated with certain payments and milestones, we expect that our revenue will decrease in future periods, as a result of both the loss of the Pfizer contract revenue and the uncertainty of timing related to achievement of milestones.

Research and Development Expenses

Research and development expenses represent costs incurred to conduct research, such as the discovery and development of our product candidates. We recognize all research and development costs as they are incurred.

Research and development expenses consist primarily of the following:

- employee-related expenses, which include salaries, benefits and stock-based compensation;
- laboratory and vendor expenses, including payments to consultants, related to the execution of preclinical, non-clinical, and clinical studies; and
- facilities and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation and amortization expense and other supplies.

The following table summarizes our research and development expenses during the years ended December 31, 2015, 2014 and 2013 (*in thousands*).

	Year ended December 31,		
	2015	2014	2013
Personnel costs	$2,991	$2,122	$2,675
Preclinical research	1,567	1,276	2,149
Facility and overhead	1,400	1,869	1,733
Total research and development expenses	$5,958	$5,267	$6,557

The largest component of our total operating expenses has historically been our investment in research and development activities, including the clinical development of our product candidates. We are currently focusing substantially all of our resources and development efforts on our preclinical pipeline. Our internal resources, employees and infrastructure are not directly tied to individual product candidates or development programs. As such, we do not maintain information regarding these costs incurred for these research and development programs on a project-specific basis.

We expect our research and development expenses will increase during the next few years as we continue the preclinical and clinical development, and pursue regulatory approval of our product candidates in the United States. Due to the termination of the research and license agreement with Pfizer, we expect to incur costs in connection with the Factor VIIa program. However, the incurrence of such costs are dependent on whether we will pursue the program on our own or enter into a new collaboration and license arrangement with another pharmaceutical or biotech company.

The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in achieving marketing approval for our product candidates. The probability of success of each product candidate may be affected by numerous factors, including clinical data, competition, manufacturing capability and commercial viability. As a result, we are unable to determine the duration of and costs to complete our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

Successful development of current and future product candidates is highly uncertain. Completion dates and costs for our research programs can vary significantly for each current and future product candidate and are difficult to predict. As a result, we cannot estimate with any degree of certainty the costs we will incur in connection with development of our product candidates. We anticipate we will make determinations as to which programs and product candidates to pursue and how much funding to direct to each program and product candidate on an ongoing basis in response to the scientific success of early research programs, results of ongoing and future clinical trials, our ability to enter into collaborative agreements with respect to programs or potential product candidates, as well as ongoing assessments as to each current or future product candidate’s commercial potential.

General and Administrative Expenses

General and administrative expenses consist of personnel costs, allocated expenses and other expenses for outside professional services, including legal, human resources, audit and accounting services. Personnel costs consist of salaries, bonus, benefits and stock-based compensation. We expect to incur additional expenses in connection with the completion of the merger, as substantially all of our current employees, including our finance staff, were the employees of Old Catalyst or are new hires who have never operated our current business as a public company, including expenses related to compliance with the rules and regulations of the SEC and NASDAQ, additional insurance expenses, investor relations activities and other administrative expenses and professional services.

Interest and Other Income

Interest and other income consists primarily of the changes in fair value of derivative liability and the warrant liability and sub-lease income earned in connection with the sub-lease of a portion of our leased facility.

The derivative liability is associated with the redeemable convertible notes we issued immediately prior to the closing of the merger in August 2015. The accounting for the redeemable convertible notes, which are convertible into shares of our common stock, requires us to bifurcate the embedded redemption feature and account for it as a derivative liability at estimated fair value upon issuance. The derivative liability is remeasured to estimated fair value as of each balance sheet date. We will record adjustments to the fair value of the derivative liability at the end of each reporting period until the earlier of the conversion, redemption or maturity of the redeemable convertible notes.

We recorded adjustments to the estimated fair value of the preferred stock warrants until they converted into warrants to purchase shares of common stock upon the closing of the merger in August 2015. At that time, we reclassified the preferred stock warrant liability into additional paid-in capital and no longer recorded any related periodic fair value adjustments.

On August 22, 2013, we entered into a sub-lease agreement with another biotech company whereby the sub-lessee agreed to sub-lease a portion of our leased facility in South San Francisco, California. Under the sub-lease agreement, the sub-lessee paid rent and a share of facility operating expenses monthly to us until our lease and the sub-lease expired in February 2015. On February 23, 2015, the Company entered into a new sub-lease, as sub-lessee, for the portion of the space it occupied in their headquarters building. The initial term of the sub-lease was set to expire on August 31, 2015. On June 8, 2015 the Company exercised its right to extend the sub-lease term through February 27, 2018.

Interest Expense

Interest expense consists of immediate accretion of debt discount related to the redeemable convertible notes subsequent to the merger as the redeemable convertible notes are immediately redeemable at the option of the holders, accrued interest costs related to our convertible notes and the amortization of debt discount for the warrants that were issued in connection with the redeemable convertible notes.

Results of Operations

The following tables set forth our results of operations data for the periods presented (*in thousands*):

	Year Ended December 31, 2015	2014	Change ($)	Change (%)
Contract revenue	$ 1,750	$ 1,813	$ (63)	(3)%
Operating expenses:				
Research and development	5,958	5,267	691	13 %
General and administrative	9,594	4,055	5,539	137 %
Total operating expenses	15,552	9,322	6,230	67 %
Loss from operations	(13,802)	(7,509)	(6,293)	84 %
Interest and other income	518	896	(378)	(42)%
Interest expense	(1,478)	—	(1,478)	100 %
Net loss	$ (14,762)	$ (6,613)	$ (8,149)	123 %

	Year Ended December 31, 2014	2013	Change ($)	Change (%)
Contract revenue	$ 1,813	$ 523	$ 1,290	247 %
Operating expenses:				
Research and development	5,267	6,557	(1,290)	(20)%
General and administrative	4,055	4,086	(31)	(1)%
Total operating expenses	9,322	10,643	(1,321)	(12)%
Loss from operations	(7,509)	(10,120)	2,611	(26)%
Interest and other income	896	154	742	482 %
Interest expense	—	—	—	—
Net loss	$ (6,613)	$ (9,966)	$ 3,353	(34)%

Contract revenue

Contract revenue decreased by $0.1 million, or 3%, from $1.8 million during the year ended December 31, 2014 to $1.7 million during the year ended December 31, 2015. The decrease in contract revenue was due primarily to the partial-year of recognition of the contract revenue payment received under our collaboration agreements with Pfizer in connection with the termination of the agreement in April 2015 and full-year recognition of contract revenues payments under our collaboration agreement with ISU Abxis in connection with the amortization of deferred revenue.

Contract revenue increased by $1.3 million, or 247%, from $0.5 million for the year ended December 31, 2013 to $1.8 million for the year ended December 31, 2014. The increase in contract revenue during 2014 was due primarily to the amortization of deferred revenue related to up-front license and annual license maintenance fees we received under our collaboration agreements with Pfizer and ISU Abxis.

We have recognized in revenue all amounts that had been previously deferred related to the terminated Pfizer collaboration and, therefore, in future periods, will not recognize any additional revenue under our previous collaboration agreement with Pfizer.

Research and Development Expenses

Research and development expenses increased by $0.7 million, or 13%, from $5.3 million during the year ended December 31, 2014 to $6.0 million during the year ended December 31, 2015. The increase was due primarily to an increase of $0.9 million in personnel-related costs in connection with increased research and development activities and hiring of additional research and development employees and an increase of $0.4 million in lab supply costs and costs related to preclinical third-party research and development service contracts. The increases were partially offset by a decrease of $0.6 million in facilities-related costs primarily as a result of the reduction in space we are leasing following the new sub-lease agreement entered into in February 2015.

Research and development expenses decreased by $1.3 million, or 20%, from $6.6 million for the year ended December 31, 2013 to $5.3 million for the year ended December 31, 2014. The decrease was due primarily to a decrease of $0.6 million in personnel-related costs primarily as a result of a reduction in workforce; a decrease of $0.2 million costs in facilities-related costs primarily as a result of our sub-leasing a portion of our space, a decrease of $0.1 million in costs related to preclinical third-party research and development service contracts, and a decrease of $0.2 million in lab supply costs.

Based on our current programs and related commitments, we expect our research and development expenses for the year ending December 31, 2016 to increase as compared with 2015, due primarily to costs associated with manufacturing for our next-generation Factor VIIa, CB 813d.

General and Administrative Expenses

General and administrative expenses increased by $5.5 million, or 137%, from $4.1 million during the year ended December 31, 2014 to $9.6 million during the year ended December 31, 2015. The increase was due primarily to an increase of $4.3 million in professional service costs, including patent related legal costs and merger related legal and accounting advisory services and an increase of $1.0 million in personnel-related costs as a result of increased head count in order to operate as a public company and $0.2 million in other expenses related to operating as a public company.

General and administrative expenses decreased by $0.03 million, or 1%, for the year ended December 31, 2014 as compared to the year ended December 31, 2013, which was related to a decrease in personnel-related costs as a result of a reduction in workforce.

During 2015 we incurred significant cost related to the reverse merger and do not expect to incur those costs during 2016.

Interest and Other Income

Interest and other income decreased by $0.4 million, or 42%, from $0.9 million for the year ended December 31, 2014 to $0.5 million for the year ended December 31, 2015. The decrease was due primarily to a $0.4 million decrease in sub-lease income recognized in connection with the February 2015 expiration of a sub-lease agreement and $0.3 million loss recognized related to the change in estimated fair value of warrant liability, partially offset by $0.3 million gain recognized related to the change in fair value of the derivative liability.

Interest and other income increased by $0.7 million, or 482%, from $0.2 million for the year ended December 31, 2013 to $0.9 million for the year ended December 31, 2014. The increase was due primarily to a $0.4 million increase in sublease income recognized in connection with a sublease agreement executed in the third quarter of 2013 and a $0.3 million gain recognized related to the change in fair value of the warrant liability related to the convertible preferred stock warrants issued in connection with the Series E convertible preferred stock financing in 2014.

Interest Expense

Interest expense for the year ended December 31, 2015 was $1.5 million and consisted of, $1.4 million for the immediate accretion of the debt discount for the redeemable convertible notes and $0.1 million for the accrued interest and amortization of the debt discount for the convertible notes issued to related parties in May and June 2015. We did not have any debt obligations in 2014 and 2013.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU 2014-09"), which amends the existing accounting standards for revenue recognition. ASU 2014-09 is based on principles that govern the recognition of revenue at an amount an entity expects to be entitled when products are transferred to customers.

The original effective date for ASU 2014-09 would have required us to adopt beginning in its first quarter of 2017. In August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606) – Deferral of the Effective Date, which defers the effective date of ASU 2014-09 for one year and permits early adoption as early as the original effective date of ASU 2014-09. Accordingly, we may adopt the standard in either our first quarter of 2017 or 2018. The new revenue standard may be applied retrospectively to each prior period presented or prospectively with the cumulative effect recognized as of the date of adoption. We are currently evaluating the timing of our adoption and the impact of adopting the new revenue standard on our consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (ASU 2014-15). This ASU introduces an explicit requirement for management to assess if there is substantial doubt about an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. In connection with each annual and interim period, management must assess if there is substantial doubt about an entity's ability to continue as a going concern within one year after the issuance date. Disclosures are required if conditions give rise to substantial doubt. ASU 2014-15 is effective for all entities in the first annual period ending after December 15, 2016. We are currently assessing the potential effects of this ASU on our consolidated financial statements.

Liquidity and Capital Resources

On August 20, 2015, we completed our merger with Targacept, which provided $41.2 million in cash, cash equivalents and short-term investments. Prior to that time, our operations had been financed primarily by net proceeds from the sale of convertible preferred stock, and the issuance of convertible notes. As of December 31, 2015, we had $32.5 million of cash, cash equivalents and short-term investments. We have an accumulated deficit of $131.0 million as of December 31, 2015.

Our primary uses of cash are to fund operating expenses, including research and development expenditures and general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in its outstanding accounts payable and accrued expenses.

We believe that our existing capital resources will be sufficient to meet our projected operating requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We plan to continue to fund losses from operations and capital funding needs through future equity and/or debt financings, as well as potential additional collaborations or strategic partnerships with other companies. The sale of additional equity or convertible debt could result in additional dilution to our stockholders. The incurrence of indebtedness would result in debt service obligations and could result in operating and financing covenants that would restrict our operations. We can provide no assurance that financing will be available in the amounts we need or on terms acceptable to us, if at all. If we are not able to secure adequate additional funding we may be forced to delay, make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially harm our business.

The following table summarizes our cash flows for the periods presented (in thousands):

	Year Ended December 31,		
	2015	2014	2013
Cash used in operating activities	$ (19,118)	$ (6,389)	$ (6,274)
Cash provided by (used in) investing activities	37,357	98	(41)
Cash provided by financing activities	9,313	5,007	5,742
Net increase (decrease) in cash and cash equivalents	$ 27,552	$ (1,284)	$ (573)

Cash Flows from Operating Activities

Cash used in operating activities for the year ended December 31, 2015 was $19.1 million. The net loss of $14.8 million was partially offset by non-cash charges of $1.5 million of interest expense related to accretion of debt discount of redeemable convertible notes and convertible notes to related parties, $0.5 million for depreciation and amortization and $0.3 million for stock-based compensation, partially offset by $0.3 million for non-cash gain related to change in fair value of the derivative liability and $0.1 million for non-cash gain related to change in fair value of warrant liability. Cash used in operating activities also reflected the change in net operating assets of $6.1 million due primarily to a $4.3 million decrease in accounts payable we assumed in connection with the merger, $1.8 million decrease in deferred revenue due to the recognition of revenue, a $1.4 million increase in prepaids and other current assets primarily associated with the prepayment related to our manufacturing agreement and $0.1 million increase in accounts receivable, partially offset by a $1.2 million increase in accrued compensation and other accrued liabilities related to our increased operating activities as a public company.

Cash used in operating activities for the year ended December 31, 2014 was $6.4 million, consisting of a net loss of $6.6 million, which was partially offset by non-cash charges of $0.7 million for depreciation and amortization, $0.2 million for stock-based compensation, partially offset by $0.4 million in non-cash gain related to the change in fair value of the warrant liability. The change in our net operating assets and liabilities of $0.5 million was due primarily to a $0.3 million decrease in deferred revenue due to the amortization of upfront license fees from our collaborations in the amount of $1.8 million, partially offset by a receipt of $1.5 million in the third quarter of 2014 under our collaboration agreement with Pfizer and a $0.2 million decrease in deferred rent for our leased facility.

Cash used by operating activities for the year ended December 31, 2013 was $6.3 million, consisting of a net loss of $10.0 million, which was partially offset by non-cash charges $1.0 million for depreciation and amortization and $0.3 million for stock-based compensation. The change in our net operating assets and liabilities of $2.4 million was due primarily to a $2.8 million increase in deferred revenue related to the receipt of $3.3 million in payments under our collaboration arrangements offset by the recognition of revenue of $0.5 million, and a $0.2 million decrease in accrued compensation and other accrued liabilities related to our reduction in workforce.

Cash Flows from Investing Activities

Cash provided by investing activities for the year ended December 31, 2015 of $37.4 million primarily related to $23.9 million of net cash proceeds from the merger and $13.9 million of proceeds from maturities of investments, partially offset by $0.3 million related to the purchase of property and equipment and $0.1 million of increase of restricted cash related to facility deposit.

Cash provided from investing activities of $0.1 million for the year ended December 31, 2014 was related to the sale of property and equipment.

Cash used in investing activities of $0.04 million for the year ended December 31, 2013 was related to the purchase of property and equipment.

Cash flows from Financing Activities

Cash provided by financing activities for the year ended December 31, 2015 of $9.3 million was primarily related to net cash proceeds from the issuance of convertible preferred stock of $7.3 million, release of restricted cash of $3.2 million related to conversion and redemption of some of the redeemable convertible notes and net cash proceeds of $1.9 million from the issuance of convertible notes and warrants to related parties, partially offset by payments of $3.0 million related to redemption of some of the redeemable convertible notes and $0.1 million related to repurchase of common stock in connection with equity awards assumed.

Cash provided by financing activities for the years ended December 31, 2014 and 2013 was primarily related to proceeds from the issuance of convertible preferred stock of $5.0 million and $5.7 million, respectively.

Contractual Obligations

The following table summarizes our fixed contractual obligations as of December 31, 2015 (*in thousands*):

	Payments due by period				
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	Total
Contractual Obligations:					
Operating lease obligations[1]	$ 723	$ 870	$ —	$ —	$ 1,593
Total contractual obligations[2][3]	$ 723	$ 870	$ —	$ —	$ 1,593

(1) Represents future minimum lease payments under the non-cancelable sub-lease for our headquarters in South San Francisco, California. The minimum lease payments above do not include any related common area maintenance charges or real estate taxes.

(2) We may be obligated to pay ISU Abxis up to $2.0 million in potential milestone payments. As the achievement and timing of these milestones are not probable and estimable, such commitments have not been included in the contractual obligation disclosed above. We may be obligated to pay Pfizer certain milestone payments. The achievement and timing of these milestones are not probable and estimable and have not been included in the contractual obligation disclosed above.

(3) We had unrecognized tax benefits in the amount of $1.3 million as of December 31, 2015 related to uncertain tax positions. However, there is uncertainty regarding when these benefits will require settlement so these amounts were not included in the contractual obligations table above.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Critical Accounting Polices and Estimates

The preparation of financial statements and related disclosures in conformity with U.S. generally accepted accounting principles (“GAAP”) and the Company’s discussion and analysis of its financial condition and operating results require the Company’s management to make judgments, assumptions and estimates that affect the amounts reported in its consolidated financial statements and accompanying notes. Our significant accounting policies and methods used in preparation of the Company’s consolidated financial statements are described in Note 2 “Summary of Significant Accounting Policies” of the Notes to Consolidated Financial Statements of this Annual Report on Form 10-K. Management bases its estimates on historical experience and on various other assumptions it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates, and such differences may be material.

Management believes the Company's critical accounting policies and estimates discussed below are critical to understanding its historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Revenue Recognition

We generate revenue from collaboration agreements pursuant to which we seek the development and commercialization of our product candidates. Collaboration agreements provide for the payment to us of up-front license fees, success-based milestone payments, FTE-based payments for research services and royalties on any future sales of commercialized products that result from the collaboration. Our performance obligations under our remaining collaboration agreement include licenses of intellectual property rights, obligations to provide research and development services, related clinical drug supply and regulatory approval services, and obligations to participate on certain development and/or commercialization committees with the collaborators.

Payments of up-front license fees are recorded as deferred revenue in our balance sheet and are recognized as contract revenue over our estimated period of performance in a manner consistent with the terms of the research and development obligations contained in the respective collaboration agreement. We regularly review the estimated periods of performance related to our collaboration agreements based on the progress made under each arrangement. Our estimates of our performance period may change over the course of the agreement term. Such a change could have a material impact on the amount of revenue we record in future periods.

Payments to us for research and development and regulatory approval services are recognized as the services are performed, in accordance with the respective contract terms. Payments for such services may be made to or by us based on the number of full-time equivalent researchers assigned to the collaboration project and the related research and development expenses incurred.

Revenue recognition for multiple element revenue arrangements will have deliverables associated with the arrangement divided into separate units of accounting provided that (i) a delivered item has value to the customer on a standalone basis and (ii) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in the control of the vendor. As a biotechnology company with unique and specialized technological undelivered performance obligations associated with our collaborations, our multiple element arrangements have in the past often involved deliverables and consideration that do not meet the criteria for having stand-alone value.

Such deliverables and consideration must be accounted for under a single unit of accounting along with other arrangement deliverables and consideration that do not have stand-alone value and are recognized as revenue over the estimated period that the performance obligations are to be performed. The revenue is recognized on a proportional performance basis when the levels of the performance obligations under an arrangement can be reasonably estimated and on a straight-line basis when they cannot.

We also adopted guidance that permits the recognition of revenue contingent upon the achievement of a milestone in its entirety, in the period in which the milestone is achieved, only if the milestone meets certain criteria and is considered to be substantive. As such, we plan to recognize revenue in the period in which the milestone is achieved, only if the milestone is considered to be substantive based on the following criteria:

- the milestone is commensurate with either (i) the vendor's performance to achieve the milestone, or (ii) the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from the vendor's performance to achieve the milestone;
- the milestone relates solely to past performance; and
- the milestone is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

Accrued Research and Development Expenses

We record accrued expenses for estimated costs of our research and development activities conducted by external service providers, which include the conduct of preclinical studies and clinical trials and contract manufacturing activities. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced, and includes these costs in accrued liabilities in the balance sheet and within research and development expense in the consolidated statement of operations. These costs are a significant component of our research and development expenses. We record accrued expenses for these costs based on the estimated amount of work completed and in accordance with agreements established with these external service providers.

We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust its accrued estimates.

Stock-based Compensation

We measure the cost of employee and director services received in exchange for an award of equity instruments based on the fair value-based measurement of the award on the date of grant and recognize the related expense over the period during which an employee or director is required to provide service in exchange for the award on a straight-line basis.

Determining the fair value of stock-based awards at the grant date requires judgment. We use the Black-Scholes option-pricing model to determine the fair value of stock options. The determination of the grant date fair value of options using an option-pricing model is affected by our assumptions regarding a number of variables including the fair value of our common stock, our expected common stock price volatility over the expected life of the options, expected term of the stock option, risk-free interest rates and expected dividends. We record stock-based compensation as a compensation expense, net of the estimated impact of forfeited awards. We apply a forfeiture rate to stock-based compensation expense using historical data to estimate pre-vesting option forfeitures. We estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ materially from those original estimates. As such, we recognize a stock-based compensation expense only for those stock-based awards that are expected to vest, over their requisite service period, based on the vesting provisions of the individual grants. See *Note 11 – Stock Based Compensation* to our consolidated financial statements included in this Report for more information.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and interest rates. We are exposed to market risks in the ordinary course of our business. Our primary exposure to market risk is interest income sensitivity in our investment portfolio. Fixed rate securities and borrowings may have their fair market value adversely impacted due to fluctuations in interest rates, while floating rate securities may produce less income than expected if interest rates fall and floating rate borrowings may lead to additional interest expense if interest rates increase. Due in part to these factors, our future investment income may fall short of expectations due to changes in interest rates or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates.

However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on the fair market value of our investment portfolio. As of December 31, 2015, we had cash and cash equivalents of $32.5 million, which consisted of bank deposits and money market funds, and short-term investments of $3.4 million. The redeemable convertible notes we issued in August 2015 in connection with the merger do not bear interest and thus a change in market interest rates would not have an impact on an interest expense related to these redeemable convertible notes. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our investment portfolio.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

CATALYST BIOSCIENCES, INC.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Catalyst Biosciences, Inc.

We have audited the accompanying consolidated balance sheets of Catalyst Biosciences, Inc. and subsidiaries (the "Company"), as of December 31, 2015 and 2014 and the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the years in the three-year period ended December 31, 2015. The consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Catalyst Biosciences, Inc. as of December 31, 2015 and 2014, and the consolidated results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America.

/s/ EisnerAmper LLP

Iselin, New Jersey
March 9, 2016

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

	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 29,096	$ 1,544
Short-term investments	3,402	—
Restricted cash	33,794	50
Deposits	133	278
Accounts receivable	492	95
Prepaid and other current assets	1,781	103
Total current assets	68,698	2,070
Restricted cash, noncurrent	125	—
Property and equipment, net	698	911
Total assets	$ 69,521	$ 2,981
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 939	$ 249
Accrued compensation	926	281
Other accrued liabilities	535	30
Deferred revenue, current portion	438	1,750
Deferred rent, current portion	19	26
Redeemable convertible notes	33,743	—
Derivative liability	1,156	—
Total current liabilities	37,756	2,336
Deferred revenue, noncurrent portion	292	729
Deferred rent, noncurrent portion	48	—
Warrant liability	—	391
Total liabilities	38,096	3,456
Commitments and contingencies		
Convertible preferred stock:		
Convertible preferred stock, $0.001 par value; 0 and 88,469,871 shares authorized as of December 31, 2015 and 2014, respectively; 0 and 87,405,011 shares issued and outstanding as of December 31, 2015 and 2014, respectively, aggregate liquidation preference of $0 and $118,678 as of December 31, 2015 and 2014, respectively.	—	108,877
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value, 5,000,000 shares and 0 shares authorized as of December 31, 2015 and 2014, respectively; 0 shares issued and outstanding as of December 31, 2015 and 2014, respectively.	—	—
Common stock, $0.001 par value, 105,000,000 shares and 110,000,000 shares authorized as of December 31, 2015 and 2014, respectively; 11,430,085 and 370,944 shares issued and outstanding as of December 31, 2015 and 2014, respectively.	11	—
Additional paid-in capital	162,450	6,923
Accumulated other comprehensive income	1	—
Accumulated deficit	(131,037)	(116,275)
Total stockholders' equity (deficit)	31,425	(109,352)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 69,521	$ 2,981

The accompanying notes are an integral part of these consolidated financial statements.

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

	Year Ended December 31,		
	2015	2014	2013
Contract revenue	$ 1,750	$ 1,813	$ 523
Operating expenses:			
Research and development	5,958	5,267	6,557
General and administrative	9,594	4,055	4,086
Total operating expenses	15,552	9,322	10,643
Loss from operations	(13,802)	(7,509)	(10,120)
Interest and other income	518	896	154
Interest expense	(1,478)	—	—
Net loss	$ (14,762)	$ (6,613)	$ (9,966)
Net loss per common share, basic and diluted	$ (3.33)	$ (17.99)	$ (27.29)
Shares used to compute net loss per common share, basic and diluted	4,429,093	367,586	365,214

The accompanying notes are an integral part of these consolidated financial statements.

Catalyst Biosciences, Inc.
Consolidated Statements of Comprehensive Loss
(In thousands)

	Year Ended December 31,		
	2015	2014	2013
Net loss	$ (14,762)	$ (6,613)	$ (9,966)
Other comprehensive income (loss):			
Unrealized gain on available-for-sale securities, net of tax	1	—	—
Total comprehensive loss	$ (14,761)	$ (6,613)	$ (9,966)

The accompanying notes are an integral part of these consolidated financial statements.

Catalyst Biosciences, Inc.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance at December 31, 2012	78,932,729	$ 98,899	365,214	$ —	$ 6,356	$ —	$ (99,696)	$ (93,340)
Stock based compensation expense associated with vesting of stock awards	—	—	—	—	298	—	—	298
Issuance of Series CC convertible preferred stock, net of issuance costs of $4	3,907,512	4,961	—	—	—	—	—	—
Issuance of Series D convertible preferred stock, net of issuance costs of $19	629,630	781	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	(9,966)	(9,966)
Balance at December 31, 2013	83,469,871	104,641	365,214	—	6,654	—	(109,662)	(103,008)
Stock based compensation expense associated with vesting of stock awards	—	—	—	—	244	—	—	244
Stock options exercised for cash	—	—	5,730	—	25	—	—	25
Issuance of Series E convertible preferred stock, net of issuance costs of $28	3,935,140	4,236	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	(6,613)	(6,613)
Balance at December 31, 2014	87,405,011	108,877	370,944	—	6,923	—	(116,275)	(109,352)
Stock based compensation expense associated with vesting of stock awards	—	—	—	—	326	—	—	326
Stock options exercised for cash	—	—	3,820	—	13	—	—	13
Conversion of convertible notes - related parties to Series F convertible preferred stock	1,511,723	1,511	—	—	—	—	—	—
Issuance of Series F convertible preferred stock, net of issuance costs of $96	5,788,522	7,259	—	—	—	—	—	—
Conversion of preferred stock to common stock in connection with merger	(94,705,256)	(117,647)	6,148,161	6	117,641	—	—	117,647
Conversion of preferred stock warrants to common stock warrants in connection with merger	—	—	—	—	774	—	—	774
Issuance of common stock in connection with reverse merger	—	—	4,881,373	5	36,532	—	—	36,537
Conversion of redeemable convertible notes to common stock	—	—	25,787	—	241	—	—	241
Unrealized gain on available-for-sale securities, net of tax	—	—	—	—	—	1	—	1
Net loss	—	—	—	—	—	—	(14,762)	(14,762)
Balance at December 31, 2015	—	$ —	11,430,085	$ 11	$ 162,450	$ 1	$ (131,037)	$ 31,425

The accompanying notes are an integral part of these consolidated financial statements.

Catalyst Biosciences, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2015	2014	2013
Operating Activities			
Net loss	$ (14,762)	$ (6,613)	$ (9,966)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	326	244	298
Depreciation and amortization	470	680	974
Non-cash interest expense on convertible notes	1,478	—	—
Loss on disposal of fixed assets	15	78	—
Impairment of patent assets	—	53	—
Gain on extinguishment of redeemable convertible notes	(52)	—	—
Change in fair value of warrant liability	(91)	(354)	—
Change in fair value of derivative liability	(242)	—	—
Changes in operating assets and liabilities:			
Accounts receivable	(79)	1	(52)
Prepaid and other current assets	(1,350)	99	54
Accounts payable	(4,273)	(106)	11
Accrued compensation and other accrued liabilities	1,150	(2)	(247)
Deferred rent	41	(156)	(138)
Deferred revenue	(1,749)	(313)	2,792
Net cash flows used in operating activities	(19,118)	(6,389)	(6,274)
Investing Activities			
Proceeds from the reverse merger	23,931	—	—
Proceeds from maturities of investments	13,823	—	—
Purchases of property and equipment	(272)	—	(41)
Change in restricted cash	(125)	—	—
Proceeds from sale of property and equipment	—	98	—
Net cash flows provided by (used in) investing activities	37,357	98	(41)
Financing Activities			
Release of restricted cash due to conversion and redemption of redeemable convertible notes	3,255	—	—
Payments for the redemption of redeemable convertible notes	(3,020)	—	—
Proceeds from issuance of convertible preferred stock, net of issuance costs	7,259	4,982	5,742
Proceeds from issuance of convertible notes and warrants to related parties	1,888	—	—
Repurchase of common stock in connection with equity award assumed	(82)	—	—
Proceeds from the exercise of common stock options	13	25	—
Net cash flows provided by financing activities	9,313	5,007	5,742
Net increase (decrease) in cash and cash equivalents	27,552	(1,284)	(573)
Cash and cash equivalents at beginning of year	1,544	2,828	3,401
Cash and equivalents at end of year	$ 29,096	$ 1,544	$ 2,828
Supplemental Disclosure of Non-Cash Investing and Financing Information:			
Conversion of convertible notes to Series F convertible preferred stock	$ 1,511	$ —	$ —
Conversion of preferred stock warrant liability to equity upon reverse merger	774	—	—
Conversion of preferred stock to equity upon reverse merger	117,647	—	—
Investment securities received from the reverse merger	17,223	—	—
Redeemable convertible notes assumed upon reverse merger	37,073	—	—
Issuance of common stock in connection with conversion of convertible notes	241	—	—
Derivative liability related to redeemable convertible notes	1,455	—	—

The accompanying notes are an integral part of these consolidated financial statements

Catalyst Biosciences, Inc.
Notes to Consolidated Financial Statements

1. Nature of Operations

Catalyst Biosciences, Inc. (the "Company" or "Catalyst"), is a clinical-stage biotechnology company focused on engineering proteases as therapeutics for hemophilia, hemeostasis, complement-mediated diseases, and other unmet medical needs. Its facilities are located in South San Francisco, California and it operates in one segment. The Company's current customers, engaged principally through collaborations are other pharmaceutical and biotechnology companies, who are also engaged in developing and commercializing therapies for patients in the areas of hemophilia and complement-mediated diseases.

Reverse Merger

Prior to August 20, 2015, the name of the Company was Targacept. On August 20, 2015, Targacept completed its business combination with Old Catalyst" in accordance with the terms of an Agreement and Plan of Merger, dated as of March 5, 2015, as amended on May 6 and May 13, 2015 (the "Merger Agreement"), by and among Targacept, Talos Merger Sub, Inc. ("Merger Sub") and Old Catalyst, pursuant to which Merger Sub merged with and into Old Catalyst, with Old Catalyst surviving as a wholly-owned subsidiary of Targacept (the "Merger"). Also on August 20, 2015, in connection with, and prior to the completion of, the Merger, Targacept effected a 7-for-1 reverse stock split of its common stock (the "Reverse Stock Split") and changed its name from Targacept, Inc. to Catalyst Biosciences, Inc. Following the completion of the merger, the business conducted by the Company became primarily the business conducted by Old Catalyst described in the paragraph above.

These consolidated financial statements reflect the historical results of Old Catalyst prior to the completion of the merger, and do not include the historical results of Targacept prior to the completion of the merger. All 2015, 2014 and 2013 share and per share disclosures have been adjusted to reflect the exchange of shares in the merger, and the 7-for-1 reverse stock split of the common stock on August 20, 2015. Under U.S. generally accepted accounting principles ("GAAP"), the merger is treated as a "reverse merger" under the purchase method of accounting. For accounting purposes, Old Catalyst is considered to have acquired Targacept. See *Note 7 - Reverse Merger* for further details on GAAP accounting treatment.

Liquidity

We had an accumulated deficit of $131.0 million as of December 31, 2015 and expect to continue to incur losses for the next several years. As of December 31, 2015, we had $32.5 million in cash, cash equivalents and short-term investments. Management believes that the currently available resources will provide sufficient funds to enable us to meet its operating plan for at least the next fifteen months. However, if we anticipated operating results are not achieved in future periods, management believes that planned expenditures may need to be reduced in order to extend the time period over which the then-available resources would be able to fund our operations.

On November 30, 2015, we entered into a Letter of Agreement (LoA) with a third-party manufacturer concerning the development and manufacturing of our human Factor VIIa. The LoA has a scope of work associated with initial key activities of the overall project and commits us to $1.5 million in payments, including prepayment of $1.1 million. For the year ended December 31, 2015, we recognized $0.1 million of the $1.1 million prepaid amount related to the Letter of Agreement in research and development expense.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its subsidiaries. Intercompany accounts and transactions have been eliminated in consolidation. The Company's consolidated financial statements have been prepared in accordance with GAAP.

Catalyst Biosciences, Inc.
Notes to Consolidated Financial Statements

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, convertible notes and related warrants up to the date of conversion, common stock and stock-based compensation. The Company bases its estimates on various assumptions that the Company believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company invests its excess cash in bank deposits, consisting primarily of money market mutual funds. The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents.

Restricted Cash

Restricted cash consists primarily of certain checking, money market and certificate of deposit accounts that are: (i) pledged to or held in a segregated escrow account by the Company's correspondent banks for the benefit of the holders of the redeemable convertible notes in order to facilitate the payment of the redeemable convertible notes upon redemption or at maturity as discussed in *Note 3 - Fair Value Measurements* or (ii) pledged as collateral for the Company's corporate credit card and deposit for its facility lease.

Fair Value of Financial Instruments

The Company applies fair value accounting for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

The fair value hierarchy requires that an entity maximize the use of observable inputs when estimating fair value. The fair value hierarchy includes the following three-level classification which is based on the market observability of the inputs used for estimating the fair value of the assets or liabilities being measured:

Level 1 – Quoted prices in active markets for identical assets or liabilities.

Level 2 – Observable inputs other than quoted prices in active markets for identical assets and liabilities, quoted prices for identical or similar assets or liabilities in inactive markets, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Inputs that are generally unobservable and typically reflect management's estimate of assumptions that market participants would use in pricing the asset or liability.

Fair value accounting is applied for all financial assets and liabilities and non-financial assets and liabilities that are recognized at fair value in the financial statements on a recurring basis (at least annually).

Catalyst Biosciences, Inc.
Notes to Consolidated Financial Statements

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets, which are three years for computer equipment and software, and three to seven years for laboratory and office equipment, furniture and leasehold improvements.

Intangible Assets

Intangible assets are amortized over their useful lives in a manner that best reflects their economic benefit. Intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. We do not have any indefinite-lived intangible assets.

Intangible assets represent patent rights purchased in 2009 in the amount of $0.1 million that were being amortized over their estimated useful life of 20 years, or life of the patent whichever is shorter, using the straight-line method. Annual amortization was $0 and $883 for 2015 and 2014, respectively. The Company abandoned this patent in 2014. No further amortization is necessary. The total amount amortized through 2014 was $0.02 million and the remaining $0.05 million was written off to amortization expense during 2014 in the accompanying statements of operations.

Investments

All investments have been classified as “available-for-sale” and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its investments at the time of purchase and reevaluates such designation as of each balance sheet date. Unrealized gains and losses are excluded from earnings and are reported as a component of comprehensive loss. Realized gains and losses and declines in fair value determined to be other-than-temporary, if any, on available-for-sale securities are included in interest and other income. The cost of securities sold is based on the specific-identification method. Interest on short-term investments is included in interest and other income.

Fair Value of Financial Instruments

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents and accounts receivable. The Company’s investment policy restricts cash investments to high credit quality, investment grade investments. The Company believes that it has established guidelines for investment of its excess cash that maintain safety and liquidity through its policies on diversification and investment maturity. The Company is exposed to credit risk in the event of default by the institutions holding the cash and cash equivalents to the extent of the amounts recorded on the balance sheets.

Derivative Liability

The embedded redemption feature in the redeemable convertible notes, which are convertible into shares of the Company’s common stock, is accounted for as a derivative liability at its estimated fair value. The derivative is subject to remeasurement at the end of each reporting period, with changes in fair value recognized as a component of interest and other income, in the consolidated statements of operations. The Company will continue to adjust the liability for changes in fair value until the earlier of the conversion, redemption or maturity of the redeemable convertible notes.

Catalyst Biosciences, Inc.
Notes to Consolidated Financial Statements

Revenue Recognition

The Company enters into collaboration arrangements that may include the receipt of payments for up-front license fees, success-based milestone payments, full time equivalent based payments for research services, and royalties on any future sales of commercialized products that result from the collaborations.

Revenue is recognized when the four basic criteria for revenue recognition are met: (1) persuasive evidence of an arrangement exists; (2) transfer of technology has been completed or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured.

Revenue recognition for multiple element revenue arrangements will have deliverables associated with the arrangement divided into separate units of accounting provided that (i) a delivered item has value to the customer on a standalone basis and (ii) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in the control of the vendor. As a biotechnology company with unique and specialized technological undelivered performance obligations associated with its collaborations, the Company's multiple element arrangements most often involve deliverables and consideration that do not meet the criteria for having stand-alone value.

Deliverables and performance obligations are accounted for under a single unit of accounting when they do not have stand-alone value and the related consideration is recognized as revenue over the estimated period of when the performance obligations are to be performed. The revenue is recognized on a proportional performance basis when the levels of the performance obligations under an arrangement can be reasonably estimated and on a straight-line basis when they cannot.

The Company's collaboration agreements entitle it to additional payments upon the achievement of performance-based milestones related to product development, regulatory actions and commercial events in certain geographic areas. Milestones that are not deemed probable or that are tied to counter-party performance are not included in the Company's revenue until the performance conditions are met. If a collaborative agreement milestone is deemed to be substantive, as defined in the accounting rules, the Company is permitted to recognize revenue related to the milestone payment in its entirety.

In the event milestones are deemed non-substantive, the Company recognizes, and defers if applicable, payments for the achievement of such non-substantive milestones over the estimated period of performance applicable to each collaborative agreement using the proportional performance method or on a straight-line basis, as appropriate.

Amounts received under a collaborative agreement prior to satisfying revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Deferred revenue is recorded on the Company's consolidated balance sheet as short-term or long-term based on its best estimate as to when such revenue will be recognized. Short-term deferred revenue consists of amounts that the Company expects to recognize as revenue in the next 12 months. Amounts that the Company expects will not be recognized prior to the next 12 months are classified as long-term deferred revenue.

The Company's performance obligations under its collaboration arrangements also consist of participation on steering committees and the performance of other research and development and business development services. The timing for satisfying these performance obligations can be difficult to estimate and can be subject to change over the course of these agreements. A change in the estimated timing for satisfying the Company's performance obligations could change the timing and amount of revenue that the Company recognizes and records in future periods.

Catalyst Biosciences, Inc.
Notes to Consolidated Financial Statements

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development costs consist of payroll and other personnel-related expenses, laboratory supplies and reagents, contract research and development services, and consulting costs, as well as allocations of facilities and other overhead costs. Under the Company's collaboration agreements, certain specific expenditures are reimbursed by third parties. During the years ended December 31, 2015, 2014 and 2013, the Company recorded a reduction to research and development expenses of $0.9 million, $0.4 million, and $0.4 million, respectively related to these reimbursements.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents and accounts receivable, resulting from research and development pass through expense reimbursement. The Company's accounts receivable at December 31, 2015 was $0.5 million, of which $0.4 million was due from Pfizer Inc. ("Pfizer"), and $0.1 million was due was due from our landlord CBRE for tenant improvements reimbursement. The Company has incurred no credit losses to date. The Company does not require collateral from its collaboration partners.

Income Taxes

Income taxes are computed using the liability method. Deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

The Company follows the authoritative guidance on accounting for uncertainty in income taxes. This guidance prescribes a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken in the Company's income tax returns. This interpretation also provides guidance on accounting for interest and penalties and associated with tax positions, accounting for income taxes in interim periods and income tax disclosures.

The Company's policy is to include penalties and interest expense related to income taxes as a component of other expense and interest expense, respectively, as necessary.

Stock-Based Compensation

The Company measures the cost of employee and director services received in exchange for an award of equity instruments based on the fair value of the award on the date of grant and recognizes the related expense over the period during which the employee or director is required to provide service in exchange for the award on a straight-line basis.

The Company uses the Black-Scholes option-pricing valuation model to estimate the grant-date fair value of stock-based awards. The determination of fair value for stock-based awards on the date of grant using an option-pricing model requires management to make certain assumptions regarding a number of variables. The Company records stock-based compensation as compensation expense, net of the estimated impact of forfeited awards. The Company applies a forfeiture rate to stock-based compensation expense using historical data to estimate pre-vesting option forfeitures. The Company estimates forfeitures at the time of grant, and revises those estimates in subsequent periods if actual forfeitures differ materially from those original estimates. As such, the Company recognizes stock-based compensation expense only for those stock-based awards that are expected to vest, over their requisite service period, based on the vesting provisions of the individual grants.

Catalyst Biosciences, Inc.
Notes to Consolidated Financial Statements

For nonemployee stock-based awards, the measurement date on which the fair value of the stock-based award is calculated is equal to the earlier of (i) the date at which a commitment for performance by the counterparty to earn the equity instrument is reached or (ii) the date at which the counterparty's performance is complete. The Company recognizes stock-based compensation expense for the fair value-based measurement of the nonemployee awards using the Black Scholes option-pricing valuation model and the awards are typically subject to periodic re-measurement over the period that services are rendered.

Deferred Rent

The Company's facilities lease agreement provides for an escalation of rent payments each year. The Company records rent expense on a straight-line basis over the term of the lease. The difference between the amount of expense recognized and the amount of rent paid is recorded as deferred rent in the accompanying consolidated balance sheets.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is the same as basic net loss per share, since the effects of potentially dilutive securities are antidilutive given the net loss of the Company for all periods presented.

3. Fair Value Measurements

For a description of the fair value hierarchy and our fair value methodology, see "*Note 2 – Summary of Significant Accounting Policies*". As of December 31, 2015 and 2014, the Company's highly liquid money market funds included within cash equivalents and restricted cash including deposit in an escrow account are financial assets that are valued using Level 1 inputs. The Company classifies its municipal bonds and corporate notes as Level 2. Level 2 inputs for the valuations are limited to quoted prices for similar assets or liabilities in active markets and inputs other than quoted prices that are observable for the asset or liability. There were no transfers in or out of Level 1 and Level 2 during the periods presented.

Liabilities that are measured at fair value consist of the derivative liability and the warrant for convertible preferred stock that utilize Level 3 inputs. There were no transfers in or out of Level 3 during the periods presented.

The following tables present the fair value hierarchy for assets and liabilities measured at fair value on a recurring basis as of December 31, 2015 and 2014 (*in thousands*):

	December 31, 2015			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 28,927	$ —	$ —	$ 28,927
Restricted cash (money market funds)(1)	33,919	—	—	33,919
Municipal bonds	—	296	—	296
Corporate notes	—	3,106	—	3,106
Total financial assets	$ 62,846	$ 3,402	$ —	$ 66,248
Financial liabilities:				
Derivative liability	$ —	$ —	$ 1,156	$ 1,156
Total financial liabilities	$ —	$ —	$ 1,156	$ 1,156

(1) $125,000 of restricted cash serves as collateral for the Company's corporate credit card and deposit for its facility lease.

Catalyst Biosciences, Inc.
Notes to Consolidated Financial Statements

	December 31, 2014			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 1,496	$ —	$ —	$ 1,496
Restricted cash (money market funds)(1)	50	—	—	50
Total financial assets	$ 1,546	$ —	$ —	$ 1,546
Financial liabilities:				
Warrant for convertible preferred stock liability	$ —	$ —	$ 391	$ 391
Total financial liabilities	$ —	$ —	$ 391	$ 391

(1) $50,000 of restricted cash serves as collateral for the Company's corporate credit card and deposit for its facility lease.

The fair value of the liability related to the warrant for convertible preferred stock was measured using the Black-Scholes option-pricing model. Inputs used to determine the estimated fair value of the warrant liability included the estimated fair value of the underlying convertible preferred stock at the valuation measurement date, the remaining contractual term of the warrant, risk-free interest rates, expected dividends and expected volatility of the price of the underlying preferred stock.

The following table presents the activity for the liability related to the warrant for convertible preferred stock for the year ended December 31, 2015 and 2014 (*in thousands*):

	Warrant Liability
Balance as of December 31, 2013	$ —
Issuance of preferred stock warrants	745
Change in fair value included in interest and other income	(354)
Balance as of December 31, 2014	$ 391
Issuance of preferred stock warrants	474
Change in fair value included in interest and other income	(91)
Reclassification of warrant liability to equity upon conversion to common stock warrants	(774)
Balance as of December 31, 2015	$ —

The fair value of the derivative liability is measured using the Black-Scholes option-pricing valuation model. Inputs used to determine the estimated fair value of the conversion option include the fair value of the underlying common stock at the valuation measurement date, the remaining contractual term of the conversion option, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock. In addition, the Company estimated the convertible redeemable note exchange rate based on an analysis of its actual exchange of notes for cash redemption or exchange of notes for conversion to common stock. See *Note 9 - Redeemable Convertible Notes* for further detail.

Catalyst Biosciences, Inc.
Notes to Consolidated Financial Statements

The following table presents the activity for the derivative liability for the year ended December 31, 2015 (*in thousands*):

	Derivative Liability
Balance as of December 31, 2014	$ —
Issuance of derivative issued with the redeemable convertible notes	1,455
Change in fair value included in interest and other income	(242)
Gain on extinguishment of redeemable convertible notes	(52)
Conversion of convertible notes to common stock	(5)
Balance as of December 31, 2015	$ 1,156

The estimated reporting date fair value-based measurement of the derivative liability was calculated using the Black-Scholes valuation model, based on the following weighted-average assumptions for the year ended December 31, 2015:

	Year Ended December 31, 2015
Expected term	2.00 years
Expected volatility	81.7%
Risk-free interest rate	1.06%
Expected dividend yield	0%

4. Financial Instruments

Cash equivalents, restricted cash and short-term and long-term investments, all of which are classified as available-for-sale securities, consisted of the following (*in thousands*):

December 31, 2015	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$ 28,927	$ —	$ —	$ 28,927
Restricted cash (money market funds)	33,919	—	—	33,919
Municipal bonds	295	1	—	296
Corporate notes	3,106	1	(1)	3,106
Total financial assets	$ 66,247	$ 2	$ (1)	$ 66,248
Classified as:				
Cash and cash equivalents				$ 28,927
Restricted cash (money market funds)				33,919
Short-term investments				3,402
				$ 66,248

December 31, 2014	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$ 1,496	$ —	$ —	$ 1,496
Restricted cash (money market funds)	50	—	—	50
Total financial assets	$ 1,546	$ —	$ —	$ 1,546
Classified as:				
Cash and cash equivalents				$ 1,496
Restricted cash (money market funds)				50
				$ 1,546

Catalyst Biosciences, Inc.
Notes to Consolidated Financial Statements

As of December 31, 2015, the remaining contractual maturities of available-for-sale securities was less than one year. There have been no significant realized gains or losses on available-for-sale securities for the periods presented.

5. Property and Equipment

Property and equipment consisted of the following (*in thousands*):

	December 31, 2015	December 31, 2014
Laboratory and office equipment	$ 4,458	$ 5,027
Furniture	321	311
Leasehold improvements	1,591	1,515
Computer equipment	21	285
Software	8	422
	6,399	7,560
Less accumulated depreciation and amortization	(5,701)	(6,649)
Property and equipment, net	$ 698	$ 911

Property and equipment depreciation and amortization expense for the years ended December 31, 2015, 2014 and 2013 was $0.5 million, $0.7 million, and $1.0 million, respectively.

6. Commitments and Contingencies

Operating Leases

On February 23, 2015, the Company entered into a new sub-lease, as sub-lessee, for the portion of the space it occupied in its headquarters building. The initial term of the sub-lease was set to expire on August 31, 2015. On June 8, 2015 the Company exercised its right to extend the sub-lease term through February 27, 2018. On March 1, 2015, the Company obtained a letter of credit in the amount of $0.05 million, fully secured by cash held in the Company's bank account, to satisfy the amount of the security deposit. In September 2015, the Company increased a letter of credit to $0.13 million, fully secured by cash held in the Company's bank account, to satisfy the amount of the security deposit.

The Company's rental expense under its operating leases was $0.7 million, $1.0 million and $1.0 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Future minimum lease payments under all non-cancelable operating leases at December 31, 2015, were as follows (*in thousands*):

Year ending December 31,	
2016	$ 723
2017	745
2018	125
Total future minimum lease payments	$ 1,593

Catalyst Biosciences, Inc.
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License Agreement Obligations

Under its technology license agreements to acquire certain technology rights, the Company has an obligation to pay minimum fees and then royalties based upon a percentage of any net sales of licensed products. License fees payable under the technology license agreements are $0.1 million in 2013 and each year thereafter until royalties commence. The technology license agreements also provide for future payments to be made by the Company upon the achievement of development milestones or cumulative sales milestones. Pursuant to the license and collaboration agreement with ISU Abxis (see *Note 13 - Collaborations*), the Company may be obligated to pay ISU Abxis up to $2.0 million in potential milestone payments. At December 31, 2015, no such milestones have been achieved. Under its agreement with Pfizer, which terminated as of June 2015, the Company may be obligated to make milestone and royalty payments to Pfizer. The final terms of this agreement have not been established.

7. Reverse Merger

Old Catalyst completed the Merger with Targacept as discussed in Note 1. Based on the terms of the Merger, Old Catalyst was deemed the acquiring company for accounting purposes, and the transaction has been accounted for as a reverse acquisition under the asset acquisition method of accounting in accordance with U.S. GAAP. Accordingly, the assets and liabilities of Targacept have been recorded as of the Merger closing date at estimated fair value.

Immediately prior to and in connection with the Merger, each share of Old Catalyst preferred stock outstanding was converted into shares of Old Catalyst common stock at ratios determined in accordance with the Old Catalyst certificate of incorporation then in effect. Under the terms of the Merger Agreement, at the effective time of the Merger, the Company issued shares of its common stock to Old Catalyst stockholders, at an exchange rate of 0.0382 shares of common stock, after taking into account the Reverse Stock Split, in exchange for each share of Old Catalyst common stock outstanding immediately prior to the Merger. The exchange rate was calculated by a formula that was determined through arms-length negotiations between Targacept and Old Catalyst. The Company assumed all of the outstanding options, whether or not vested, under the Catalyst 2004 Stock Plan, as amended (the “Catalyst Plan”), all of the standalone options of Old Catalyst that were not issued under the Catalyst Plan, and the warrants of Old Catalyst, whether or not vested, outstanding immediately prior to the Merger, with such options and warrants henceforth representing the right to purchase a number of shares of the Company’s common stock equal to 0.0382 multiplied by the number of shares of Old Catalyst common stock previously represented by such options and warrants. For accounting purposes, the Company is also deemed to have assumed the Targacept 2015 Stock Incentive Plan, the Targacept 2006 Stock Incentive Plan and the Targacept 2000 Equity Incentive Plan, as well as a standalone inducement stock option to Targacept’s former chief executive officer upon commencement of his employment with Targacept in December 2012 (together, the “Targacept Plans and Options”).

Immediately after the Merger, there were 11,416,984 shares of the Company’s common stock outstanding and, Old Catalyst equity holders beneficially owned approximately 59% of the common stock of the Company. In connection with the reverse merger, we incurred $2.0 million for related transaction costs, included in general and administrative expenses in the accompanying statements of operations.

Catalyst Biosciences, Inc.
Notes to Consolidated Financial Statements

Purchase Consideration

The purchase price for Targacept on August 20, 2015, the closing date of the Merger, was as follows (*in thousands*):

Estimated fair value of shares issued	$ 34,664
Estimated fair value of awards assumed	1,955
Estimated fair value of redeemable convertible notes	37,073
Estimated total purchase price of net assets acquired, including assumed debt	$ 73,692

Allocation of Purchase Consideration

Under the acquisition method of accounting, the total purchase price was allocated to tangible and identifiable intangible assets acquired and liabilities assumed of Targacept on the basis of their estimated fair values as of the transaction closing date on August 20, 2015.

The following table summarizes the allocation of the purchase consideration to the assets acquired and liabilities assumed based on their fair values as of August 20, 2015 (*in thousands*):

Cash, cash equivalents and short-term investments	$ 41,154
Restricted cash	37,000
Accounts receivable	318
Prepaid and other current assets	183
Accounts payable and accrued liabilities	(4,963)
Estimated total purchase price of net assets acquired, including assumed debt	$ 73,692

The Company believes that the historical values of Targacept's current assets and current liabilities approximate their fair values based on the short-term nature of such items.

8. Convertible Notes – Related Parties

In May and June 2015, Old Catalyst issued and sold convertible promissory notes in a series of closings in the aggregate principal amount of $1.9 million to existing stockholders, together with warrants to purchase shares of either the Old Catalyst's Series E preferred stock or the capital stock issued during the next financing. The convertible promissory notes accrued interest at a rate of 12% per annum and were to mature one year from the date of issuance.

In connection with the debt financing, Old Catalyst also issued and sold to each investor purchasing a convertible promissory note a warrant to purchase equity securities of the same type that the principal amount of the convertible promissory note issued to such investor converts into. The warrants were exercisable for up to a number of shares equal to the quotient of: (a) 25% multiplied by the principal amount of the convertible promissory note issued to such investor divided by (b) the stock purchase price equal to: (i) in the case the notes convert in connection with a financing the price per share of the securities paid by investors in such financing or (ii) in the case that the warrant shares are Series E Preferred Stock, $1.2706 per share. The purchase price for each warrant was equal to 0.1% of the principal amount of the corresponding convertible promissory note. The exercise price for the warrant shares is equal to the stock purchase price.

Catalyst Biosciences, Inc.
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The Company recorded the aggregate fair value of the warrants of $0.5 million as a debt discount and convertible preferred stock warrant liability upon issuance of the convertible notes. The debt discount was being accreted as additional interest expense over the term of the convertible promissory notes. The Company estimated the fair value of the warrants using the Black-Scholes option-pricing valuation model with the following assumptions: expected term of five years, risk-free interest rate of 0.11% and 0.18%, expected volatility of 80.0% and a dividend yield of 0%.

For the year ended December 31, 2015, the Company recognized interest expense of $0.1 million related to the accrued interest and amortization of the debt discount within interest expense on the Company's consolidated statement of operations.

In conjunction with the second closing of the Series F convertible preferred stock financing discussed in *Note 10 - Convertible Preferred Stock and Warrants*, Old Catalyst and the majority holders of the notes amended the notes such that the closing constituted a qualified financing and, accordingly, the total outstanding principal amount of the Notes of $1.9 million and all unpaid accrued interest of $0.03 million, were converted into 1,511,723 shares of Series F convertible preferred stock and warrants for the purchase of 372,045 shares of Series F convertible preferred stock were issued to the Notes holders in connection with the conversion of the Notes to Series F convertible preferred stock. All preferred stock and warrants were converted to common stock and warrants to purchase common stock upon the closing of the Merger.

As the recipients of the convertible promissory notes each have an equity ownership in the Company, the convertible promissory notes are considered to be a related-party transaction.

9. Redeemable Convertible Notes

On August 19, 2015, immediately prior to the merger, the Company issued to Targacept stockholders non-interest bearing redeemable convertible notes (the "Notes") in the aggregate principal amount of $37.0 million, which is approximately $1.08 per share of the Company's common stock as of the record date, or $7.56 per share after giving effect to the Reverse Stock Split (the "Pre-Closing Dividend"). The Notes do not bear interest. The principal amount of the Notes are convertible, at the option of each noteholder, into cash or into shares of the Company's common stock at a conversion rate of $9.19 per share (after taking into account the Reverse Stock Split), and are payable in cash, if not previously redeemed or converted, at maturity on February 19, 2018, the 30-month anniversary of the closing of the issuance of the Notes.

In connection with the Pre-Closing Dividend, on August 19, 2015, Targacept entered into an indenture (the "Indenture") with American Stock Transfer & Trust Company, LLC, as trustee, and an escrow agreement with American Stock Transfer & Trust Company, LLC and Delaware Trust Company, LLC, as escrow agent, under which $37.0 million, which represented the initial principal amount of the convertible notes, was deposited in a segregated escrow account for the benefit of the holders of the notes in order to facilitate the payment of the notes upon redemption or at maturity (the amount of such deposit together with interest accrued and capitalized thereon, the "Escrow Funds"). The Notes are the Company's secured obligation, and the Indenture does not limit its other indebtedness, secured or unsecured.

Holders of the Notes may submit conversion notices, which are irrevocable, instructing the trustee to convert such the Notes into shares of the common stock at a conversion price of $9.19 per share. Following each conversion date, the Company will issue the number of whole shares of common stock issuable upon conversion as promptly as practicable (and in any event within 10 business days). The trustee will in turn release to the Company the respective amount of restricted cash to cover the stock issuance.

The conversion to common stock feature of the Notes was determined to be a derivative liability requiring bifurcation and separate accounting. The fair value of such conversion feature at issuance was determined to be $1.5 million. The Company estimated the fair value of the conversion option using the Black-Scholes

option-pricing valuation model with the following assumptions: expected term of 2.25 years, risk-free interest rate of 0.84%, expected volatility of 70.0%, anticipated future exchange rate of the Notes and a dividend yield of 0%.

The bifurcation of the derivative liability from the estimated fair value of the Notes of $37.1 million at issuance resulted in a debt discount of $1.4 million. The Company elected to accrete the entire debt discount as interest expense immediately subsequent to the merger. In addition, changes in the fair value of the derivative liability will be recorded within interest and other income in the consolidated statement of operations. The Company will remeasure the derivative liability to fair value until the earlier of the conversion, redemption or maturity of the redeemable convertible notes.

For the year ended December 31, 2015, the Company recognized interest expense of $1.4 million related to the amortization of the debt discount within interest expense on the Company's consolidated statement of operations as the redeemable convertible notes are immediately fully redeemable at the option of the holders.

As of December 31, 2015, $3.0 million of the Notes were redeemed and $0.3 million of the Notes were converted into common stock. The Company recognized $0.1 million of gain on the extinguishment of Notes upon the redemption of the Notes during the year ended December 31, 2015.

10. Convertible Preferred Stock and Warrants

In January 2015, Old Catalyst completed a Series F convertible preferred stock offering that generated cash proceeds of $3.3 million, net of $0.1 million of issuance costs. In the offering, Old Catalyst issued 2,623,650 shares of Series F convertible preferred stock at a price of $1.2706 per share. The Series F convertible preferred stock had a conversion rate of 1:10 such that each individual share of Series F convertible preferred stock was convertible into ten shares of common stock. In July 2015, Old Catalyst completed a second closing of a Series F convertible preferred stock financing and issued 3,164,872 shares for cash proceeds of $4.0 million, net of $0.02 million of issuance costs.

The following table sets forth the total preferred shares authorized, issued and outstanding, the liquidation value, and the carrying value per Series at December 31, 2014:

	Shares Authorized	Shares Issued and Outstanding	Liquidation Preference Per Share
Series AA	7,327,166	7,327,166	$ 1.0000
Series BB	23,104,618	23,104,618	$ 1.2706
Series BB-1	5,978,477	5,978,477	$ 1.5054
Series CC	46,429,980	46,429,980	$ 1.2706
Series D	629,630	629,630	$ 6.3530
Series E	5,000,000	3,935,140	$ 2.5412
	88,469,871	87,405,011	

As discussed in *Note 7 - Reverse Merger*, all outstanding shares of Old Catalyst's convertible preferred stock and warrants to purchase convertible preferred stock were converted into shares of the Company's common stock and warrants to purchase common stock upon completion of the merger.

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Notes to Consolidated Financial Statements

The rights, privileges, and preferences of the convertible preferred stock were as follows:

Voting

Each share of convertible preferred stock was entitled to voting rights equivalent to the number of shares of common stock into which each share would have been converted. Each share of common stock was entitled to one vote.

Conversion

Each share of convertible preferred stock was convertible at the holder's option at any time into common stock, subject to adjustment for anti-dilution. The conversion price for Series AA convertible preferred stock was $1.00 per share, for Series BB convertible preferred stock was $1.2706 per share, for Series BB-1 convertible preferred stock was $1.3843 per share, and for Series CC, Series D and Series E convertible preferred stock was $1.2706 per share. Conversion would have been automatic upon the closing of an underwritten public offering with an offering price of at least $3.8118 per share and aggregate gross proceeds of at least $40 million, or upon the written consent of holders of at least 66.67% of the then-outstanding convertible preferred stock.

Warrants

Old Catalyst previously issued (i) warrants to purchase shares of Series A convertible preferred stock in 2005 in connection with a loan, (ii) warrants to purchase shares of Series E convertible preferred stock in 2014 in connection with the issuance of Series E convertible preferred stock, and (iii) warrants to purchase shares of Series F convertible preferred stock in 2015 in connection with the issuance of convertible promissory notes. In connection with the merger, such warrants were assumed by the Company and are now exercisable, respectively, (i) at any time until the 7-year anniversary of the merger for an aggregate of 1,289 shares of the Company's common stock at an exercise price of $26.18 per share, (ii) at any time until the 5-year anniversary of the original date of issuance for an aggregate of 37,554 shares of the Company's common stock at an exercise price of $33.27 per share, and (iii) at any time until the 5-year anniversary of the original date of issuance for an aggregate of 142,111 shares of the Company's common stock at an exercise price of $3.33 per share, for a combined total of 180,954 shares of common stock issuable upon the exercise of warrants outstanding with a combined weighted average exercise price of $9.70 per share.

11. Stock Based Compensation

As discussed in Note *7 - Reverse Merger*, the Company assumed all of the outstanding options, whether or not vested, under the Catalyst Plan, all of the standalone options of Old Catalyst that were not issued under the Catalyst Plan, whether or not vested, outstanding immediately prior to the Merger, with such options henceforth representing the right to purchase that number of shares of the Company's common stock equal to 0.0382 multiplied by the number of shares of Old Catalyst common stock previously represented by such options. For accounting purposes, however, the Company is instead deemed to have assumed all of the Targacept Plans and Options (outstanding immediately prior to the Merger (together with the Catalyst Plan and the standalone Catalyst options, the "Plans"). No additional grants were made from the Plans on or after the Merger Effective Date.

Immediately prior to the Merger Effective Date:

- The Catalyst Plan expired effective January 2014, with options for 230,997 shares remaining outstanding. Such options were assumed in the Merger pursuant to the Merger Agreement.

Catalyst Biosciences, Inc.
Notes to Consolidated Financial Statements

- 35,545 standalone options of Old Catalyst were outstanding. Such options were assumed in the Merger pursuant to the Merger Agreement.
- The Targacept 2006 Plan (the "2006 Plan") had 1,420,823 options outstanding and 591,757 shares available for issuance. The outstanding options under the 2006 Plan were assumed in the Merger for accounting purposes, and the shares available for issuance were contributed to the Targacept 2015 Stock Incentive Plan (the "Targacept 2015 Plan").

The 2015 Plan

As of August 18, 2015, Targacept shareholders approved the Targacept 2015 Plan. The Targacept 2015 Plan had no shares authorized for issuance as of the approval date. Upon the Merger, the Targacept 2015 Plan was assumed by the Company for accounting purposes and 591,757 unused and available shares remaining in the Targacept 2006 Plan were contributed to the Targacept 2015 Plan. In addition, following the Merger, any option shares canceled or expired in the Plans (as defined above) are automatically, and without action by the company, contributed to the Targacept 2015 Plan and become available for issuance under the Targacept 2015 Plan.

The Targacept 2015 Plan was amended and restated on October 14, 2015, to reflect, among other things, rename it as the Catalyst Biosciences, Inc. 2015 Stock Incentive Plan (As Amended and Restated Effective October 14, 2015) and to reflect the Company's seven-for-one reverse stock split, and the plan was further amended on December 14, 2015 to increase certain award limitations provided therein (as so amended, the "2015 Plan" referred to in this 10-K).

As of December 31, 2015, 103,129 shares of common stock were available for future grant and options to purchase shares of common stock were outstanding under the 2015 Stock Plan, as amended.

Catalyst Biosciences, Inc.
Notes to Consolidated Financial Statements

The following table summarizes stock option activity under the plans including stock options granted to non-employees, and related information:

	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (thousands)
Outstanding — December 31, 2012	193,177	$ 8.12	6.29	6.29
Options granted	57,313	$		
Options exercised	—	$ 11.52		
Options forfeited	(4,641)	$ 9.45		
Outstanding — December 31, 2013	245,849	$ 8.88	6.18	
Options granted	12,415	$ 7.59		
Options exercised	(5,730)	$ 4.36		
Options forfeited	(2,279)	$ 3.82		
Outstanding — December 31, 2014	250,255	$ 8.96	5.51	
Options assumed in merger(1)	1,420,823	$ 15.16	4.01	
Options granted	675,585	$ 2.98	9.81	
Options exercised	(3,820)	$ 3.38		
Options forfeited	(36,547)	$ 8.48		
Options canceled	(106,787)	$ 47.20		
Outstanding — December 31, 2015	2,199,509	$ 9.84	4.51	$ 11.06
Exercisable — December 31, 2015	1,560,477	$ 11.99	2.37	$ 8.08
Vested and expected to vest — December 31, 2015	2,139,323	$ 9.99	4.37	
Shares Available to be granted — December 31, 2015	103,129			

(1) In connection with the merger, the Company assumed stock options covering an aggregate of 1,420,823 shares of common stock. The company also assumed 2,856 shares of Restricted Stock Awards which vest in two equal annual installments beginning on December 31, 2015 and fully vesting on December 31, 2016. Total stock based compensation related to these restricted stock awards was $6,052 for year ended December 31, 2015.

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Notes to Consolidated Financial Statements

Total stock-based compensation recognized was as follows (*in thousands*):

	Year Ended December 31,		
	2015	2014	2013
Research and development	$ 95	$ 81	$ 127
General and administrative	231	163	171
Total stock-based compensation	$ 326	$ 244	$ 298

The estimated grant-date fair value-based measurements of the employee stock options were calculated using the Black-Scholes valuation model, based on the following weighted-average assumptions in the years ended December 31, 2015, 2014 and 2013:

	Year Ended December 31,		
	2015	2014	2013
Expected term	5.56 years	5.14 years	5.98 years
Expected volatility	68.64%	64.62%	78.15%
Risk-free interest rate	1.34%	1.61%	1.06%
Expected dividend yield	0%	0%	0%

Expected Term. Under the Company's stock option plans, the expected term of options granted is determined using the simplified method which calculates expected term as the midpoint between the vesting date and the expiration date for each award.

Expected Volatility. Since the Company was a private entity prior to the merger in August 2015 with no historical data regarding the volatility of its common stock, the expected volatility used is based on the volatility of similar publicly traded entities, referred to as "guideline" companies.

Risk-Free Interest Rate. The risk-free rate is based on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term of the options.

Expected Dividend Yield. The Company has never declared or paid any cash dividends and does not plan to pay cash dividends in the foreseeable future, and, therefore, assumed an expected dividend yield of zero.

As of December 31, 2015, the Company had unrecognized employee stock-based compensation expense of $1.6 million, related to unvested stock awards, which is expected to be recognized over an estimated weighted-average period of 3.39 years.

Options Granted to Nonemployees

During the years ended December 31, 2015, 2014 and 2013, options to purchase 19,760, 12,415 and 5,717 shares, respectively, of common stock were issued to consultants that vest over one to four years with a weighted-average exercise price of $6.52, $7.60 and $11.51 per share, respectively. During the years ended December 31, 2015, 2014 and 2013, the Company recorded stock-based compensation expense attributable to these nonemployee stock awards of $0.04 million, $0.1 million and $0.1 million, respectively.

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The estimated grant-date fair values of the nonemployee stock options were determined using the Black-Scholes valuation model and the following assumptions:

	Year Ended December 31,		
	2015	2014	2013
Risk-free interest rate	1.30%	1.61%	1.06%
Expected volatility	69.98%	64.62%	78.00%
Expected dividend yield	0%	0%	0%
Weighted-average contractual term	5.64 years	5.14 years	5.98 years

12. Income Taxes

The Company has incurred cumulative net operating losses since inception and, consequently, has not recorded any income tax expense for the years ended December 31, 2015, 2014 and 2013 due to its net operating loss position.

The reconciliation of the federal statutory income tax rate to the Company's effective tax rate for the years ended December 31, 2015, and 2014 are as follows:

	Year Ended December 31,	
	2015	2014
Tax at statutory federal rate	34.00%	34.00%
State Tax (benefit)—net of federal benefit	1.33%	-3.24%
Permanent differences	-8.00%	1.83%
R&D Credits	11.59%	1.97%
Derecognition due to Sec. 382 and 383 Limitations	-240.87%	0.00%
Change in Valuation Allowance	204.17%	-34.25%
Other	-2.22%	-0.31%
Effective tax rate	0.00%	0.00%

Significant components of the Company's deferred tax assets as of December 31, 2015 and 2014 consist of the following (*in thousands*):

	Year Ended December 31,	
	2015	2014
Deferred tax assets:		
Accruals and reserves	$ 1,285	$ 1,382
Net Operating Loss Carry forward	17,650	44,083
R&D Tax Credit Carry forward	2,625	6,467
Fixed and intangible assets	95	43
Valuation Allowance	(21,655)	(51,975)
Net deferred tax assets:	$ —	$ —

Based on the available objective evidence at December 31, 2015, the Company does not believe it is more likely than not that the net deferred tax assets will be fully realizable. Accordingly, the Company has provided a full valuation allowance against its net deferred tax assets at December 31, 2015 and 2014.

As of December 31, 2015, after consideration of certain limitations (see below), the Company had approximately $44.8 million federal and $41.6 million state net operating loss carry forwards ("NOL")

available to reduce future taxable income which, if unused, will begin to expire in 2025 for federal and 2016 for state tax purposes. Of the above NOL amounts, $0.02 million for federal and state purposes relate to windfall stock based compensation deductions which, when utilized, will be credited to equity.

As of December 31, 2015, the Company also had tax credit carry forwards available to offset future tax liabilities of approximately $5.2 million for state purposes. The state tax credit does not expire.

If the Company experiences a greater than 50 percentage point aggregate change in ownership over a three-year period (a Section 382 ownership change), utilization of its pre-change NOL carry forwards are subject to annual limitation under Section 382 of the Internal Revenue Code (California has similar provisions). The annual limitation is determined by multiplying the value of the Company's stock at the time of such ownership change by the applicable long-term tax-exempt rate. Such limitations may result in expiration of a portion of the NOL carry forwards before utilization. The Company has determined that ownership changes occurred on December 31, 2007 and August 20, 2015. Approximately $78.5 million and $61.9 million of the NOLs will expire unutilized for federal and California purposes, respectively. The Company has derecognized NOL related DTAs in the tax affected amounts of $26.7 million and $3.3 million for federal and California purposes, respectively.

All of the federal R&D credits could expire unutilized as well, whereas none of the California R&D credits are subject to expiration. Approximately $5.6 million of gross federal R&D credit-related DTAs were derecognized due to the Section 383 limitation. The ability of the Company to use its remaining NOL carry forwards may be further limited if the Company experiences a Section 382 ownership change as a result of future changes in its stock ownership.

Accounting for Uncertainty in Income Taxes

The Company only recognizes tax benefits if it is more likely than not that they will be sustained upon audit by the relevant tax authority based upon their technical merits. An uncertain tax position will not be recognized if it has less than a 50% likelihood of being sustained.

The Company had approximately $1.3 million and $2.6 million of unrecognized tax benefits as of both December 31, 2015 and 2014. As the Company has a full valuation allowance on its deferred tax assets, the unrecognized tax benefits have reduced the deferred tax assets and the valuation allowance in the same amount. The Company does not expect the amount of unrecognized tax benefits to materially change in the next twelve months. A reconciliation of the beginning and ending balance of the unrecognized tax benefits is as follows (*in thousands*):

Beginning Balance at January 1, 2014	**$ 2,517**
Increase/(Decrease) of unrecognized tax benefits taken in prior years	—
Increase/(Decrease) of unrecognized tax benefits related to current year	53
Ending Balance at December 31, 2014	**$ 2,570**
Beginning Balance at January 1, 2015	**$ 2,570**
Increase/(Decrease) of unrecognized tax benefits taken in prior years	(1,347)
Increase/(Decrease) of unrecognized tax benefits related to current year	91
Ending Balance at December 31, 2015	**$ 1,314**

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The Company files income tax returns in the United States and California. The Company is not currently under examination by income tax authorities in federal, state or other jurisdictions. As of December 31, 2015 and 2014, the Company had no uncertain tax positions which affected its financial position and its results of operations or its cash flow, and will continue to evaluate for uncertain positions in the future. The open tax years for the Company are December 31, 2012 through December 31, 2015 and are subject to examination by the IRS and other various taxing authorities, generally for three years after tax returns are filed.

13. Collaborations

Pfizer

On August 20, 2013 the Company and Pfizer entered into an amendment to the Factor VIIa collaboration agreement whereby the companies agreed to provide specific mutual releases and covenants and modify certain milestone payment schedules in the agreement. Per the amendment, Pfizer agreed to make two non-refundable $1.5 million annual license maintenance payments to the Company, payable on August 1, 2014 and August 1, 2013. The annual license maintenance payments received were being amortized to contract revenue over the estimated expected performance period under the arrangement, which the Company estimated was to the end August 1, 2015.

On April 2, 2015, Pfizer notified the Company that it was exercising its right to terminate in its entirety the collaboration agreement. The termination became effective 60 days after the Company's receipt of the termination notice. On June 1, 2015, the license and certain rights under the research and license agreement terminated and reverted back to the Company. Pfizer is in the process of transferring clinical trial data, regulatory documentation and related technology under the research and license agreement to the Company. The Company plans to continue clinical development of this product candidate. The Company revised the expected period of performance to end on June 1, 2015, which was the effective termination of all performance obligations of the Company under the research and license agreement. Accordingly, all deferred revenue was recognized through June 1, 2015.

Contract revenue related to the agreement with Pfizer was $1.3 million, $1.4 million and $0.3 million during the years ended December 31, 2015, 2014 and 2013, respectively. The deferred revenue balance related to the Pfizer collaboration was zero and $1.3 million as of December 31, 2015 and 2014, respectively.

ISU Abxis

On June 16, 2013, the Company entered into a license and collaboration agreement with ISU Abxis, whereby the Company licensed its proprietary human Factor IX products to ISU Abxis for initial development in South Korea. Under the terms of the agreement, ISU Abxis is responsible for development and manufacturing of the licensed products through Phase 1/2 clinical trials. Until the completion of Phase 1/2 development, ISU Abxis also has a right of first refusal with respect to commercialization rights for the licensed products in South Korea. The Company has the sole rights and responsibility for worldwide development, manufacture and commercialization of Factor IX products after Phase 1/2 development, unless ISU Abxis has exercised its right of first refusal regarding commercialization rights in South Korea, in which case the Company's rights are in the entire world excluding South Korea. ISU's rights will also terminate in the event that the Company enters into a license agreement with another party to develop, manufacture and commercialize Factor IX products in at least two major market territories.

ISU Abxis paid the Company an up-front signing fee of $1.75 million and is obligated to pay to the Company contingent milestone-based payments on the occurrence of certain defined development events, and reimbursement for a portion of the Company's costs relating to intellectual property filings and

maintenance thereof on products. The Company is obligated to pay ISU Abxis a percentage of all net profits it receives from collaboration products.

Contract revenue of $0.4 million, $0.4 million and $0.1 million for the years ended December 31, 2015, 2014 and 2013, respectively, reflected the amortization of the up-front fee over the estimated period of the Company's performance obligations under the agreement, which was assessed to be four years beginning in September 2013 when the agreement was executed. The deferred revenue balance related to the ISU Abxis collaboration was $0.7 million and $1.2 million as of December 31, 2015 and 2014, respectively.

14. Net Loss per Common Share

The following table sets forth the computation of the basic and diluted net loss per common share during the years ended December 31, 2015, 2014 and 2013 (*in thousands, except share and per share data*):

	Year Ended December 31,		
	2015	2014	2013
Net loss	$ (14,762)	$ (6,613)	$ (9,966)
Weighted-average number of shares used in computing net loss per share, basic and diluted	4,429,093	367,586	365,214
Net loss per share, basic and diluted	$ (3.33)	$ (17.99)	$ (27.29)

Since the Company was in a loss position for all periods presented, diluted net loss per share is the same as basic net loss per share for all periods as the inclusion of all potential common shares outstanding would have been anti-dilutive. Potentially dilutive securities on an as-if converted basis that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	Year Ended December 31,		
	2015	2014	2013
Convertible preferred stock	—	3,338,871	3,188,549
Options to purchase common stock	2,200,890	250,255	257,889
Convertible preferred stock warrants	—	37,580	—
Common stock warrants	180,954	1,289	1,862
Redeemable convertible notes	3,671,745	—	—
Total	6,053,589	3,627,995	3,448,300

15. Selected Quarterly Financial Data (unaudited)

Selected quarterly results from operations for the years ended December 31, 2015 and 2014 are as follows (in thousands, except per share amounts):

	2015 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Contract Revenue	$ 672	$ 860	$ 109	$ 109
Total operating expenses	3,704	3,060	3,994	4,794
Loss from operations	(3,033)	(2,201)	(3,885)	(4,683)
Net loss	(2,858)	(1,724)	(5,051)	(5,129)
Net loss per share– basic and diluted	$ (7.67)	$ (4.60)	$ (0.93)	$ (0.45)

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	2014 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Contract Revenue	$ 297	$ 297	$ 547	$ 672
Total operating expenses	2,160	2,507	2,185	2,470
Loss from operations	(1,863)	(2,210)	(1,638)	(1,798)
Net loss	(1,734)	(2,075)	(1,502)	(1,302)
Net loss per share– basic and diluted	$ (4.75)	$ (5.68)	$ (4.08)	$ (3.51)

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2015. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2015, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

Other than as discussed below, there have not been any changes in our internal controls over financial reporting (as such item is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during our fiscal year ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report on internal control over financial reporting of our registered public accounting firm. Prior to the completion of the merger in August 2015, Old Catalyst had been a private company with limited accounting personnel to adequately execute the accounting processes and other supervisory resources with which to address Old Catalyst’s internal control over financial reporting. Following the merger, the Company did not acquire the accounting systems or accounting personnel of Targacept and due to the business combination being a reverse merger, the internal control over financial

reporting is directed by former Old Catalyst employees or new hires and not former Targacept employees. As a consequence of the reverse merger and subsequent transition, an attestation on the legal acquirers, (Targacept's) controls would not be meaningful and the accounting acquirer, (Old Catalyst's) controls had not been in existence long enough to perform adequate testing. Due to the extensive changes to our internal control environment, and the timing of the merger, the auditor attestation component of SOX 404 will be completed as of December 31, 2016 should the Company still be an accelerated filer.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information required by this item will be contained in our definitive proxy statement to be filed with the Securities and Exchange Commission on Schedule 14A in connection with our 2016 Annual Meeting of Stockholders (the "Proxy Statement"), which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2015, under the headings "Executive Officers," "Election of Directors," "Corporate Governance," and " Section 16(a) Beneficial Ownership Reporting Compliance," and is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics that applies to our officers, directors and employees which is available on our website at www.catalystbiosciences.com. The Code of Business Conduct and Ethics is intended to qualify as a "code of ethics" within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, we intend to promptly disclose (1) the nature of any amendment to our Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

Item 11. Executive Compensation

Information required by this item will be contained in the Proxy Statement under the headings "Executive Compensation" and "Director Compensation," and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Information required by this item will be contained in the Proxy Statement under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information," and is incorporated herein by reference.

Item 13. Certain Relationships, Related Transactions and Director Independence

Information required by this item will be contained in the Proxy Statement under the headings "Certain Relationships and Related Party Transactions" and "Corporate Governance," and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

Information required by this item will be contained in the Proxy Statement under the heading "Principal Accountant Fees and Services," and is incorporated herein by reference.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a) The following documents are filed as part of this report:

1. Consolidated Financial Statements

   See Index to Consolidated Financial Statements at Item 8 herein.

2. Consolidated Financial Statement Schedules

   All schedules are omitted because they are not applicable or the required information is shown under Item 8. “Financial Statements and Supplementary Data.”

3. Exhibits

   The list of exhibits filed as part of this report is set forth on the Exhibit Index immediately following the signature page of this report and is incorporated by reference in this Item 15(a)(3).

(b) Exhibits

See Exhibit List.

(c) Separate Financial Statements and Schedules.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CATALYST BIOSCIENCES, INC.

By: /s/ Nassim Usman, Ph.D.
Nassim Usman, Ph.D.
President and Chief Executive Officer

Date: March 9, 2016

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Nassim Usman and Fletcher Payne, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this annual report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Nassim Usman, Ph.D. **Nassim Usman, Ph.D.**	President and Chief Executive Officer (*Principal Executive Officer*)	March 9, 2016
/s/ Fletcher Payne **Fletcher Payne**	Chief Financial Officer (*Principal Financial and Accounting Officer*)	March 9, 2016
/s/ Harold E. Selick, Ph.D. **Harold E. Selick, Ph.D.**	Chairman of the Board of Directors	March 9, 2016
/s/ Errol B. De Souza, Ph.D. **Errol B. De Souza, Ph.D.**	Director	March 9, 2016
/s/ Jeff Himawan, Ph.D. **Jeff Himawan, Ph.D.**	Director	March 9, 2016
/s/ Augustine Lawlor **Augustine Lawlor**	Director	March 9, 2016

Signature	Title	Date
/s/ John P. Richard **John P. Richard**	Director	March 9, 2016
/s/ Stephen M. Hill, M.D. **Stephen M. Hill, M.D.**	Director	March 9, 2016

EXHIBIT INDEX

Exhibit Number	Description
2.1(a)	Agreement and Plan of Merger dated as of March 5, 2015, by and among Targacept, Catalyst Biosciences, Inc. and Talos Merger Sub, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, as filed with the SEC on March 6, 2015)
2.1(b)	Amendment No. 1 to Agreement and Plan of Merger by and among Targacept, Talos Merger Sub, Inc., and Catalyst dated May 6, 2015 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on May 12, 2015)
2.1(c)	Amendment No. 2 to Agreement and Plan of Merger by and among Targacept, Talos Merger Sub, Inc., and Catalyst dated May 13, 2015 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on May 14, 2015)
3.1	Fourth Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 4.1 to the Company's Form S-8 (Reg. No. 333-133881), as filed with the SEC on May 8, 2006)
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on August 20, 2015)
3.3	Bylaws of the Company, as amended (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on March 6, 2015)
4.1	Form of Indenture by and between Targacept, Inc. and American Stock Transfer and Trust Company, LLC (incorporated by reference to Annex G to the Company's Form S-4 (Reg. No. 333-204423), filed with the SEC on May 22, 2015)
4.2	Form of Global Security (incorporated by reference to Annex G, Exhibit A to the Company's Form S-4 (Reg. No. 333-204423), filed with the SEC on May 22, 2015)
4.3	Warrant to Purchase Stock of Catalyst Biosciences, Inc., issued to Silicon Valley Bank on March 3, 2005
4.4	Form of Warrant to Purchase Stock of Catalyst Biosciences, Inc., issued to purchasers of Series E Preferred Stock
4.5	Form of Warrant to Purchase Stock of Catalyst Biosciences, Inc., issued to purchasers of convertible promissory notes
10.1*	Catalyst Biosciences, Inc. 2015 Stock Incentive Plan (As Amended and Restated Effective October 14, 2015) (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2015)
10.2	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.1 to Amendment No. 3 to the Company's Form S-1 (Reg. No. 333-131050), filed with the SEC on March 16, 2006)
10.3*	Offer Letter, executed February 21, 2006, by and between Catalyst and Dr. Nassim Usman (incorporated by reference to Exhibit 10.35 to the Company's Form S-4 (Reg. No. 333-204423), filed with the SEC on May 22, 2015)
10.4*	Offer Letter, executed December 1, 2003, by and between Catalyst and Dr. Edwin Madison (incorporated by reference to Exhibit 10.36 to the Company's Form S-4 (Reg. No. 333-204423), filed with the SEC on May 22, 2015

10.5(a)*	Letter Agreement, dated February 15, 2007, by and between Catalyst and Dr. Edwin Madison (incorporated by reference to Exhibit 10.37(a) to the Company's Form S-4 (Reg. No. 333-204423), filed with the SEC on May 22, 2015)
10.5(b)*	Amendment to Letter Agreement, dated September 24, 2008, by and between Catalyst and Dr. Edwin Madison (incorporated by reference to Exhibit 10.37(b) to the Company's Form S-4 (Reg. No. 333-204423), filed with the SEC on May 22, 2015)
10.5(c)*	Amendment Letter Agreement, dated February 12, 2013 by and between Catalyst and Dr. Edwin Madison (incorporated by reference to Exhibit 10.37(c) to the Company's Form S-4 (Reg. No. 333-204423), filed with the SEC on May 22, 2015)
10.6*	Offer Letter, dated March 30, 2015, by and between Catalyst and Fletcher Payne (incorporated by reference to Exhibit 10.39 to the Company's Form S-4 (Reg. No. 333-204423), filed with the SEC on May 22, 2015)
10.7(a)*	Employment Agreement, effective as of November 14, 2012, by and between the Company and Stephen A. Hill (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on November 16, 2012)
10.7(b)*	Amendment No. 1 to Employment Agreement, dated January 24, 2014, by and between the Company and Stephen A. Hill (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on January 28, 2014)
10.8*	Nonqualified Stock Option Agreement, dated December 3, 2012, by and between the Company and Stephen A. Hill (incorporated by reference to Exhibit 99.1 to the Company's Registration Statement on Form S-8, as filed with the SEC on January 4, 2013 (Registration No. 333-185888))
10.9*	Employment Agreement, effective as of June 28, 2013, by and between the Company and Mauri K. Hodges (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on December 16, 2014)
10.10	Form of Targacept Voting Agreement dated as of March 5, 2015, entered into by and among Targacept, Catalyst and certain stockholders of Targacept (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on March 6, 2015)
10.11	Form of Catalyst Voting Agreement dated as of March 5, 2015, entered into by and among Catalyst, Targacept and certain stockholders of Catalyst (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on March 6, 2015)
10.12	Form of Lock-Up Agreement dated as of March 5, 2015, entered into by and among Catalyst, Targacept and certain stockholders of Catalyst (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, as filed with the SEC on March 6, 2015)
10.13	Form of Targacept Voting Agreement dated as of May 13, 2015 entered into by and among Targacept, Catalyst and certain stockholders of Targacept, as amended (incorporated by reference to Exhibit 10.2 to the Targacept's Current Report on Form 8-K, as filed with the SEC on May 14, 2015)
10.14	Form of Catalyst Voting Agreement dated as of May 13, 2015 entered into by and among Catalyst, Targacept and certain stockholders of Catalyst, as amended (incorporated by reference to Exhibit 10.3 to the Targacept's Current Report on Form 8-K, as filed with the SEC on May 14, 2015)
10.15	Escrow Agreement, dated August 19, 2015, by and between Targacept, Inc., American Stock Transfer and Trust Company, LLC, and Delaware Trust Company (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K/A, as filed with the SEC on September 4, 2015, as amended by Amendment No. 2 filed with the SEC on October 23, 2015)
10.16	Sublease Agreement, dated February 23, 2015, by and between Catalyst Biosciences, Inc. and Reset Therapeutics, Inc. (incorporated by reference to Exhibit 10.29 to the Company's Form S-4 (Reg. No. 333-204423), filed with the SEC on May 22, 2015)

10.17(a)+	License and Collaboration Agreement, dated September 16, 2013, by and between Catalyst and ISU Abxis (incorporated by reference to Exhibit 10.30(a) to the Company's Form S-4 (Reg. No. 333-204423), filed with the SEC on May 22, 2015)
10.17(b)+	Amendment No. 1 to License and Collaboration Agreement, dated October 31, 2014, by and between Catalyst and ISU Abxis (incorporated by reference to Exhibit 10.30(b) to the Company's Form S-4 (Reg. No. 333-204423), filed with the SEC on May 22, 2015)
10.18(a)*	Catalyst's 2004 Stock Plan (incorporated by reference to Exhibit 10.31(a) to the Company's Form S-4 (Reg. No. 333-204423), filed with the SEC on May 22, 2015)
10.19(b)*	Form of Stock Option Agreement—Early Exercise under Catalyst's 2004 Stock Plan (incorporated by reference to Exhibit 10.31(b)).
10.20*	Consulting Agreement, dated January 14, 2015, by and between the Catalyst and Fletcher Payne (incorporated by reference to Exhibit 10.38 to the Company's Form S-4 (Reg. No. 333-204423), filed with the SEC on May 22, 2015)
10.21(a)*	Stock Option Agreement—Early Exercise, No. 427, dated January 22, 2015, by and between Catalyst and Fletcher Payne (incorporated by reference to Exhibit 10.30(a) to the Company's Form S-4 (Reg. No. 333-204423), filed with the SEC on May 22, 2015)
10.21(b)*	Stock Option Agreement—Early Exercise, No. 428, dated January 22, 2015, by and between Catalyst and Fletcher Payne (incorporated by reference to Exhibit 10.40(b) to the Company's Form S-4 (Reg. No. 333-204423), filed with the SEC on May 22, 2015)
10.21(c)	Stock Option Agreement—Early Exercise, No. 429, dated May 8, 2015, by and between Catalyst and Fletcher Payne (incorporated by reference to Exhibit 10.40(b) to the Company's Form S-4 (Reg. No. 333-204423), filed with the SEC on May 22, 2015)
21.1	List of subsidiaries of the Company
23.1	Consent of EisnerAmper LLP, Independent Registered Public Accounting Firm.
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from the Company's Annual Report on Form 10-K for the year ended December 31, 2015, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets as of December 31, 2015 and December 31, 2014; (ii) the Consolidated Statement of Operations for the years ended December 31, 2015, 2014 and 2013; (iii) the Consolidated Statements of Comprehensive Income for the years ended December 31, 2015, 2014 and 2013; (iv) the Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit as of December 31, 2015; (v) the Consolidated Statements of Cash Flows for the twelve months ended December 31, 2015, 2014 and 2013; and (vi) the Notes to Consolidated Financial Statements.

* Denotes management contract, compensatory plan or arrangement.

\+ Confidential treatment has been granted with respect to certain portions of this Exhibit, which portions have been omitted and filed separately with the SEC as part of an application for confidential treatment.

THIS WARRANT AND THE SHARES ISSUABLE HEREUNDER HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AND PURSUANT TO THE PROVISIONS OF ARTICLE 5 BELOW, MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, PLEDGED OR HYPOTHECATED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND APPLICABLE STATE SECURITIES LAW OR, IN THE OPINION OF LEGAL COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE ISSUER OF THESE SECURITIES, SUCH OFFER, SALE OR TRANSFER, PLEDGE OR HYPOTHECATION IS EXEMPT FROM REGISTRATION.

WARRANT TO PURCHASE STOCK

Company:	CATALYST BIOSCIENCES, INC., a Delaware corporation
Number of Shares:	33,750
Class of Stock:	Series A Preferred
Warrant Price:	$1.00 per share
Issue Date:	March 3rd, 2005
Expiration Date:	The greater of (a) the date seven (7) years after an initial public offering of Borrower's stock; or (b) the date ten (10) years from the Issue Date

THIS WARRANT CERTIFIES THAT, for the agreed upon value of $1.00 and for other good and valuable consideration, SILICON VALLEY BANK ("Holder") is entitled to purchase the number of fully paid and nonassessable shares of the class of securities (the "Shares") of the company (the "Company") at the Warrant Price all as set forth above and as adjusted pursuant to Article 2 of this Warrant, subject to the provisions and upon the terms and conditions set forth in this Warrant.

ARTICLE 1. EXERCISE.

1.1 Method of Exercise. Holder may exercise this Warrant by delivering a duly executed Notice of Exercise in substantially the form attached as Appendix 1 to the principal office of the Company. Unless Holder is exercising the conversion right set forth in Article 1.2, Holder shall also deliver to the Company a check, wire transfer (to an account designated by the Company), or other form of payment acceptable to the Company for the aggregate Warrant Price for the Shares being purchased.

1.2 Conversion Right. In lieu of exercising this Warrant as specified in Article 1.1, Holder may from time to time convert this Warrant, in whole or in part, into a number of Shares determined by dividing (a) the aggregate fair market value of the Shares or other securities otherwise issuable upon exercise of this Warrant minus the aggregate Warrant Price of such Shares by (b) the fair market value of one Share. The fair market value of the Shares shall be determined pursuant to Article 1.3.

1.3 Fair Market Value. If the Company's common stock is traded in a public market and the Shares are common stock, the fair market value of each Share shall be the closing price of a Share reported for the business day immediately before Holder delivers its Notice of Exercise to the Company (or in the instance where the Warrant is exercised immediately prior to the effectiveness of the Company's initial public offering, the "price to public" per share price specified in the final prospectus relating to such offering). If the Company's common stock is traded in a public market and the Shares are preferred stock, the fair market value of a Share shall be the closing price of a share of the Company's common stock reported for the business day immediately before Holder delivers its Notice of Exercise to the Company (or, in the instance

where the Warrant is exercised immediately prior to the effectiveness of the Company's initial public offering, the initial "price to public" per share price specified in the final prospectus relating to such offering), in both cases, multiplied by the number of shares of the Company's common stock into which a Share is convertible. If the Company's common stock is not traded in a public market, the Board of Directors of the Company shall determine fair market value in its reasonable good faith judgment.

1.4 Delivery of Certificate and New Warrant. Promptly after Holder exercises or converts this Warrant and, if applicable, the Company receives payment of the aggregate Warrant Price, the Company shall deliver to Holder certificates for the Shares acquired and, if this Warrant has not been fully exercised or converted and has not expired, a new Warrant representing the Shares not so acquired.

1.5 Replacement of Warrants. On receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and, in the case of loss, theft or destruction, on delivery of an indemnity agreement reasonably satisfactory in form and amount to the Company or, in the case of mutilation, or surrender and cancellation of this Warrant, the Company shall execute and deliver, in lieu of this Warrant, a new warrant of like tenor.

1.6 Treatment of Warrant Upon Acquisition of Company.

1.6.1 "Acquisition". For the purpose of this Warrant, "Acquisition" means any sale, license, or other disposition of all or substantially all of the assets of the Company, or any reorganization, consolidation, or merger of the Company where the holders of the Company's securities before the transaction beneficially own less than 50% of the outstanding voting securities of the surviving entity after the transaction.

1.6.2 Treatment of Warrant at Acquisition.

(a) Upon the written request of the Company, Holder agrees that, in the event of an Acquisition that is not an asset sale and in which the sole consideration is cash, either (i) Holder shall exercise its conversion or purchase right under this Warrant and such exercise will be deemed effective immediately prior to the consummation of such Acquisition; or (ii) if Holder elects not to exercise the Warrant, this Warrant will expire upon the consummation of such Acquisition. The Company shall provide the Holder with written notice of its request relating to the foregoing (together with such reasonable information as the Holder may request in connection with such contemplated Acquisition giving rise to such notice), which is to be delivered to Holder not less than ten (10) days prior to the closing of the proposed Acquisition.

(b) Upon the written request of the Company, Holder agrees that, in the event of an Acquisition that is a sale of all or substantially all of the Company's assets (and only its assets) to a third party that is not an Affiliate (as defined below) of the Company (a "Third Party Asset Sale"), either (i) Holder shall exercise its conversion or purchase right under this Warrant and such exercise will be deemed effective immediately prior to the consummation of such Acquisition; or (ii) if Holder elects not to exercise the Warrant, this Warrant will continue until the Expiration Date if the Company continues as a going concern following the closing of any such Third Party Asset Sale. The Company shall provide the Holder with written notice of its request relating to the foregoing (together with such reasonable information as the Holder may request in connection with such contemplated Acquisition giving rise to such notice), which is to be delivered to Holder not less than ten (10) days prior to the closing of the proposed Acquisition.

(c) Upon the closing of any Acquisition other than those particularly described in subsections (a)and (b) above, the successor entity shall assume the obligations of this Warrant, and this Warrant shall be exercisable for the same securities, cash, and property as would be payable for the Shares issuable upon exercise of the unexercised portion of this Warrant as if such Shares were outstanding on the record date for the Acquisition and subsequent closing. The Warrant Price and/or number of Shares shall be adjusted accordingly.

(d) Notwithstanding the foregoing provisions of this Section 1.6.2., in the event that the acquiror in an Acquisition does not agree to assume this Warrant at and as of the closing thereof, this Warrant, to the extent not exercised or converted on or prior to such closing, shall terminate and be of no further force or effect as of immediately following such closing if all of the following conditions are met: (i) the acquiror is subject to the reporting requirements of Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended, (ii) the class of stock or other security of the acquiror that would be received by Holder in connection with such Acquisition were Holder to exercise or convert this Warrant on or prior to the closing thereof is listed for trading on a national securities exchange or approved for quotation on an automated inter-dealer quotation system, (iii) the value (determined as of the closing of such Acquisition in accordance with the definitive agreements therefor) of the acquiror stock and/or other securities that would be received by Holder in respect of each Share were Holder to exercise or convert this Warrant on or prior to the closing of such Acquisition is equal to or greater than three (3) times the then-effective Warrant Price, and (iv) Holder would be able to publicly resell all of the acquiror stock and/or other securities that would be received by Holder in such Acquisition were Holder to exercise or convert this Warrant on or prior to the closing of such Acquisition during the three (3) month period immediately following the closing thereof pursuant to an effective registration statement under the covering such acquiror stock and/or other securities or pursuant to the provisions of Rule 144 under the Act.

(e) As used herein “Affiliate” shall mean any person or entity that owns or controls directly or indirectly twenty-five percent (25%) or more of the stock of Company, any person or entity that controls or is controlled by or is under common control with such persons or entities, and each of such person’s or entity’s officers, directors, or partners, as applicable.

ARTICLE 2 ADJUSTMENTS TO THE SHARES.

2.1 Stock Dividends, Splits, Etc. If the Company declares or pays a dividend on the Shares payable in common stock, or other securities, then upon exercise of this Warrant, for each Share acquired, Holder shall receive, without cost to Holder, the total number and kind of securities to which Holder would have been entitled had Holder owned the Shares of record as of the date the dividend occurred. If the Company subdivides the Shares by reclassification or otherwise into a greater number of shares or takes any other action which increase the amount of stock into which the Shares are convertible, the number of shares purchasable hereunder shall be proportionately increased and the Warrant Price shall be proportionately decreased. If the outstanding shares are combined or consolidated, by reclassification or otherwise, into a lesser number of shares, the Warrant Price shall be proportionately increased and the number of Shares shall be proportionately decreased.

2.2 Reclassification, Exchange, Combinations or Substitution. Upon any reclassification, exchange, substitution, or other event that results in a change of the number and/or class of the securities issuable upon exercise or conversion of this Warrant, Holder shall be entitled to receive, upon exercise or conversion of this Warrant, the number and kind of securities and property that Holder would have received for the Shares if this Warrant had been exercised immediately before such reclassification, exchange, substitution, or other event. Such an event shall include any automatic conversion of the outstanding or issuable securities of the Company of the same class or series as the Shares to common stock pursuant to the terms of the Company’s Articles or Certificate (as applicable) of Incorporation. The Company or its successor shall promptly issue to Holder an amendment to this Warrant setting forth the number and kind of such new securities or other property issuable upon exercise or conversion of this Warrant as a result of such reclassification, exchange, substitution or other event that results in a change of the number and/or class of securities issuable upon exercise or conversion of this

Warrant. The amendment to this Warrant shall provide for adjustments which shall be as nearly equivalent as may be practicable to the adjustments provided for in this Article 2 including, without limitation, adjustments to the Warrant Price and to the number of securities or property issuable upon exercise of the new Warrant. The provisions of this Article 2.2 shall similarly apply to successive reclassifications, exchanges, substitutions, or other events.

2.3 Adjustments for Diluting Issuances. The Warrant Price and the number of Shares issuable upon exercise of this Warrant or, if the Shares are Preferred Stock, the number of shares of common stock issuable upon conversion of the Shares, shall be subject to adjustment, from time to time in the manner set forth in the Company's Articles or Certificate of Incorporation as if the Shares were issued and outstanding on and as of the date of any such required adjustment. The provisions set forth for the Shares in the Company's Articles or Certificate (as applicable) of Incorporation relating to the above in effect as of the Issue Date may not be amended, modified or waived, without the prior written consent of Holder unless such amendment, modification or waiver affects the rights associated with the Shares in the same manner as such amendment, modification or waiver affects the rights associated with all other shares of the same series and class as the Shares granted to the Holder; provided, that, notwithstanding the foregoing, the prior written consent of the Holder shall not be required if the rights associated with the Shares are affected in a different manner due to the number of shares held by the holders thereof or due to any action taken or not taken by the holders thereof.

2.4 No Impairment. The Company may take any corporate action (including an amendment of its Articles or Certificate (as applicable) of Incorporation or a reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action) so long as (a) the Company receives any necessary stockholder and Board of Director approvals required pursuant to the Company's Articles or Certificate (as applicable) of Incorporation and the Delaware General Corporate Law; and (b) any such amendment to its Articles or Certificate (as applicable) of Incorporation or any such reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action does not avoid or seek to avoid the observance or performance of any of the terms to be observed or performed under this Warrant by the Company. The Company shall at all times in good faith assist in carrying out of all the provisions of this Article 2 and in taking all such action as may be necessary or appropriate to protect Holders rights under this Article against impairment.

2.5 Fractional Shares. No fractional Shares shall be issuable upon exercise or conversion of the Warrant and the number of Shares to be issued shall be rounded down to the nearest whole Share. If a fractional share interest arises upon any exercise or conversion of the Warrant, the Company shall eliminate such fractional share interest by paying Holder the amount computed by multiplying the fractional interest by the fair market value of a full Share.

2.6 Certificate as to Adjustments. Upon each adjustment of the Warrant Price, the Company shall promptly notify Holder in writing, and, at the Company's expense, promptly compute such adjustment, and furnish Holder with a certificate of its Chief Financial Officer setting forth such adjustment and the facts upon which such adjustment is based. The Company shall, upon written request, furnish Holder a certificate setting forth the Warrant Price in effect upon the date thereof and the series of adjustments leading to such Warrant Price.

ARTICLE 3 REPRESENTATIONS AND COVENANTS OF THE COMPANY.

3.1 Representations and Warranties. The Company represents and warrants to the Holder as follows:

3.1.1 The initial Warrant Price referenced on the first page of this Warrant is not greater than the price per share at which the Shares were last issued in an arms-length transaction in which at least $500,000 of the Shares were sold.

3.1.2 All Shares which may be issued upon the exercise of the purchase right represented by this Warrant, and all securities, if any, issuable upon conversion of the Shares, shall, upon issuance, be duly authorized, validly issued, fully paid and nonassessable, and free of any liens and encumbrances except for restrictions on transfer provided for herein or under applicable federal and state securities laws.

3.1.3 The Capitalization Table dated 19 Feb '05 remains true and complete as of the Issue Date.

3.2 Notice of Certain Events. If the Company proposes at any time (a) to declare any dividend or distribution upon any of its stock, whether in cash, property, stock, or other securities and whether or not a regular cash dividend; (b)) to offer for sale any shares of the Company's capital stock (or other securities convertible into such capital stock), other than (i) pursuant to the Company's stock option or other compensatory plans; (ii) in connection with commercial credit arrangements or equipment financings; or (iii) in connection with strategic transactions for purposes other than capital raising; or series of the Company's stock; (c) to effect any reclassification or recapitalization of any of its stock; (d) to merge or consolidate with or into any other corporation, or sell, lease, license, or convey all or substantially all of its assets, or to liquidate, dissolve or wind up; or (e) offer holders of registration rights the opportunity to participate in an underwritten public offering of the company's securities for cash, then, in connection with each such event, the Company shall give Holder: (1) at least ten (10) days prior written notice of the date on which a record will be taken for such dividend, distribution, or subscription rights (and specifying the date on which the holders of common stock will be entitled thereto) or for determining rights to vote, if any, in respect of the matters referred to in (c) and (d) above; (2) in the case of the matters referred to in (c) and (d) above at least ten (10) days prior written notice of the date when the same will take place (and specifying the date on which the holders of common stock will be entitled to exchange their common stock for securities or other property deliverable upon the occurrence of such event); and (3) in the case of the matter referred to in (e) above, the same notice as is given to the holders of such registration rights.

3.3 Registration Under Securities Act of 1933, as amended. The Company agrees that the Shares, or if the Shares are convertible into common stock of the Company, such common stock, shall have certain incidental, or "Piggyback," registration rights pursuant to and as set forth in the Company's Investor Rights Agreement dated October 31, 2003, among the Company and the other parties named therein (as the same may be amended from time to time, the "Investor Rights Agreement"). The provisions set forth in the Company's Investor Rights Agreement in effect as of the Issue Date may not be amended, modified or waived without the prior written consent of Holder unless such amendment, modification, or waiver affects the incidental, or "Piggyback," rights associated with the Shares in the same manner as such amendment, modification or waiver affects such rights associated with all other shares of the same series and class as the Shares granted to the Holder; provided, that, notwithstanding the foregoing, the prior written consent of the Holder shall not be required if such rights associated with the Shares are affected in a different manner due to the number of shares held by the holders thereof or due to any action taken or not taken by the holders thereof.

3.4 No Shareholder Rights. Except as provided in this Warrant, the Holder will not have any rights as a shareholder of the Company until the exercise of this Warrant.

ARTICLE 4 REPRESENTATIONS, WARRANTIES OF THE HOLDER.

The Holder represents and warrants to the Company as follows:

4.1 Purchase for Own Account. This Warrant and the securities to be acquired upon exercise of this Warrant by the Holder will be acquired for investment for the Holder's account, not as a nominee or agent, and not with a view to the public resale or distribution within the meaning of the Act. Holder also represents that the Holder has not been formed for the specific purpose of acquiring this Warrant or the Shares.

4.2 Disclosure of Information. The Holder has received or has had full access to all the information it considers necessary or appropriate to make an informed investment decision with respect to the acquisition of this Warrant and its underlying securities. The Holder further has had an opportunity to ask questions and receive answers from the Company regarding the terms and conditions of the offering of this Warrant and its underlying securities and to obtain additional information (to the extent the Company possessed such information or could acquire it without unreasonable effort or expense) necessary to verify any information furnished to the Holder or to which the Holder has access.

4.3 Investment Experience. The Holder understands that the purchase of this Warrant and its underlying securities involves substantial risk. The Holder has experience as an investor in securities of companies in the development stage and acknowledges that the Holder can bear the economic risk of such Holder's investment in this Warrant and its underlying securities and has such knowledge and experience in financial or business matters that the Holder is capable of evaluating the merits and risks of its investment in this Warrant and its underlying securities and/or has a preexisting personal or business relationship with the Company and certain of its officers, directors or controlling persons of a nature and duration that enables the Holder to be aware of the character, business acumen and financial circumstances of such persons.

4.4 Accredited Investor Status. The Holder is an "accredited investor" within the meaning of Regulation D promulgated under the Act.

4.5 The Act. The Holder understands that this Warrant and the Shares issuable upon exercise or conversion hereof have not been registered un the Act in reliance upon a specific exemption therefrom, which exemption depends upon, among other things, the bona fide nature of the Holder's investment intent as expressed herein. The Holder understands that this Warrant and the Shares issued upon any exercise or conversion hereof must be held indefinitely unless subsequently registered under the 1933 Act and qualified under applicable state securities laws, or unless exemption from such registration and qualification are otherwise available.

ARTICLE 5 MISCELLANEOUS.

5.1 Term. This Warrant is exercisable in whole or in part at any time and from time to time on or before the Expiration Date.

5.2 Market Stand-Off Agreement. Holder hereby agrees that Holder shall not sell or otherwise transfer, make any short sale of, grant any option for the purchase of, or enter into any hedging or similar transaction with the same economic effect as a sale, of any common stock (or other securities) of the Company during the one hundred eighty (180) day period following the effective date of the Company's initial public offering. The obligations described in this Section 5.2 shall not apply to a registration relating solely to employee benefit plans on Form S-1 or Form S-8 or similar forms that may be promulgated in the future, or a registration relating solely to a transaction on Form S-4 or similar forms that may be promulgated in the future. The Company may impose stop-transfer instructions and may stamp the certificates representing the Shares (and the securities issuable, directly or indirectly, upon conversion of the Shares, if any) with a legend describing the foregoing restriction until the end of such one hundred eighty (180) day period. Holder agrees to execute a market standoff agreement with said underwriters in customary form consistent with the provisions of this Section 5.2. The obligations under this Section 5.2 shall apply only if all officers, directors and one-percent security holders of the Company are bound by similar agreements.

5.3 Legends. This Warrant and the Shares (and the securities issuable, directly or indirectly, upon conversion of the Shares, if any) shall be imprinted with a legend in substantially the following form:

> THIS WARRANT AND THE SHARES ISSUABLE HEREUNDER HAVE NOT BEEN REGISTERED UNDER THE ACT, OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AND PURSUANT TO THE PROVISIONS OF ARTICLE 5 BELOW, MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, PLEDGED OR HYPOTHECATED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND APPLICABLE STATE SECURITIES LAW OR, IN THE OPINION OF LEGAL COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE ISSUER OF THESE SECURITIES, SUCH OFFER, SALE OR TRANSFER, PLEDGE OR HYPOTHECATION IS EXEMPT FROM REGISTRATION.

5.4 Compliance with Securities Laws on Transfer. This Warrant and the Shares issuable upon exercise of this Warrant (and the securities issuable, directly or indirectly, upon conversion of the Shares, if any) may not be transferred or assigned in whole or in part without compliance with applicable federal and state securities laws by the transferor and the transferee (including, without limitation, the delivery of investment representation letters and legal opinions reasonably satisfactory to the Company, as reasonably requested by the Company). The Company shall not require Holder to provide an opinion of counsel if the transfer is to Silicon Valley Bancshares (Holder's parent company) or any other affiliate of Holder. Additionally, the Company shall also not require an opinion of counsel if there is no material question as to the availability of current information as referenced in Rule 144(c), Holder represents that it has complied with Rule 144(d) and (e) in reasonable detail, the selling broker represents that it has complied with Rule 144(f), and the Company is provided with a copy of Holder's notice of proposed sale.

5.5 Transfer Procedure. Upon receipt by Holder of the executed Warrant, Holder will transfer all of this Warrant to Silicon Valley Bancshares, Holder's parent company, by execution of an Assignment substantially in the form of Appendix 2. Subject to the provisions of Article 5.4 and upon providing Company with written notice, Silicon Valley Bancshares and any subsequent Holder may transfer all or part of this Warrant or the Shares issuable upon exercise of this Warrant (or the Shares issuable directly or indirectly, upon conversion of the Shares, if any) to any transferee, provided, however, in connection with any such transfer, (i) Silicon Valley Bancshares or any subsequent Holder will give the Company notice of the portion of the Warrant being transferred with the name, address and taxpayer identification number of the transferee, (ii) Holder will surrender this Warrant to the Company for reissuance to the transferee(s) (and Holder if applicable), and (iii) the transferee(s) shall agree to be bound by the terms and conditions of this Warrant, including without limitation the market standoff agreement set forth in Section 5.2 above. The Company may refuse to transfer this Warrant or the Shares to any person who directly competes with the Company, unless, in either case, the stock of the Company is publicly traded.

5.6 Notices. All notices and other communications from the Company to the Holder, or vice versa, shall be deemed delivered and effective when given personally or mailed by first-class registered or certified mail, postage prepaid, at such address as may have been furnished to the Company or the Holder, as the case may (or on the first business day after transmission by facsimile) be, in writing by the Company or such holder from time to time. Effective upon receipt of the fully executed Warrant and the initial transfer described in Article 5.5 above, all notices to the Holder shall be addressed as follows until the Company receives notice of a change of address in connection with a transfer or otherwise:

Silicon Valley Bancshares
Attn: Treasury Department
3003 Tasman Drive, HA 200
Santa Clara, CA 95054
Telephone: 408-654-7400
Facsimile: 408-496-2405

Notice to the Company shall be addressed as follows until the Holder receives notice of a change in address:

Catalyst Biosciences, Inc.
Attn: David O'Reilly
290 Utah Avenue
South San Francisco CA, 94080
Telephone: (415) 476-8146.
Facsimile: (415) 871-2475

5.7 Waiver. This Warrant and any term hereof may be changed, waived, discharged or terminated only by an instrument in writing signed by the party against which enforcement of such change, waiver, discharge or termination is sought.

5.8 Attorney's Fees. In the event of any dispute between the parties concerning the terms and provisions of this Warrant, the party prevailing in such dispute shall be entitled to collect from the other party all costs incurred in such dispute, including reasonable attorney's fees.

5.9 Automatic Conversion upon Expiration. In the event that, upon the Expiration Date, the fair market value of one Share (or other security issuable upon the exercise hereof) as determined in accordance with Article 1.3 above is greater than the Exercise Price in effect on such date, then this Warrant shall automatically be deemed on and as of such date to be converted pursuant to Article 1.2 above as to all Shares (or such other securities) for which it shall not previously have been exercised or converted, and the Company shall promptly deliver a certificate representing the Shares (or such other securities) issued upon such conversion to the Holder.

5.10 Counterparts. This Warrant may be executed in counterparts, all of which together shall constitute one and the same agreement.

5.11 Governing Law. This Warrant shall be governed by and construed in accordance with the laws of the State of California, without giving effect to its principles regarding conflicts of law.

"COMPANY"

CATALYST BIOSCIENCES, INC.

By: /s/ David O'Reilly
Title: President

"HOLDER"

SILICON VALLEY BANK

By:
Title: Vice President
Warrant Effective Date: March 3, 2005

APPENDIX 1

NOTICE OF EXERCISE

1. Holder elects to purchase _____ shares of the Common/Series _____ Preferred [strike one] Stock of OUR GREATEST CUSTOMER, INC. pursuant to the terms of the attached Warrant, and tenders payment of the purchase price of the shares in full.

[or]

1. Holder elects to convert the attached Warrant into Shares/cash [strike one] in the manner specified in the Warrant. This conversion is exercised for _____ of the Shares covered by the Warrant.

[Strike paragraph that does not apply.]

2. Please issue a certificate or certificates representing the shares in the name specified below:

_____

Holders Name

_____

_____

(Address)

3. By its execution below and for the benefit of the Company, Holder hereby restates each of the representations and warranties in Article 4 of the Warrant as the date hereof.

HOLDER:

_____

By: _____

Name: _____

Title: _____

(Date): _____

ASSIGNMENT

For value received, Silicon Valley Bank hereby sells, assigns and transfers unto:

Name: Silicon Valley Bancshares
Address: 3003 Tasman Drive (HA-200)
Santa Clara, CA 95054

TaxID: 91-1962278

that certain Warrant to Purchase Stock issued by Catalyst Biosciences, Inc. **(the "Company"), on March 3, 2005 (the "Warrant") together with all rights, title and interest therein.**

SILICON VALLEY BANK

By: /s/ Peter Scott

Name: Peter Scott

Title: SRM

Date: 2/22/05

By its execution below, and for the benefit of the Company, Silicon Valley Bancshares makes each of the representations and warranties set forth in Article 4 of the Warrant as of the date hereof.

SILICON VALLEY BANCSHARES

By: /s/ Paulette Mehas

Name: Paulette Mehas

Title: Treasurer

Exhibit 4.4

THIS WARRANT AND THE SHARES PURCHASABLE HEREUNDER HAVE BEEN ACQUIRED FOR INVESTMENT AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR QUALIFIED UNDER ANY STATE SECURITIES LAWS. SUCH SECURITIES MAY NOT BE SOLD OR TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR QUALIFICATION OR AN EXEMPTION THEREFROM UNDER SAID ACT AND ANY APPLICABLE STATE SECURITIES LAWS.

THIS WARRANT AND THE SHARES PURCHASABLE HEREUNDER ARE SUBJECT TO RESTRICTIONS ON TRANSFER CONTAINED IN THAT CERTAIN SERIES E PREFERRED STOCK PURCHASE AGREEMENT, DATED APRIL __, 2014, WHICH RESTRICTIONS ON TRANSFER ARE INCORPORATED HEREIN BY REFERENCE.

PWE-___

Dated: April __, 2014

WARRANT TO PURCHASE STOCK OF

CATALYST BIOSCIENCES, INC.

This certifies that _____, or its assigns (the "Holder"), for value received, is entitled to purchase, from Catalyst Biosciences, Inc., a Delaware corporation (the "Company"), up to that number of fully paid and nonassessable shares of the Company's Series E Preferred Stock, equal to the quotient obtained in accordance with the following calculation:

Warrant Shares (as defined below) issuable upon exercise of this Warrant	=	The number of shares of Series E Preferred Stock issued by the Company to Holder on the date hereof) x 0.25

This Warrant is issued pursuant to the terms of that certain Series E Preferred Stock Purchase Agreement, dated April __, 2014, by and among the Company and the investors set forth in the Schedule of Investors attached thereto as Exhibit A (the "Agreement"). This Warrant is one of a series of warrants (the "Warrants") having like tenor and effect (except for variations necessary to express the name of the holder and the date on which each Warrant is issued) issued or to be issued by the Company in accordance with the terms of the Agreement. Capitalized terms not otherwise defined herein shall have the meanings set forth in the Agreement.

This Warrant shall be exercisable at any time from time to time from and after the date hereof (such date being referred to herein as the "Initial Exercise Date") up to and including 5:00 p.m. (Pacific Time) until the first to occur of (i) immediately prior to the closing of any Liquidation Transaction (as defined in the Company's Amended and Restated Certificate of Incorporation, as amended from time to time), or (ii) the 5th anniversary of the date hereof (such earlier date being referred to herein as the "Expiration Date"), upon surrender to the Company at its principal office (or at such other location as the Company may advise the Holder in writing) of this Warrant properly endorsed with (i) the Form of Subscription attached hereto duly completed and executed, (ii) payment pursuant to Section 2 of the aggregate Exercise Price for the number of

Warrant Shares for which this Warrant is being exercised determined in accordance with the provisions hereof. Notwithstanding the foregoing, if Holder has not exercised this Warrant by the Expiration Date, then the exercise of this Warrant shall be deemed to have been automatically effected prior to the close of business on the Expiration Date pursuant to the Net Issuance provisions in Section 2 of this Warrant. The Exercise Price and the number of Warrant Shares purchasable hereunder are subject to adjustment as provided in Section 4 of this Warrant.

The term "Warrant Shares" shall shares of the Company's Series E Preferred Stock.

The term "Exercise Price" shall mean $1.2706 per share (as adjusted for stock splits, stock dividends, reclassification and the like).

The term "IPO" shall mean a Qualified IPO as defined in the Company's Amended and Restated Certificate of Incorporation.

1. Exercise; Issuance of Certificates; Acknowledgement. This Warrant is exercisable at the option of the holder of record hereof, at any time or from time to time from or after the Initial Exercise Date up to the Expiration Date for all or any part of the Warrant Shares (but not for a fraction of a share) which may be purchased hereunder. The Company agrees that the Warrant Shares purchased hereunder shall be and are deemed to be issued to the Holder hereof as the record owner of such shares as of the close of business on the date on which this Warrant shall have been surrendered, properly endorsed, the completed, executed Form of Subscription delivered and payment made for such shares. Certificates for the Warrant Shares so purchased, together with any other securities or property to which the Holder hereof is entitled upon such exercise, shall be delivered to the Holder hereof by the Company at the Company's expense within a reasonable time after the rights represented by this Warrant have been so exercised. Each certificate so delivered shall be in such denominations of the Warrant Shares as may be requested by the Holder hereof and shall be registered in the name of such Holder. In case of a purchase of less than all the Warrant Shares, the Company shall execute and deliver to Holder within a reasonable time an Acknowledgement in the form attached hereto indicating the number of Warrant Shares which remain subject to this Warrant, if any.

2. Payment for Shares. The aggregate purchase price for Warrant Shares being purchased hereunder may be paid either (i) by cash or wire transfer of immediately available funds, (ii) by surrender of a number of Warrant Shares which have a fair market value equal to the aggregate purchase price of the Warrant Shares being purchased ("Net Issuance") as determined herein, or (iii) any combination of the foregoing. If the Holder elects the Net Issuance method of payment, the Company shall issue to Holder upon exercise a number of shares of Warrant Shares determined in accordance with the following formula:

$$X = \frac{Y(A-B)}{A}$$

where: X = the number of Warrant Shares to be issued to the Holder;

Y = the number of Warrant Shares with respect to which the Holder is

exercising its purchase rights under this Warrant;

A = the fair market value of one (1) share of the Warrant Shares on the date of exercise; and

B = the Exercise Price.

No fractional shares arising out of the above formula for determining the number of shares to be issued to the Holder shall be issued, and the Company shall in lieu thereof make payment to the Holder of cash in the amount of such fraction multiplied by the fair market value of one (1) share of the Warrant Shares on the date of exercise. For purposes of the above calculation, the fair market value of one (1) share of the Warrant Shares shall mean (a) if the date of exercise is after the commencement of trading of the Common Stock on a securities exchange or over-the-counter but prior to the closing of the IPO, the price per share to the public set forth on the final prospectus relating to the IPO, multiplied by the number of shares of Common Stock into which each share of the Warrant Shares is then convertible, (b) if the Common Stock is then traded on a securities exchange, the average of the closing prices of such Common Stock on such exchange over the thirty (30) calendar day period (or portion thereof) ending three (3) days prior to the date of exercise, multiplied by the number of shares of Common Stock into which each share of the Warrant Shares is then convertible, (c) if the Common Stock is then regularly traded over-the-counter, the average of the closing sale prices or secondarily the closing bid of such Common Stock over the thirty (30) calendar day period (or portion thereof) ending three (3) days prior to the date of exercise, multiplied by the number of shares of Common Stock into which each share of the Warrant Shares is then convertible, or (d) if there is no active public market for the Common Stock, the fair market value of one share of the Warrant Shares as determined in good faith by the Board of Directors of the Company .

3. Shares to be Fully Paid. The Company covenants and agrees that all Warrant Shares which may be issued upon the exercise of the rights represented by this Warrant will, upon issuance, be duly authorized, validly issued, fully paid and nonassessable and free from all preemptive rights of any stockholder and free of all taxes, liens and charges with respect to the issue thereof.

4. Adjustment of Exercise Price and Number of Shares. The Exercise Price and the number of shares purchasable upon the exercise of this Warrant shall be subject to adjustment from time to time upon the occurrence of certain events described in this Section 4. Upon each adjustment of the Exercise Price, the Holder of this Warrant shall thereafter be entitled to purchase, at the Exercise Price resulting from such adjustment, the number of shares obtained by multiplying the Exercise Price in effect immediately prior to such adjustment by the number of shares purchasable pursuant hereto immediately prior to such adjustment, and dividing the product thereof by the Exercise Price resulting from such adjustment.

4.1 Subdivisions, Combinations and Dividends. In case the Company shall at any time subdivide its outstanding shares of capital stock into a greater number of shares or pay a dividend in capital stock in respect of outstanding shares of capital stock, the Exercise Price in effect immediately prior to such subdivision or at the record date of such dividend shall be

proportionately reduced, and conversely, in case the outstanding shares of the capital stock of the Company shall be combined into a smaller number of shares, the Exercise Price in effect immediately prior to such combination shall be proportionately increased.

4.2 Reclassification. If any reclassification of the capital stock of the Company shall be effected in such a way that holders thereof shall be entitled to receive stock, securities, or other assets or property, then, as a condition of such reclassification, lawful and adequate provisions shall be made whereby the Holder hereof shall thereafter have the right to purchase and receive (in lieu of the shares of the capital stock immediately theretofore purchasable and receivable upon the exercise of the rights represented hereby) such shares of stock, securities or other assets or property as may be issued or payable with respect to or in exchange for a number of outstanding shares of such capital stock equal to the number of shares of such capital stock immediately theretofore purchasable and receivable upon the exercise of the rights represented hereby. In any reclassification described above, appropriate provision shall be made with respect to the rights and interests of the Holder of this Warrant to the end that the provisions hereof (including, without limitation, provisions for adjustments of the Exercise Price and of the number of shares purchasable and receivable upon the exercise of this Warrant) shall thereafter be applicable, as nearly as may be, in relation to any shares of stock, securities or assets thereafter deliverable upon the exercise hereof.

4.3 Notice of Adjustment. Upon any adjustment of the Exercise Price or any increase or decrease in the number of shares purchasable upon the exercise of this Warrant, the Company shall give written notice thereof, by first class mail postage prepaid, addressed to the registered Holder of this Warrant at the address of such Holder as shown on the books of the Company. The notice shall be signed by the Company's Chief Financial Officer and shall state the Exercise Price resulting from such adjustment and the increase or decrease, if any, in the number of shares purchasable at such price upon the exercise of this Warrant, setting forth in reasonable detail the method of calculation and the facts upon which such calculation is based.

4.4 Other Notices. If at any time:

(1) the Company shall declare any cash dividend upon its capital stock; or

(2) there shall be any Liquidation Transaction.

then, in any one or more of said cases, the Company shall give, by first class mail, postage prepaid, addressed to the Holder of this Warrant at the address of such Holder as shown on the books of the Company, (a) at least ten (10) days prior written notice of the date on which the books of the Company shall close or a record shall be taken for such dividend or for determining rights to vote in respect of any such reorganization, reclassification, consolidation, merger, sale, dissolution, liquidation or winding-up, and (b) in the case of any such reorganization, reclassification, consolidation, merger, sale, dissolution, liquidation, winding-up or public offering, at least ten (10) days prior written notice of the date when the same shall take place; provided, however, that the Holder shall make a best efforts attempt to respond to such notice as early as possible after the receipt thereof. Any notice given in accordance with the foregoing clause (a) shall also specify, in the case of any such dividend, the date on which the holders of

capital stock shall be entitled thereto. Any notice given in accordance with the foregoing clause (b) shall also specify the date on which the holders of capital stock shall be entitled to exchange their capital stock for securities or other property deliverable upon such reorganization, reclassification, consolidation, merger, sale, dissolution, liquidation, winding-up, conversion or public offering, as the case may be.

5. No Voting or Dividend Rights. Nothing contained in this Warrant shall be construed as conferring upon the Holder hereof the right to vote or to consent to receive notice as a stockholder of the Company or any other matters or any rights whatsoever as a stockholder of the Company. No dividends or interest shall be payable or accrued in respect of this Warrant or the interest represented hereby or the shares purchasable hereunder until, and only to the extent that, this Warrant shall have been exercised.

6. Warrants Non-Transferable. Neither this Warrant nor any of the rights hereunder may be transferred, in whole or in part, without the prior written consent of the Company.

7. Lost Warrants. Upon receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction, or mutilation of this Warrant and, in the case of any such loss, theft or destruction, upon receipt of an indemnity reasonably satisfactory to the Company, or in the case of any such mutilation upon surrender and cancellation of such Warrant, the Company, at its expense, will make and deliver a new Warrant, of like tenor, in lieu of the lost, stolen, destroyed or mutilated Warrant.

8. Amendment. Any term of this Warrant and all Warrants issued pursuant to the Agreement may be amended and the observance of any term of this Warrant and all Warrants issued pursuant to the Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively), only with the written consent of the Company and the holders of Warrants representing 66 2/3% of the Warrant Shares issued pursuant to the Agreement; provided any such amendment or waiver that affects by its terms any holder(s) in a manner that is different in any material respect from all holders shall require the approval of the Company, such holder(s) and the holders of 66 2/3% of the Warrant Shares issued pursuant to the Agreement. Any amendment or waiver effected in accordance with this paragraph shall be binding upon the Company, the Holder and the holders of all Warrants issued pursuant to the Agreement.

9. Notices. Except as may be otherwise provided herein, all notices, requests, waivers and other communications made pursuant to this Warrant shall be made in accordance with Section 7.2 of the Agreement.

10. Governing Law; Venue. This Warrant is to be construed in accordance with and governed by the internal laws of the State of California without giving effect to any choice of law rule that would cause the application of the laws of any jurisdiction other than the internal laws of the State of California to the rights and duties of the parties. All disputes and controversies arising out of or in connection with this Warrant shall be resolved exclusively by the state and federal courts located in Santa Clara County in the State of California, and each party hereto agrees to submit to the jurisdiction of said courts and agrees that venue shall lie exclusively with such courts.

* * *

IN WITNESS WHEREOF, the Company has caused this Warrant to be duly executed by its officers, thereunto duly authorized as of the date first above written.

CATALYST BIOSCIENCES, INC.

By: _____

Name: Nassim Usman

Title: Chief Executive Officer

FORM OF SUBSCRIPTION

(To be signed only upon exercise of Warrant)

To: Catalyst Biosciences, Inc.

The undersigned, the holder of a right to purchase shares of Catalyst Biosciences, Inc., a Delaware corporation (the "Company"), pursuant to that certain Warrant to Purchase Stock of the Company (the "Warrant"), dated as of April __, 2014, hereby irrevocably elects to exercise the purchase right represented by such Warrant for, and to purchase thereunder, _____ (_____) shares of _____ Stock of the Company and herewith makes payment of _____ Dollars ($_____) therefor by the following method:

(Check one of the following):

_____ (check if applicable) The undersigned hereby elects to make payment of _____ Dollars ($_____) therefor in cash.

_____ (check if applicable) The undersigned hereby elects to make payment for the aggregate exercise price of this exercise using the Net Issuance method pursuant to Section 2 of the Warrant.

The undersigned represents that it is acquiring such securities for its own account for investment and not with a view to or for sale in connection with any distribution thereof and in order to induce the issuance of such securities makes to the Company, as of the date hereof, the representations and warranties set forth in Section 4 of the Series E Preferred Stock Purchase Agreement, dated as of April __, 2014, by and among the Company and the investors listed on Exhibit A thereto.

DATED: _____

[HOLDER NAME]

By:_____

Name:_____

Its:_____

ACKNOWLEDGMENT

To: _____

The undersigned hereby acknowledges that as of the date hereof, _____ (_____) shares remain subject to the right of purchase in favor of _____ pursuant to that certain Warrant to Purchase Stock of Catalyst Biosciences, Inc., dated as of April __, 2014.

DATED: _____

CATALYST BIOSCIENCES, INC.

By:_____

Name:_____

Title:_____

Exhibit 4.5

THIS WARRANT AND THE SHARES PURCHASABLE HEREUNDER HAVE BEEN ACQUIRED FOR INVESTMENT AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR QUALIFIED UNDER ANY STATE SECURITIES LAWS. SUCH SECURITIES MAY NOT BE SOLD OR TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR QUALIFICATION OR AN EXEMPTION THEREFROM UNDER SAID ACT AND ANY APPLICABLE STATE SECURITIES LAWS.

THIS WARRANT AND THE SHARES PURCHASABLE HEREUNDER ARE SUBJECT TO RESTRICTIONS ON TRANSFER CONTAINED IN THAT CERTAIN NOTE AND WARRANT PURCHASE AGREEMENT, DATED , 2015, WHICH RESTRICTIONS ON TRANSFER ARE INCORPORATED HEREIN BY REFERENCE.

PW-

Dated: , 2015

WARRANT TO PURCHASE

STOCK OF

CATALYST BIOSCIENCES, INC.

This certifies that , or assigns (collectively, the "***Holder***"), for value received, is entitled to purchase, at the applicable Stock Purchase Price (as define below), from **CATALYST BIOSCIENCES, INC.**, a Delaware corporation (the "***Company***"), up to that number of fully paid and nonassessable shares of Warrant Securities (as defined below), equal to the quotient of: (a) twenty five percent (25%) multiplied by the principal amount of the convertible promissory note issued to the Holder pursuant to the Agreement (as defined below) at the Closing (b) divided by the applicable Stock Purchase Price. Capitalized terms not otherwise defined herein shall have the meanings set forth in the Agreement.

The term "***Agreement***" shall mean that certain Note and Warrant Purchase Agreement, dated , 2015 by and among the Company and the investors set forth in the Schedule of Investors attached thereto as Exhibit A.

The term "***Warrant Securities***" shall mean the Equity Securities that the principal amount of the convertible promissory note issued to the Holder pursuant to the Agreement converts into.

The term "***Stock Purchase Price***" shall mean (i) in the case that the Warrant Securities are Qualified Financing Securities, the price per share of the Qualified Financing Securities paid by investors in the Qualified Financing (as adjusted for stock split, stock dividends, recapitalizations and the like), (ii) in the case that the Warrant Securities are Non-Qualified Financing Securities, the price per share of the Non-Qualified Financing Securities paid by investors in the Non-Qualified Financing (as adjusted for stock split, stock dividends,

recapitalizations and the like), or (iii) in the case that the Warrant Securities are Series E Preferred Stock, $1.2706 (as adjusted for stock split, stock dividends, recapitalizations and the like).

The term "***Exercise Price***" shall mean the Stock Purchase Price.

This Warrant is issued pursuant to the terms of the Agreement. This Warrant is one of a series of warrants (the "***Warrants***") having like tenor and effect (except for variations necessary to express the name of the holder and the date on which each Warrant is issued) issued or to be issued by the Company in accordance with the terms of the Agreement.

This Warrant shall be exercisable at any time from time to time from and after the date hereof (such date being referred to herein as the "***Initial Exercise Date***") up to and including 5:00 p.m. (Pacific Time) until the 5th anniversary of the date hereof (the "***Expiration Date***"), upon surrender to the Company at its principal office (or at such other location as the Company may advise the Holder in writing) of this Warrant properly endorsed with (i) the Form of Subscription attached hereto duly completed and executed, (ii) payment pursuant to Section 2 of the aggregate Exercise Price for the number of Warrant Securities for which this Warrant is being exercised determined in accordance with the provisions hereof. Notwithstanding the foregoing, if Holder has not exercised this Warrant by the Expiration Date, then the exercise of this Warrant shall be deemed to have been automatically effected prior to the close of business on the Expiration Date pursuant to the Net Issuance provisions in Section 2 of this Warrant (the "***Automatic Exercise***"), except, if the Exercise Price is greater than the fair market value of one (1) share of the Warrant Securities for which this Warrant is being exercised, then the Automatic Exercise shall not occur. The Exercise Price and the number of Warrant Securities purchasable hereunder are subject to adjustment as provided in Section 4 of this Warrant.

1. Exercise; Issuance of Certificates; Acknowledgement. This Warrant is exercisable at the option of the holder of record hereof, at any time or from time to time from or after the Initial Exercise Date up to the Expiration Date for all or any part of the Warrant Securities (but not for a fraction of a share) which may be purchased hereunder. The Company agrees that the Warrant Securities purchased hereunder shall be and are deemed to be issued to the Holder hereof as the record owner of such shares as of the close of business on the date on which this Warrant shall have been surrendered, properly endorsed, the completed, executed Form of Subscription delivered and payment made for such shares. Certificates for the Warrant Securities so purchased, together with any other securities or property to which the Holder hereof is entitled upon such exercise, shall be delivered to the Holder hereof by the Company at the Company's expense within a reasonable time after the rights represented by this Warrant have been so exercised. Each certificate so delivered shall be in such denominations of the Warrant Securities as may be requested by the Holder hereof and shall be registered in the name of such Holder. In case of a purchase of less than all the Warrant Securities, the Company shall execute and deliver to Holder within a reasonable time an Acknowledgement in the form attached hereto indicating the number of Warrant Securities which remain subject to this Warrant, if any.

2. Payment for Shares. The aggregate purchase price for Warrant Securities being purchased hereunder may be paid either (i) by cash or wire transfer of immediately available funds, (ii) by surrender of a number of Warrant Securities which have a fair market value equal

to the aggregate purchase price of the Warrant Securities being purchased ("***Net Issuance***") as determined herein, or (iii) any combination of the foregoing. If the Holder elects the Net Issuance method of payment, the Company shall issue to Holder upon exercise a number of shares of Warrant Securities determined in accordance with the following formula:

$$X = \frac{Y(A-B)}{A}$$

where: X = the number of Warrant Securities to be issued to the Holder;

Y = the number of Warrant Securities with respect to which the Holder is exercising its purchase rights under this Warrant;

A = the fair market value of one (1) share of the Warrant Securities on the date of exercise; and

B = the Exercise Price.

No fractional shares arising out of the above formula for determining the number of shares to be issued to the Holder shall be issued, and the Company shall in lieu thereof make payment to the Holder of cash in the amount of such fraction multiplied by the fair market value of one (1) share of the Warrant Securities on the date of exercise. For purposes of the above calculation, the fair market value of one (1) share of the Warrant Securities shall mean (a) if the Common Stock is then traded on a securities exchange, the average of the closing prices of such Common Stock on such exchange over the thirty (30) calendar day period (or portion thereof) ending three (3) days prior to the date of exercise, multiplied by the number of shares of Common Stock into which each share of the Warrant Securities is then convertible, (b) if the Common Stock is then regularly traded over-the-counter, the average of the closing sale prices or secondarily the closing bid of such Common Stock over the thirty (30) calendar day period (or portion thereof) ending three (3) days prior to the date of exercise, multiplied by the number of shares of Common Stock into which each share of the Warrant Securities is then convertible, or (c) if there is no active public market for the Common Stock, the fair market value of one share of the Warrant Securities as determined in good faith by the Board of Directors of the Company.

3. Shares to be Fully Paid. The Company covenants and agrees that all Warrant Securities which may be issued upon the exercise of the rights represented by this Warrant will, upon issuance, be duly authorized, validly issued, fully paid and nonassessable and free from all preemptive rights of any stockholder and free of all taxes, liens and charges with respect to the issue thereof.

4. Adjustment of Exercise Price and Number of Shares. The Exercise Price and the number of shares purchasable upon the exercise of this Warrant shall be subject to adjustment from time to time upon the occurrence of certain events described in this Section 4. Upon each adjustment of the Exercise Price, the Holder of this Warrant shall thereafter be entitled to purchase, at the Exercise Price resulting from such adjustment, the number of shares obtained by

multiplying the Exercise Price in effect immediately prior to such adjustment by the number of shares purchasable pursuant hereto immediately prior to such adjustment, and dividing the product thereof by the Exercise Price resulting from such adjustment.

4.1 Subdivisions, Combinations and Dividends. In case the Company shall at any time subdivide its outstanding shares of capital stock into a greater number of shares or pay a dividend in capital stock in respect of outstanding shares of capital stock, the Exercise Price in effect immediately prior to such subdivision or at the record date of such dividend shall be proportionately reduced, and conversely, in case the outstanding shares of the capital stock of the Company shall be combined into a smaller number of shares, the Exercise Price in effect immediately prior to such combination shall be proportionately increased.

4.2 Reclassification. In the event that the Warrant Securities are converted into any different securities, or if any reclassification of the capital stock of the Company shall be effected in such a way that holders thereof shall be entitled to receive stock, securities, or other assets or property, then, as a condition of such reclassification, lawful and adequate provisions shall be made whereby the Holder hereof shall thereafter have the right to purchase and receive (in lieu of the shares of the capital stock immediately theretofore purchasable and receivable upon the exercise of the rights represented hereby) such shares of stock, securities or other assets or property as may be issued or payable with respect to or in exchange for a number of outstanding shares of such capital stock equal to the number of shares of such capital stock immediately theretofore purchasable and receivable upon the exercise of the rights represented hereby. In any reclassification described above, appropriate provision shall be made with respect to the rights and interests of the Holder of this Warrant to the end that the provisions hereof (including, without limitation, provisions for adjustments of the Exercise Price and of the number of shares purchasable and receivable upon the exercise of this Warrant) shall thereafter be applicable, as nearly as may be, in relation to any shares of stock, securities or assets thereafter deliverable upon the exercise hereof.

4.3 Notice of Adjustment. Upon any adjustment of the Exercise Price or any increase or decrease in the number of shares purchasable upon the exercise of this Warrant, the Company shall give written notice thereof, by first class mail postage prepaid, addressed to the registered Holder of this Warrant at the address of such Holder as shown on the books of the Company. The notice shall be signed by the Company's Chief Financial Officer and shall state the Exercise Price resulting from such adjustment and the increase or decrease, if any, in the number of shares purchasable at such price upon the exercise of this Warrant, setting forth in reasonable detail the method of calculation and the facts upon which such calculation is based.

4.4 Other Notices. If at any time:

(1) the Company shall declare any cash dividend upon its capital stock; or

(2) there shall be any Liquidation Transaction (as defined in the Company's Amended and Restated Certificate of Incorporation, as may be amended from time to time) other than the Merger,

then, in any one or more of said cases, the Company shall give, by first class mail, postage prepaid, addressed to the Holder of this Warrant at the address of such Holder as shown on the books of the Company, (a) at least ten (10) days prior written notice of the date on which the books of the Company shall close or a record shall be taken for such dividend or for determining rights to vote in respect of any such reorganization, reclassification, consolidation, merger, sale, dissolution, liquidation or winding-up, and (b) in the case of any such reorganization, reclassification, consolidation, merger, sale, dissolution, liquidation, winding-up or public offering, at least ten (10) days prior written notice of the date when the same shall take place; provided, however, that the Holder shall make a best efforts attempt to respond to such notice as early as possible after the receipt thereof. Any notice given in accordance with the foregoing clause (a) shall also specify, in the case of any such dividend, the date on which the holders of capital stock shall be entitled thereto. Any notice given in accordance with the foregoing clause (b) shall also specify the date on which the holders of capital stock shall be entitled to exchange their capital stock for securities or other property deliverable upon such reorganization, reclassification, consolidation, merger, sale, dissolution, liquidation, winding-up, conversion or public offering, as the case may be.

5. No Voting or Dividend Rights. Nothing contained in this Warrant shall be construed as conferring upon the Holder hereof the right to vote or to consent to receive notice as a stockholder of the Company or any other matters or any rights whatsoever as a stockholder of the Company. No dividends or interest shall be payable or accrued in respect of this Warrant or the interest represented hereby or the shares purchasable hereunder until, and only to the extent that, this Warrant shall have been exercised.

6. Warrants Non-Transferable. Neither this Warrant nor any of the rights hereunder may be transferred, in whole or in part, without the prior written consent of the Company.

7. Lost Warrants. Upon receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction, or mutilation of this Warrant and, in the case of any such loss, theft or destruction, upon receipt of an indemnity reasonably satisfactory to the Company, or in the case of any such mutilation upon surrender and cancellation of such Warrant, the Company, at its expense, will make and deliver a new Warrant, of like tenor, in lieu of the lost, stolen, destroyed or mutilated Warrant.

8. Amendment. Any term of this Warrant and all Warrants issued pursuant to the Agreement may be amended and the observance of any term of this Warrant and all Warrants issued pursuant to the Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively), only with the written consent of the Company and the holders of Warrants issued pursuant to the Agreement representing at least two-thirds of the Warrant Securities; provided any such amendment or waiver that affects by its terms any holder(s) in a manner that is different in any material respect from all holders shall require the approval of the Company, such holder(s) and the holders of at least two-thirds of the Warrant Securities issued pursuant to the Agreement. Any amendment or waiver effected in accordance with this paragraph shall be binding upon the Company, the Holder and the holders of all Warrants issued pursuant to the Agreement.

9. Notices. Except as may be otherwise provided herein, all notices, requests, waivers and other communications made pursuant to this Warrant shall be made in accordance with Section 5.6 of the Agreement.

10. Governing Law; Venue. This Warrant is to be construed in accordance with and governed by the internal laws of the State of Delaware without giving effect to any choice of law rule that would cause the application of the laws of any jurisdiction other than the internal laws of the State of Delaware to the rights and duties of the parties. All disputes and controversies arising out of or in connection with this Warrant shall be resolved exclusively by the state and federal courts located in the State of Delaware, and each party hereto agrees to submit to the jurisdiction of said courts and agrees that venue shall lie exclusively with such courts.

* * *

IN WITNESS WHEREOF, the Company has caused this Warrant to be duly executed by its officers, thereunto duly authorized as of the date first above written.

CATALYST BIOSCIENCES, INC.

By: _____

Name: Nassim Usman, Ph.D.

Title: President & Chief Executive Officer

FORM OF SUBSCRIPTION

(To be signed only upon exercise of Warrant)

To: Catalyst Biosciences, Inc.

The undersigned, the holder of a right to purchase shares of Stock of **CATALYST BIOSCIENCES, INC.**, a Delaware corporation (the "***Company***"), pursuant to that certain Warrant to Purchase Stock of **CATALYST BIOSCIENCES, INC.** (the "***Warrant***"), dated as of , 2015, hereby irrevocably elects to exercise the purchase right represented by such Warrant for, and to purchase thereunder, ( ) shares of Stock of the Company and herewith makes payment of Dollars ($) therefor by the following method:

(Check one of the following):

_____ (check if applicable) The undersigned hereby elects to make payment of Dollars ($) therefor in cash.

_____ (check if applicable) The undersigned hereby elects to make payment for the aggregate exercise price of this exercise using the Net Issuance method pursuant to Section 2 of the Warrant.

The undersigned represents that it is acquiring such securities for its own account for investment and not with a view to or for sale in connection with any distribution thereof and in order to induce the issuance of such securities makes to the Company, as of the date hereof, the representations and warranties set forth in Section 3 of the Note and Warrant Purchase Agreement, dated as of , 2015, by and among the Company and the investors listed on Exhibit A thereto.

DATED: _____

[NAME OF HOLDER]

By: _____

Name: _____

Its: _____

ACKNOWLEDGMENT

To: [name of Holder]

The undersigned hereby acknowledges that as of the date hereof, ( ) shares of Stock remain subject to the right of purchase in favor of [name of Holder] pursuant to that certain Warrant to Purchase Stock of **CATALYST BIOSCIENCES, INC.**, dated as of , 2015.

DATED: _____

CATALYST BIOSCIENCES, INC.

By: _____

Name: _____

Title: _____

Exhibit 21.1

List of Subsidiaries of Catalyst Biosciences, Inc.

Name	Jurisdiction of Incorporation
Catalyst Bio, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Catalyst Biosciences, Inc. and Subsidiaries on Form S-8 (Nos. 333-133882, 333-189143, 333-133881, 333-160331, 333-185888, 333-206523 and 333-206526) and Form S-3 (No. 333-192552) of our report dated March 9, 2016, on our audits of the consolidated financial statements as of December 31, 2015 and 2014, and for each of the years in the three-year period ended December 31, 2015, which report is included in the Annual Report on Form 10-K to be filed on or about March 9, 2016.

/s/ EisnerAmper LLP

Iselin, New Jersey
March 9, 2016

Exhibit 31.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Nassim Usman, certify that:

1. I have reviewed this report on Form 10-K of Catalyst Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2016

/s/ Nassim Usman, Ph.D.

Nassim Usman, Ph.D.
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Fletcher Payne, certify that:

1. I have reviewed this report on Form 10-K of Catalyst Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2016

/s/ Fletcher Payne

Fletcher Payne
Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Catalyst Biosciences, Inc. (the "Company") on Form 10-K for the year ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Nassim Usman, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 9, 2016

/s/ Nassim Usman, Ph.D.

Nassim Usman, Ph.D.
President and Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Catalyst Biosciences, Inc. (the "Company") on Form 10-K for the year ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Fletcher Payne, Chief Financial Officer and Principal Accounting Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 9, 2016

/s/ Fletcher Payne

Fletcher Payne
Chief Financial Officer