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, 2017

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	☒

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒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 15, 2018 was 11,893,644. The aggregate market value of the voting stock held by non-affiliates of the registrant as of June 30, 2017, was approximately $22,438,884.

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 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;
- our focus on specific product candidates;
- the progress, outcomes, 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;
- future performance and obligations under agreements we have entered into, such as the definitive agreement related to the termination of the Pfizer Agreement;
- 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 considering 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 our subsidiary, Catalyst Bio, Inc., which we refer to as "Catalyst Bio." See "Item 1 - Business - Business Overview."

ITEM 1. BUSINESS.

Overview

We are a clinical-stage biopharmaceutical company focused on developing novel medicines to address serious medical conditions for individuals who need new or better treatment options. We are focusing our product development efforts in the field of hemostasis (the process that regulates bleeding) and have a mission to develop valuable therapies for individuals with hemophilia. We engineered three improved therapeutic candidates that regulate bleeding and are advancing two into mid-stage clinical trials at this time.

Our most advanced program, a highly potent, subcutaneously administered, next-generation coagulation Factor VIIa variant, marzeptacog alfa (activated) ("MarzAA"), is currently enrolling individuals with hemophilia with an inhibitor in a Phase 2/3 subcutaneous dosing trial. The Phase 2 open-label subcutaneous efficacy trial will evaluate the ability of MarzAA to minimize spontaneous bleeding episodes in individuals with hemophilia A or B with an inhibitor. The trial will enroll up to 12 individuals with hemophilia and an inhibitor across up to ten clinical trial sites globally. MarzAA has successfully completed an intravenous Phase 1 clinical trial evaluating the pharmacokinetics, pharmacodynamics and coagulation activity in individuals with severe hemophilia A and B with and without an inhibitor. MarzAA has been granted orphan drug designation by the U.S. Food and Drug Administration ("FDA") for routine prophylaxis to prevent bleeding episodes in individuals with hemophilia A or B with inhibitors. Interim data is expected to be announced in July 2018.

Our next most advanced program, a highly potent next-generation coagulation Factor IX variant, CB 2679d/ISU304, has completed enrollment of a Phase 1/2 subcutaneous dosing trial in South Korea, that evaluated the safety and efficacy of CB 2679d/ISU304 in individuals with severe hemophilia B, sponsored by our collaborator, ISU Abxis. The objective of this study was to demonstrate the feasibility of increasing Factor IX activity trough levels from ~1% (severe hemophilia) to >12% (mild hemophilia with a reduced chance of spontaneous joint bleeds) with six daily subcutaneous injections. CB 2679d/ISU304 has been granted orphan drug designation by the FDA and orphan medicinal product designation by the Committee for Orphan Medicinal Products ("COMP") of the European Commission ("EC"). ISU Abxis initiated this trial in June 2017 and top line data was presented on February 9, 2018. Data from Cohorts 1 through 3 (three subjects in each cohort) showed that a single subcutaneous dose of either 75 or 150 IU/kg three days after a single intravenous dose of 75 IU/kg significantly increased the half-life of CB 2679d to 98.7 hours, equivalent to the half-life of extended-half-life intravenous agents. Cohort 4 was omitted as we observed sufficient activity of CB 2679d/ISU304 in cohorts 2 and 3.

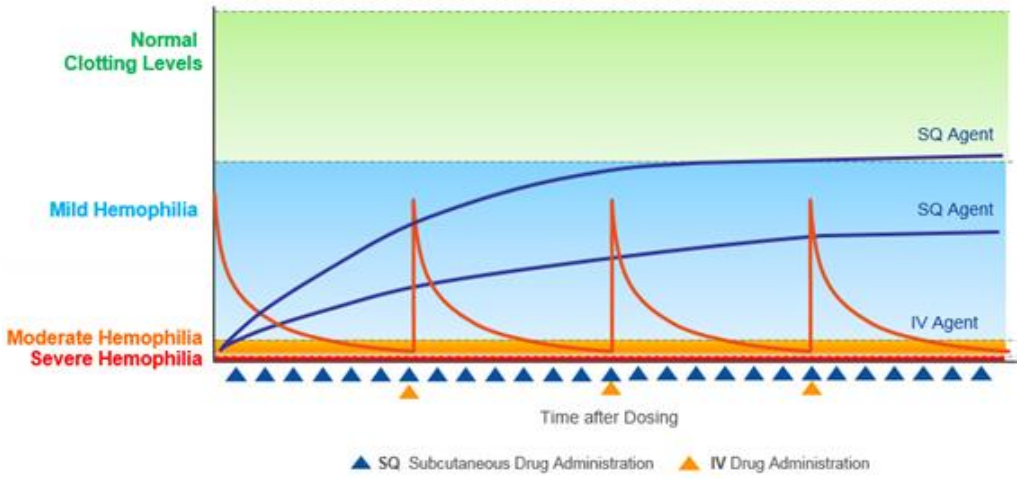
In cohort 5, 5 subjects were dosed daily for six days with a subcutaneous dose of 140 IU/kg without a preceding intravenous dose. We observed increased Factor IX activity levels in all five subjects from very low levels after washout of prior therapy to a median Factor IX activity level of 16% (range 11.5-18%), that is well into the mild hemophilia range (5-40%), and is higher than a level required to prevent spontaneous hemarthrosis. The observed increase in Factor IX activity levels after the daily dosing was linear, indicating that continued subcutaneous dosing may achieve high-mild hemophilia Factor IX clotting activity.

Terminal subcutaneous half-life was 63.2 hours (interquartile range 60.2-64 hours) with the result that activity levels were still 4-6.4% 5 days after the last dose. No inhibitors to CB 2679d/ISU304 or Factor IX were detected to date. One subject had moderate adverse events of pain, erythema and redness after the first 2 injections and mild rating after subsequent injections. Other subjects in cohort 5 reported some of these adverse events, mainly with initial injections. Two subjects had bruising after injection when Factor IX activity levels were low that did not occur with subsequent injections as Factor IX activity levels rose.

The substantially enhanced potency of marzeptacog alfa (activated) and CB 2679d/ISU304 compared with existing treatment options may allow for effective subcutaneous prophylactic treatment of individuals with hemophilia A or B with an inhibitor or individuals with hemophilia B, respectively, especially in children, and may ultimately deliver substantially better outcomes for individuals with hemophilia.

We believe that subcutaneous dosing of our next-generation factors may result in progressive increases in activity levels until they reach a stable therapeutic target range in the blood (ideally mild hemophilia to normal levels). Conversely, dosing by intravenous infusions results in high initial Factor levels in the blood followed by a rapid fall off in activity to a trough level in a range that is measured as moderate or severe hemophilia and resulting in higher bleeding risk. This concept is illustrated in the diagram below.

Time in Mild to Normal Predicts Protection from Spontaneous Bleeds
Illustrative Clotting Agent Activity Level



Stable and higher factor levels could potentially yield a significant improvement in outcomes and have the added benefit of convenience over competing intravenous therapeutics, particularly when administered to children, and where venous access is challenging.

We also have several Factor Xa variants that have demonstrated efficacy in several preclinical models and have the potential to be used as a universal procoagulant. We have delayed initiating further work on our Factor Xa therapeutic program at this time to focus our efforts on the Factor VIIa and Factor IX clinical programs.

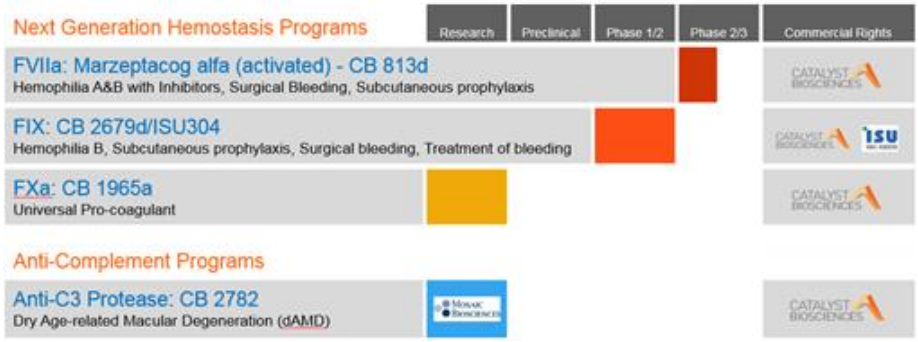
We continue to explore licensing opportunities for our anti-complement programs in dry AMD, however our focus remains on advancing marzeptacog alfa (activated) and CB 2679d/ISU304 through Phase 2/3 and Phase 2b clinical trials for hemophilia indications, respectively. In October 2017, we announced a strategic research collaboration with Mosaic Biosciences, Inc. to develop intravitreal anti-complement factor 3 products for the treatment of dry AMD and other retinal diseases.

Based on industry reports, we estimate annual worldwide sales in 2017 for FDA-approved recombinant protease products for individuals with hemophilia A and B and an inhibitor were approximately $1.2 billion and approximately $2.2 billion when including prothrombin complex concentrate products.

Our Product Candidate Pipeline

We are currently focused on the clinical development of improved, next-generation enhanced potency Factor VIIa and Factor IX variants for subcutaneous prophylaxis. We have delayed initiating further research on our Factor Xa therapeutic program at this time, and we have a strategic research collaboration for our novel anti-C3 protease program for dry AMD, CB 2728 that we intend to out-license.

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 reduced clotting factor levels.

Individuals with hemophilia suffer from spontaneous bleeding episodes and substantially prolonged bleeding times that can become limb- or life-threatening following injury or trauma. In cases of severe hemophilia, spontaneous bleeding into muscles or joints is frequent and often results in permanent, disabling joint damage. Individuals with hemophilia are currently treated with replacement therapy of key coagulation proteins, Factor VIII for Hemophilia A or Factor IX for Hemophilia B.

We believe that the shortcomings of currently approved therapies, including a requirement for intravenous infusion, are barriers to prophylactic treatment strategies that, if surmounted, could provide meaningfully improved long-term clinical outcomes for individuals with hemophilia. Catalyst's engineered FVIIa and FIX were designed to overcome current treatment limitations by allowing delivery via subcutaneous injection, which we believe will facilitate prophylactic treatment, especially in children, and may ultimately deliver substantially better outcomes for individuals with hemophilia.

Hemophilia A occurs in approximately 1 in 5,000 male births, and hemophilia B in 1 in 20,000 male births. The prevalence of hemophilia A and B in the United States is approximately 20,000 individuals out of an estimated, 400,000 individuals worldwide.

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

Based on our research, we estimate worldwide sales of all Factor IX-containing products for the treatment of hemophilia B in 2017 were at least $1.2 billion, including approximately $0.6 billion as reported by Pfizer, Inc. for its BeneFIX® product and $0.4 billion as reported by Bioverativ and Swedish Orphan Biovitrum for their Alprolix® product.

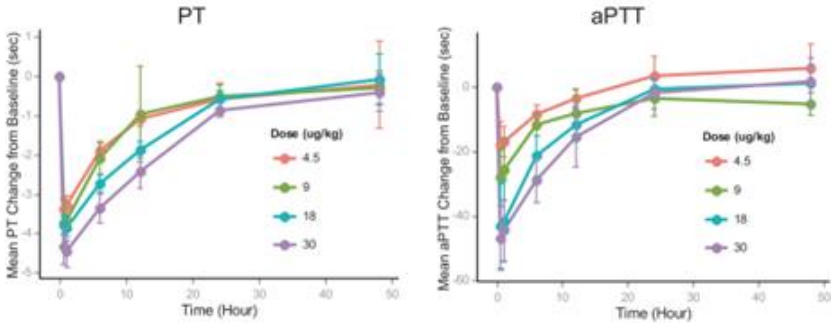
A complication for individuals with hemophilia who are receiving factor replacement therapy is the production of neutralizing antibodies, also called inhibitors, that inactivate the replacement factor. The overall prevalence of inhibitor formation is up to 30% in individuals with hemophilia A and up to 5% in individuals with hemophilia B. Individuals with an inhibitor 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 or inactivated in individuals with hemophilia A and B, respectively. Currently available bypassing agents include recombinant Factor VIIa, NovoSeven® RT produced by Novo Nordisk, activated prothrombin complex concentrates, marketed as FEIBA by Shire and Hemlibra®, produced by Roche. NovoSeven® was first approved in 1999 and is indicated for treatment of bleeding episodes, prevention of bleeding during surgeries in individuals with hemophilia A or B with inhibitors, and individuals with congenital Factor VII deficiency. In 2006, it was approved for the treatment of acquired hemophilia. NovoSeven® RT was approved in 2014 and is also indicated for treatment of Glanzmann's thrombasthenia. Sales of NovoSeven® RT in 2017, were $1.5 billion as reported by Novo Nordisk. FEIBA is approved for use in individuals with hemophilia A and B with an inhibitor, which we estimate, based on our research, had 2017 sales of $0.8 billion. Hemlibra® is a bispecific antibody that replaces the role of the cofactor FVIII by bringing FIXa and FX together for activation of FX and was approved by the FDA on November 16, 2017. Sales figures for Hemlibra® are not yet available.

Hemophilia Inhibitors—Clinical Stage Factor VIIa Program

Our most advanced product candidate is marzeptacog alfa (activated), a potent, subcutaneously administered, next-generation Factor VIIa variant, which was tested in an intravenous Phase 1 clinical trial that was completed in February 2015 to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and coagulation activity of marzeptacog alfa (activated) in severe hemophilia A and B with and without inhibitors. Marzeptacog alfa (activated) is being developed for the prophylactic treatment of individuals with severe hemophilia A and B with inhibitors. Pfizer filed the Investigational New Drug Application (IND) with the FDA for the Phase 1 trial in August 2011 for adult males with hemophilia A or B, with or without inhibitors to Factor VIII or Factor IX. We have received the IND application filed with the FDA from Pfizer and have initiated the Phase 2 portion of a Phase 2/3 clinical subcutaneous prophylaxis efficacy trial in December 2017 and interim data is expected to be announced in July 2018. Marzeptacog alfa (activated) has received orphan drug designation in the United States from the FDA.

In the Phase 1 clinical trial of intravenous marzeptacog alfa (activated) conducted by Pfizer, 25 individuals with severe hemophilia A and B with and without an inhibitor were enrolled and treated. The clinical trial design was a single ascending dose-escalation study with 1 individual treated at 0.5 µg/kg followed by 4 cohorts of 6 individuals 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 marzeptacog alfa (activated) were well tolerated and there were no instances of bleeding or thrombosis. As shown in the graph below, marzeptacog alfa (activated) demonstrated pharmacological efficacy as measured by significant shortening of aPTT (activated partial thromboplastin time) and PT (prothrombin time) for up to 24-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.

Substantial and dose dependent correction of PT & aPTT at all dose levels

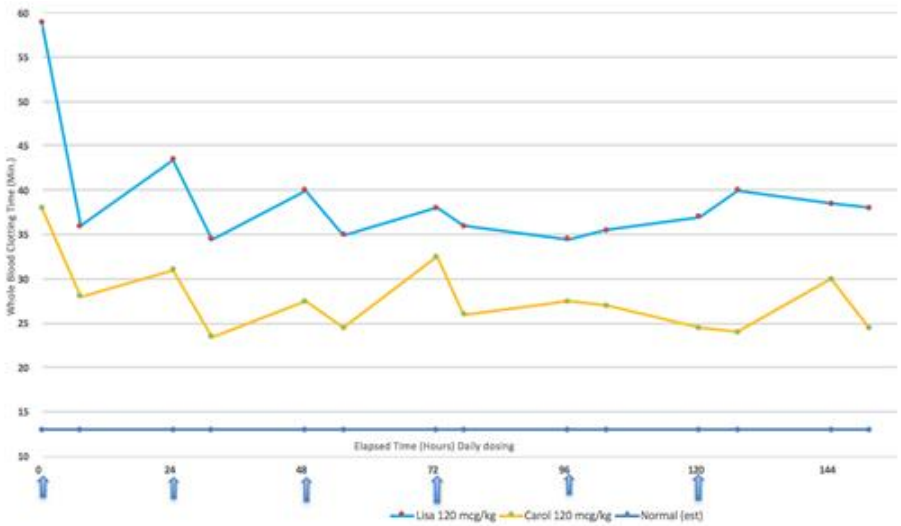


We designed marzeptacog alfa (activated) to combine higher clot-generating activity, or potency, at the site of bleeding and improved duration of action in vivo to allow for the effective, long-term, prophylaxis in individuals with hemophilia with inhibitors. We anticipate that this product candidate, if approved, could be used prophylactically to prevent bleeding episodes with subcutaneous administration that may be superior to intravenous infusions. We have previously demonstrated in several bleeding models that marzeptacog alfa (activated) can treat or prevent bleeding when dosed intravenously. The next step required to develop marzeptacog alfa (activated) for subcutaneous use was to test its ability to correct bleeding times in hemophilia models and to achieve sufficient plasma (blood) levels of activity when dosed subcutaneously.

During the past 12 months, we have presented data at scientific conferences demonstrating that daily subcutaneous administration in hemophilia B mice and hemophilia A dogs resulted in steady-state blood levels of marzeptacog alfa (activated) that correct the hemophilia coagulation impairment present at baseline as measured by whole blood clotting time and aPTT.

Marzeptacog alfa (activated) was dosed daily subcutaneously for 6 days in hemophilia A dogs and clotting parameters were measured. Whole blood clotting time after daily subcutaneous administration of 120 µg/kg marzeptacog alfa (activated) in hemophilia A dogs was substantially reduced.

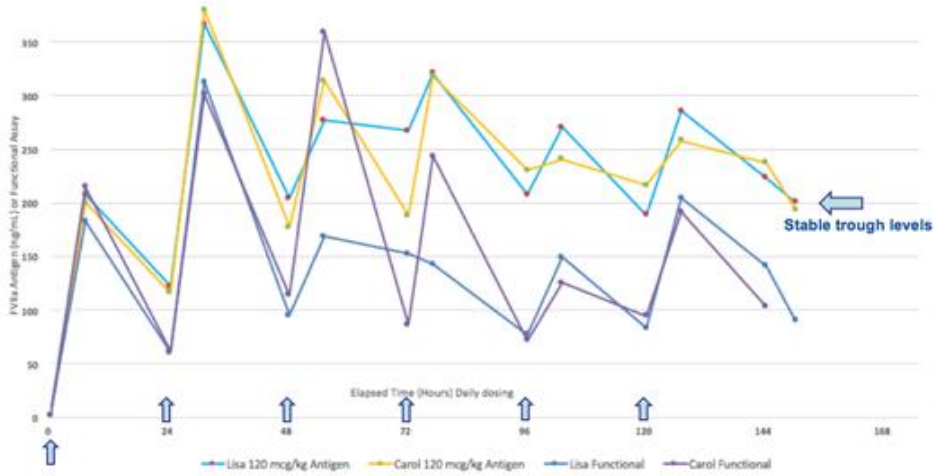
Whole blood clotting time after daily subcutaneous administration of 120 µg/kg marzeptacog alfa (activated)



Daily subcutaneous injections (arrows) can correct the whole blood clotting time in hemophilia A dogs

Antigen levels and functional assay after daily subcutaneous administration of 120 µg/kg marzeptacog alfa (activated) in dogs reached stable trough levels in our target range where we believe that similar results in humans will provide satisfactory continuous protection from spontaneous bleeding.

Antigen levels and functional assay after daily subcutaneous administration of 120 µg/kg marzeptacog alfa (activated)



Daily subcutaneous dosing (arrows) resulted in stable trough levels

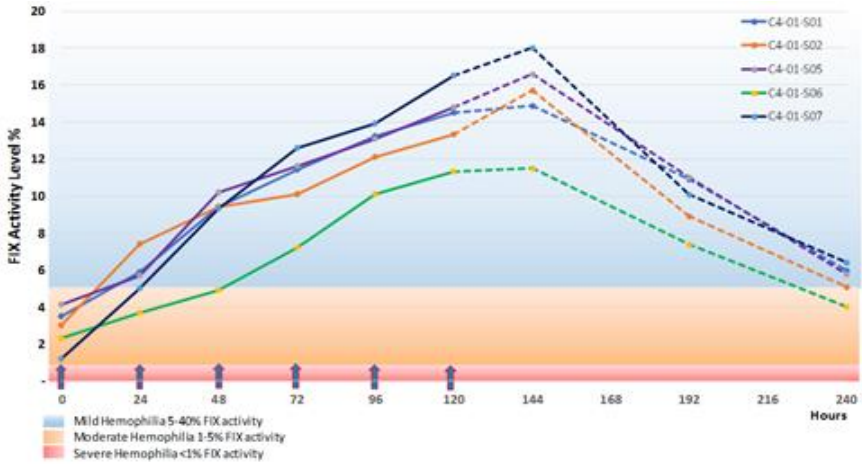
Hemophilia B—Factor IX

Our next most advanced product candidate is CB 2679d/ISU304, a next-generation subcutaneously dosed Factor IX drug for the prophylactic treatment of individuals with hemophilia B. The National Hemophilia Foundation has recommended chronic, prophylactic treatment as the optimal therapy for individuals with severe hemophilia B. We entered into a co-development agreement with ISU Abxis in 2013. 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 manufacturing preclinical development activities and clinical development through a proof-of-concept Phase 1/2 study in individuals with hemophilia B that was conducted 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. ISU Abxis may exercise its right of first refusal to acquire commercialization rights in South Korea, in which case they would be entitled to net profit sharing on worldwide sales.

Our partner ISU has completed enrollment of a Phase 1/2 subcutaneous dosing trial, evaluating safety and efficacy of CB 2679d/ISU304 in individuals with hemophilia B, sponsored by our collaborators, ISU Abxis. The objective of this study was to demonstrate the feasibility of increasing Factor IX activity trough levels from ~1% (severe hemophilia) to >12% (mild hemophilia with a reduced chance of spontaneous joint bleeds) with six daily subcutaneous injections. CB 2679d/ISU304 has been granted orphan drug designation by the FDA and orphan medicinal product designation by the Committee for Orphan Medicinal Products (“COMP”) of the European Commission (“EC”). ISU Abxis initiated this trial in June 2017 and top line data was presented on February 9, 2018.

Data from Cohort 1 demonstrated that CB 2679d/ISU304 has 22-fold higher potency than BeneFIX®, Pfizer’s currently marketed Factor IX therapeutic and an increased half-life. Cohorts 2 and 3 (three patients in each cohort) showed that a single subcutaneous dose of either 75 or 150 IU/kg three days after a single intravenous dose of 75 IU/kg significantly increased the half-life of CB 2679d to 98.7 hours, equivalent to the half-life of extended-half-life intravenous agents. Cohort 4 was omitted as we observed sufficient activity of CB 2679d/ISU304 in cohorts 2 and 3. In cohort 5, five patients were each dosed daily for 6 days with a subcutaneous dose of 140 IU/kg without a preceding intravenous dose. We observed increased Factor IX activity levels in the 5 patients from very low levels after washout of prior therapy to a median Factor IX activity level of 16% (range 11.5-18%), that is well into the mild hemophilia range (5-40%) and is higher than a level required to prevent spontaneous hemarthrosis. The observed increase in Factor IX activity levels after the daily dosing was linear, indicating that continued subcutaneous dosing may achieve high-mild hemophilia Factor IX clotting activity. The terminal subcutaneous half-life was 63.2 hours (interquartile range 60.2-64 hours) resulting in activity levels that were 4-6.4%, 5 days after the last dose. No inhibitors to CB 2679d/ISU304 or Factor IX have been detected to date.

Activity levels after six days daily subcutaneous administration of 140 IU/kg CB 2679d/ISU304 and washout



CB 2679d/ISU304 has demonstrated higher potency than BeneFIX®, Pfizer's currently marketed Factor IX therapeutic, and Alprolix®, Bioverativ's approved Factor IX-Fc fusion protein in preclinical studies and the Phase 1/2 clinical study, and therefore may allow for subcutaneous administration that provides trough Factor IX activity levels in blood in the high mild hemophilia range and provide prophylaxis against bleeding episodes. We are further evaluating the results from the Phase 1/2 clinical study and intend to commence a Phase 2b clinical trial of CB2679d/ISU304 in the third quarter of 2018.

The Complement Cascade as a Target for Inflammatory Disease

The complement cascade is a series of naturally occurring molecular processes that play a central role in the body's inflammatory and immune responses. It helps to localize certain 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 Dry Age-Related Macular Degeneration

Dry age-related macular degeneration, or dry AMD, is the leading cause of blindness in the elderly worldwide. According to the BrightFocus Foundation, AMD affects approximately 11 million people in the United States and 90% of the cases are related to dry AMD, with the potential size of the dry AMD market worldwide estimated at over $5 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 individuals with AMD. Dry AMD is the most common form of early to intermediate stage AMD and occurs in approximately 90% of individuals 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. Recently Apellis Pharmaceuticals (APL-2, anti-Complement Factor 3 cyclic peptide) announced positive statistical significant results from a randomized Phase 2 trial in reduction in geographic atrophy (GA) lesion growth associated with dry AMD with a monthly intravitreal injection over 12 months of therapy. This is the first clinical study to validate inhibition of complement, and specifically Complement Factor 3, as a treatment approach for GA associated dry AMD.

We have demonstrated that our novel anti-C3 proteases can clear C3 in the vitreous of primates and are well tolerated in single-dose studies. In October 2017, we announced a strategic research collaboration with Mosaic Biosciences, Inc. to develop intravitreal anti-complement factor 3 (C3) products for the treatment of dry AMD and other retinal diseases, allowing us to continue to focus our efforts and resources on advancing marzeptacog alfa (activated) and CB 2679d/ISU304 through Phase 2/3 and Phase 1/2 clinical trials, respectively.

Our Strategy

Our goal is to build a clinical-stage biopharmaceutical company whose mission is to develop valuable therapies for individuals with hemophilia who need new or better treatment options. 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, marzeptacog alfa (activated), for the treatment of hemophilia and to facilitate surgery in hemophilia, has completed a Phase 1 intravenous dosing clinical trial evaluating safety and tolerability as well as pharmacokinetics, pharmacodynamics and coagulation activity. We have advanced marzeptacog alfa (activated) into the Phase 2 portion of a Phase 2/3 subcutaneous dosing clinical efficacy trial in individuals with hemophilia A and B with an inhibitor in December 2017. In addition, our collaborator ISU Abxis has completed enrollment of a Phase 1/2 subcutaneous dosing clinical trial of CB 2679d/ISU304, our next-generation Factor IX drug candidate in individuals with severe hemophilia B, and we are expecting to advance this product candidate into a Phase 2b clinical study.

- ***Leverage Existing Strategic Factor IX Collaboration:*** We have a collaboration with ISU Abxis for its CB 2679d/ISU304 program. We are entitled to milestone payments 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.

- ***Build a Hemostasis Franchise:*** We intend to build on our recent clinical success of our Factor VIIa and Factor IX candidates by completing the Phase 2 portion of a Phase 2/3 clinical efficacy trial of our Factor VIIa program in 2018 and initiating a Phase 2b trial of our Factor IX product candidate in the third quarter of 2018. The combination of these two product candidates in later-stage clinical development may allow us to build a hemostasis franchise if these product candidates are approved.

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. 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. On December 8, 2016, we signed a definitive agreement related to the termination of the Pfizer Agreement. Pursuant to this termination agreement, Pfizer granted us an exclusive license to Pfizer's proprietary rights for manufacturing materials and processes that apply to Factor VIIa variants, CB 813a and marzeptacog alfa (activated). Pfizer also transferred to us the IND application and documentation related to the development, manufacturing and testing of the Factor VIIa products as well as the orphan drug designation.

Pursuant to this agreement, we agreed to make contingent cash payments to Pfizer in an aggregate amount equal to up to $17.5 million, payable upon the achievement of clinical, regulatory and commercial milestones. Following commercialization of any covered product, Pfizer would also receive a single-digit royalty on net product sales on a country-by-country basis for a predefined royalty term. In February 2018, we paid Pfizer a $1 million milestone payment based on the dosing of the first patient in the ongoing Phase 2 study.

ISU Abxis

On September 16, 2013, we signed a License and Collaboration Agreement with ISU Abxis, as subsequently amended on October 31, 2014 and on December 7, 2016, or the ISU Abxis agreement. Under the terms of the agreement, ISU Abxis is responsible for manufacturing, preclinical development activities and clinical development through completion of a proof-of-concept Phase 1/2 study in individuals with hemophilia B. The Company has the sole rights and responsibility for worldwide development, manufacture, and commercialization of Factor IX

products after Phase 1/2 development. ISU Abxis may exercise its right of first refusal to acquire commercialization rights in South Korea, in which case they would be entitled to profit sharing on worldwide sales. ISU's rights will also terminate if the Company enters into a license agreement with another party to develop, manufacture and commercialize Factor IX products in the United States, European Union or Asia, subject to ISU's retained rights in South Korea.

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 $2.75 million payable based upon the achievement of predefined development milestones, of which two have been achieved for a total of $0.9 million as of December 31, 2017. In addition, we agreed to pay ISU Abxis, for certain preclinical IND enabling studies and will owe 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 1/2 clinical study is not completed by a certain date.

As of December 31, 2017, the cumulative aggregate payments received and recognized by us under this agreement were $2.4 million, and we had made reimbursements of $0.4 million to ISU Abxis, associated with certain preclinical studies. We had a deferred revenue balance of $0.2 million as of December 31, 2017 related to the ISU Abxis collaboration.

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 26, 2018, our patent portfolio included approximately 145 patents; including 15 issued U.S. patents and 130 foreign granted and accepted patents, and 2 U.S. patent applications, plus an additional 33 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.

We are aware of a patent that issued in Europe (with counterparts in Australia, China, Japan, Poland and South Korea) that includes a claim that may read on marzeptacog alfa (activated). This patent expires in September 2021. An opposition proceeding with respect to this patent sustained the patent; we filed an appeal on November 11, 2016. There can also be no assurance whether the claims of such patent would be found to read on marzeptacog alfa (activated) even if a claim survives opposition. There is another patent family pending in the U.S. and Europe in which claims that may read on marzeptacog alfa (activated) have been filed. We, however, do not believe such claims, are patentable. If they were to issue, we would take appropriate action to challenge their enforceability and/or validity. 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 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 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 (4 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:

- 66 patents, including 2 issued U.S. patents, and 7 patent applications, including 1 pending U.S. patent application, covering modified Factor VII polypeptides, such as our lead product candidate, marzeptacog alfa (activated), and methods of production of modified Factor VII polypeptides. The U.S. patents, with

patent term adjustment, expire in 2031 and 2029. The foreign patents and patent applications, if granted, expire, or are expected to expire, respectively, in 2028-2029.

- 16 patents, including 3 issued U.S. patents, and 11 patent applications, including 1 U.S. patent application, covering modified Factor IX polypeptides, such as our clinical candidate CB 2679d/ISU304. The issued U.S. patents, including patent term adjustment, expire in 2030-2032 and the foreign patents and patent applications, if granted, expire, or are expected to expire, respectively, in 2031.

- 6 patents, including 2 issued U.S. patents, and 10 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.

- 53 patents, including 5 issued U.S. patents, and 7 patent applications, covering novel proteases. The U.S. patents, including patent term adjustment, expire in 2025-2029, and the foreign patents and foreign patent applications, if granted, expire, or are expected to expire, in 2025-2027.

- 4 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 and 2030, and the foreign patents expire in 2027.

- 1 issued U.S. patent covering the MTSP-1 protease scaffold used for our novel proteases, which expires 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. The regulatory review period that occurs after the patent to be extended was issued is eligible to be counted for extension. The extension is calculated as one-half of the time of the testing phase added to time in the approval phase. The testing phase is the period between the effective date of an investigational product exemption (Investigational New Drug Application) and the initial submission of the marketing application (New Drug Application). The approval phase is the period between the submission and approval of the marketing application. Extensions can be reduced by any time that the applicant did act not with due diligence as determined by the FDA. 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 marzeptacog alfa (activated), CB 2679d/ISU304, 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 intellectual property described above, we obtained the intellectual property related to a neural nicotinic receptor ("NNR") portfolio from our business combination with Targacept, Inc. completed in August 2015 (See "Business Organization"). We completed the process of out-licensing, selling off and terminating the remaining NNR portfolio in 2016.

Manufacturing

We do not have any manufacturing facilities. We currently rely, and expect 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 was responsible for manufacturing marzeptacog alfa (activated) for clinical trials pursuant to our license and collaboration agreement with Pfizer.

On May 20, 2016, we signed a Development and Manufacturing Agreement (the DMA Agreement) with AGC Biologics, Inc. (AGC), formerly known as CMC ICOS Biologics, Inc., pursuant to which AGC will conduct drug substance manufacturing development and, upon successful development of the manufacturing process, manufacture the drug substance marzeptacog alfa (activated) that the Company intends to use in its clinical trials on a fee-for-services basis. We will own all intellectual property developed in such manufacturing development activities that are specifically related to marzeptacog alfa (activated) and will have a royalty free and perpetual license to use AGC's intellectual property to the extent reasonably necessary to make marzeptacog alfa (activated), including commercial manufacturing. We have agreed to a total of $3.8 million in payments to AGC pursuant to the initial statement of work under the DMA Agreement, subject to completion of applicable work stages, $3.1 million has been paid as of December 31, 2017. We have completed the transfer of manufacturing technology from Pfizer to AGC and together with AGC we have successfully manufactured marzeptacog alfa (activated) for the Phase 2 portion of a planned Phase 2/3 clinical trial.

On December 14, 2016, we signed a Master Services Agreement with Symbiosis Pharmaceutical Services Limited, pursuant to which Symbiosis will conduct Drug Product manufacturing development and, upon successful development of the manufacturing process, manufacture the Drug Product marzeptacog alfa (activated) that the Company intends to use in its clinical trials on a fee-for-services basis. We have completed the transfer of manufacturing technology from Pfizer to Symbiosis and together with Symbiosis have successfully manufactured marzeptacog alpha (activated) for our Phase 2/3 clinical trial.

ISU Abxis was responsible for manufacturing CB 2679d/ISU304, our next-generation Factor IX drug candidate, through the completion of Phase 1/2 clinical trials, after which point we will be responsible for manufacturing this product candidate. In February 2018 we engaged AGC for the process transfer and commercial-scale cGMP manufacturing of CB 2679d/ISU 304. We have agreed to a total of approximately $5.6 million in payments pursuant to the new statement of work, including the commercial scale manufacturing of CB 2679d/ISU 304, subject to completion of applicable work stages.

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/ISU304 in South Korea, we generally expect to retain commercial rights for our 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.

Competition

Some of our product candidates will face competition from approved therapeutics. Competition for our product candidate pipeline 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 individuals into clinical trials.

In addition to current standard of care for individuals, clinical trials are being pursued by several 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 publicly 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 approved by the FDA in 1999 for use in the treatment of individuals with hemophilia A or B with an inhibitor to Factor VIII or Factor IX. The treatment has since been approved for use in individuals with Factor VII deficiency and Glanzmann's thrombasthenia. Shire's FEIBA is a plasma-based composition of coagulation factors indicated for on-demand and prophylactic use in the treatment of individuals with hemophilia A or B with an inhibitor to Factor VIII or Factor IX and has been on the market for more than 30 years. Roche's Hemlibra®, a bispecific Factor IXa-Factor X monoclonal antibody for routine prophylaxis in adults and children with hemophilia A with a Factor VIII inhibitor received approval from the FDA on November 16, 2017. Several other companies have competing products under development, including companies developing biosimilars of NovoSeven®, such as rEVO Biologics LF769, whose BLA is currently under review by the FDA, Alnylam, whose investigational RNAi therapeutic targeting antithrombin for the treatment of hemophilia is in a Phase 3 clinical trial. CSL Behring is developing an albumin–linked Factor VIIa that has an extended half-life and is currently in a Phase 2/3 study and OPKO Biologics, whose recombinant Factor VIIa product that may also be administered subcutaneously, is in a Phase 1/2 clinical trial. Novo Nordisk, Bayer and Pfizer are also developing subcutaneously administered agents that neutralize Tissue Pathway Factor Inhibitor that are in mid-stage trials.

- ***Factor IX Competition:*** BeneFIX, a recombinant Factor IX indicated for treatment of individuals with hemophilia B, was approved in 1997 and is marketed by Pfizer, which, according to Pfizer's Annual Report on Form 10-K, reported 2017 revenues of $0.6 billion. In addition, Alprolix®, a Factor IX-Fc fusion product was approved in 2014, and is marketed by Bioverativ and Swedish Orphan Biovitrum (SOBI - in Europe, Russia, North Africa and the Middle East) with 2017 revenues of $0.4 billion, and Rixubis, a recombinant Factor IX biosimilar was approved in 2013, and is marketed by Baxalta. CSL Behring announced that their biologics license application (BLA) for their Idelvion (rFIX) product was approved by the FDA on March 4, 2016 and Novo Nordisk's glycopegylated-Factor IX product was approved by the FDA on May 31, 2017, but is not indicated for routine prophylaxis.

- ***Dry AMD Competition:*** While there are no currently approved treatments for dry AMD that we believe would pose a long term competitive risk, several companies, including Apellis, Ophthotech and Novartis are developing cyclic peptide, aptamer or antibody-based anti-complement product candidates for the treatment of dry AMD that are currently in, or have completed, Phase 2 studies. Of note, Apellis' APL-2 (anti-C3 cyclic peptide) demonstrated statistically significant efficacy in reducing the growth rate of geographic atrophy lesions associated with dry AMD in a randomized Phase 2 study with monthly intravitreal injections over a 12-month period.

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 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 or untitled 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.

US 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 substantial 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 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 may 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.

- ***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.

In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in instances where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible such as in rare or orphan diseases like hemophilia. In the case of hemophilia, almost all clinical trials are conducted as open-label trials, in which both the researchers and participants know which treatment is being administered and there is no placebo or blinded portion of the trial because there are too few subjects available in these orphan populations to perform statistically powered placebo or active comparator trials. Endpoints for on-demand therapies are the number of treatments required to control bleeding episodes and for prophylaxis therapies are the calculated annualized bleeding rates. Bleeding rates during the trial are compared to historic bleeding rates for participating individuals. Patients are studied for at least 50 treatment days to see if neutralizing anti-drug antibodies (inhibitors) develop.

Pursuant to the 21st Century Cures Act, which was enacted on December 13, 2016, the manufacturer of an investigational drug for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access to such investigational drug. This requirement applies on the later of 60 calendar days after the date of enactment of the law or the initiation of a Phase 2 or Phase 3 trial of the investigational drug.

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.

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.

US 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 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. Marzeptacog alfa (activated) has been granted orphan drug designation for routine prophylaxis to prevent bleeding episodes in individuals with hemophilia A and B with inhibitors.

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 generally 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 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 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 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 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 areas 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 a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Marzeptacog alfa (activated) has been granted orphan drug designation for routine prophylaxis to prevent bleeding episodes in individuals with hemophilia A and B with inhibitors. 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.

Marketing Exclusivity and U.S. Patent Term Restoration

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, 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.

Disclosure of clinical trial information

Sponsors of clinical trials of FDA-regulated products, including biological products, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

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 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 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 its facts and circumstances. Our practices may not in all cases meet all 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 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.

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 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 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 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. This is also true of Medicare reimbursement, where different vendors process payments, so that coverage by one vendor does not assure that all other vendors will provide coverage. 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. In addition, the United States federal government position on matters related to drug pricing is evolving and uncertain, and any changes could have a material impact on drug pricing generally in the United States, including for our product candidates if approved.

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. NICE in the United Kingdom also requires consideration of cost-benefit analysis. 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 $12.8 million and $11.6 million for the years ended December 31, 2017 and 2016, 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, 2017, we had 13 full-time employees, 3 of whom have Ph.D. or M.D. degrees. Of these full-time employees, 6 employees are engaged in manufacturing and clinical development activities and 7 employees are engaged in finance, business development, 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.

Business Organization

We commenced operations in 2002 and are a Delaware corporation. On August 20, 2015, we ("Catalyst Bio") completed our 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 Catalyst Bio prior to the merger. In this annual report, we refer to the business combination as the "merger," to the Company prior to the merger as "Targacept." Discussions of historical results reflect the results of Catalyst Bio 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 in South San Francisco, California. 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 "*Part II - Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations*" and our consolidated financial statements and related notes.

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 $21.6 million and $16.9 million for the years ended December 31, 2017 and 2016, respectively. As of December 31, 2017, we had an accumulated deficit of $173.5 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 through issuances of shares of common stock, from private placements of convertible preferred stock, and from payments under collaboration agreements.

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 marzeptacog alfa (activated);
- continue clinical development of CB 2679d/ISU304;
- further develop the manufacturing process for our product candidates;
- 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-license 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.

In addition, in connection with the license granted to us by Pfizer, we agreed to make contingent cash payments to Pfizer in an aggregate amount equal to up to $17.5 million, payable upon the achievement of clinical, regulatory and commercial milestones, the timing of which is uncertain. Following commercialization of any Factor VIIa products, Pfizer would also receive a single-digit royalty on net product sales on a country-by-country basis for a predefined royalty term. See "*Item 1 - Business—Collaborations*" in this Annual Report on Form 10-K.

Further, in connection with an initial statement of work under the Development and Manufacturing Agreement that we have entered into with AGC Biologics, Inc. ("AGC"), formerly known as CMC ICOS Biologics, Inc., we have agreed to a total of $3.8 million in payments to AGC, of which $3.1 million has been paid as of December 31, 2017, subject to the completion of work relating to the manufacturing development of marzeptacog alfa (activated). We have also agreed to pay AGC approximately $5.6 million the process transfer and commercial scale cGMP manufacturing of CB 2679d, Catalyst's highly potent next-generation coagulation FIX variant being developed for the treatment of severe hemophilia B. See "*Item 1 - Business - Collaborations*" in this Annual Report on Form 10-K.

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, 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 with our ongoing activities, particularly activities related to the continued clinical development of marzeptacog alfa (activated) and CB 2679d, including clinical efficacy trials for each compound. We believe that our available cash will be sufficient to fund our operations at for at least the next 12 months from the date of this Annual Report on Form 10-K. However, we will need to raise substantial additional capital to complete the development and commercialization of marzeptacog alfa (activated), CB 2679d/ISU304, and depending on the availability of capital, may need to delay development of some of our product candidates.

Until we can generate a sufficient 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 marzeptacog alfa (activated) and CB 2679d/ISU304;
- 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.

In March 2016, we filed a shelf registration statement on Form S-3 with the SEC, which registration statement was declared effective on April 28, 2016 and allows us to offer up to $50 million of securities from time to time in one or more offerings (the 2016 Registration Statement). Through a Capital on Demand™ Sales Agreement with JonesTrading Institutional Services LLC (“JonesTrading”), we sold an aggregate of 479,681 shares of common stock in the open market at a weighted-average selling price of $13.55 per share, for net proceeds (net of commissions) of $6.3 million through December 31, 2017, of which $5.5 million were sold in the year ended December 31, 2017, in the Capital on Demand™ program. In addition, in December 2017, we sold an aggregate of 1,105,263 registered shares of common stock at a price to the public of $9.50 per share, for net proceeds to us, after deducting underwriting discounts and commissions and offering expenses payable by us, of approximately $9.7 million. Pursuant to the 2016 Registration Statement, we may sell up to approximately $33 million in additional securities in one or more offerings. In addition, in January 2018, we filed a shelf registration statement with the SEC, which registration statement was declared effective on February 6, 2018, and allows us to offer up to $150 million of securities from time to time in one or more offerings. (the 2018 Registration Statement). On February 13, 2018, we sold an aggregate of 3,382,352 registered shares of common stock at a price to the public of $34 per share, for net proceeds to us, after deducting underwriting discounts and offering expenses payable by us, of approximately $106.7 million. Pursuant to the 2018 Registration Statement, we may sell up to approximately $35 million in additional securities in one or more offerings.

Any additional sales in the public market of our common stock or other securities under these shelf registration statements could adversely affect prevailing market prices for our common stock.

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.

Redemption of our outstanding redeemable convertible notes will reduce our assets and liabilities

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. Holders were able to elect to convert any principal amount of the notes into shares of common stock at a price of $137.85 per share on or before February 19, 2018. As of December 31, 2017, $31.6 million in aggregate principal has been redeemed and $0.3 million had been converted to common stock. On February 19, 2018, the remaining $5.1 million in outstanding notes were redeemed, resulting in release of the restricted cash held in escrow to pay all redemptions.

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

We are substantially dependent upon the success of marzeptacog alfa (activated) and CB 2679d/ISU304.

The failure of marzeptacog alfa (activated) or CB 2679d/ISU304 to achieve successful clinical trial endpoints, or delays in clinical development, unanticipated adverse side effects or any other adverse developments or information related to marzeptacog alfa (activated) or CB 2679d/ISU304 would significantly harm our business, its prospects and the value of the company's common stock. We expect to continue and complete the Phase 2 portion of a Phase 2/3 subcutaneous dosing trial of marzeptacog alfa (activated) in individuals with hemophilia A and B inhibitors and to advance CB 2679d/ISU304 into a Phase 2b study in 2018. There is no guarantee that the results of these clinical trials, if they occur, will be positive or will not generate unanticipated safety concerns. The Phase 1 clinical trial of marzeptacog alfa (activated) 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 marzeptacog alfa (activated) in individuals who received the product candidate. While so far none of the patients in this trial developed any inhibitory antibodies, there can be no assurance that such antibodies will not be observed in the future, either in the patients who have already received CB 2679d/ISU 304, or in new patients. If the current subcutaneous multi-dose trials of marzeptacog alfa (activated) or of CB 2679d/ISU304 demonstrate treatment-related neutralizing immunological responses, development of such product could be halted. Even if the next trials of marzeptacog alfa (activated) and CB 2679d/ISU304 are positive, each product candidate may require substantial additional trials and other testing before being approved for marketing.

Marzeptacog alfa (activated) and CB 2679d/ISU304 are not expected to be commercially available in the near term, if at all. Further, the commercial success of each product candidate 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 marzeptacog alfa (activated) and CB 2679d/ISU304, 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.

Even if the FDA or other regulatory agency approves marzeptacog alfa (activated) or CB 2679d/ISU304, 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 marzeptacog alfa (activated) or CB 2679d/ISU304 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 marzeptacog alfa (activated) or CB 2679d/ISU304 would be limited.

We are developing the clinical trial plan for CB 2679d/ISU304, and the timing and expense of future clinical trials of CB 2679d/ISU304 is uncertain.

While we have announced top-line data from our Phase 1/2 study of subcutaneous prophylactic candidate CB 2679d/ISU304 and plans to commence a Phase 2b clinical trial in the third quarter of 2018, we are still analyzing data from the Phase 1/2 clinical trial and are evaluating plans for subsequent clinical trials, including the specific trial design, inclusion/exclusion criteria, number of patients, clinical trial sites and other factors. We are not certain when additional trials of CB 2679d/ISU304 will begin, how long such trials will take to enroll or complete, or how much they will cost. Any additional trials we conduct may not start when anticipated, may take longer to enroll or cost more than expected, and may not generate positive results.

We are conducting clinical trials for subcutaneous dosing trials of marzeptacog alfa (activated) and CB 2679d/ISU304, which is an untested route of administration for these product candidates in humans.

We are conducting a subcutaneous prophylaxis clinical trial of marzeptacog alfa (activated), results of which are expected in July 2018. There can be no assurance that marzeptacog alfa (activated) will achieve efficacious levels of biological activity when administered subcutaneously. There can also be no assurance that the clinical trial results will be positive or that the clinical trials will not generate unanticipated safety concerns. In addition, ISU Abxis had conducted a subcutaneous prophylaxis clinical trial of CB2679d/ISU304, initial results of which have been disclosed. The failure of either product to achieve successful clinical trial endpoints, delays in clinical development, unanticipated adverse side effects, adverse immunological responses, or any other adverse developments or information related to our product candidates would significantly harm our business, its prospects and the value of our common stock.

Marzeptacog alfa (activated) and CB 2679d/ISU304 may cause the generation of neutralizing antibodies, which could prevent their further development.

Both marzeptacog alfa (activated) and CB 2679d/ISU304 are protein molecules which may cause the generation of antibodies in individuals who receive them. The Phase 1 clinical trial of marzeptacog alfa (activated) was a single-dose intravenous escalation trial that would not, compared with multi-dose trials or higher doses administered subcutaneously, be expected to exclude the possibility of an immunological response to marzeptacog alfa (activated) in individuals who received the product candidate. CB 2679d/ISU304 has only recently been used in a multi-dose subcutaneous clinical trial in five patients. While so far none of the patients in this trial developed any inhibitory antibodies, there can be no assurance that such antibodies will not be observed in the future, either in the patients who have already received CB 2679d/ISU 304, or in new patients.

If multi-dose trials demonstrate a treatment-related neutralizing immunological response in individuals, development of marzeptacog alfa (activated) or of CB 2679d/ISU304 could be halted.

Marzeptacog alfa (activated) and CB 2679d/ISU304 are in early clinical trials, and all of our other product candidates are still in preclinical development. If we are unable to obtain regulatory clearance and commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

Marzeptacog alfa (activated) and CB 2679d/ISU304 are in Phase 2/3 and Phase 1/2 clinical trials, respectively. All our other product candidates are still in preclinical development. Engineered protease biopharmaceuticals are a relatively new class of therapeutics. There can be no assurance as to the length of the trial period, the number of

individuals the FDA will require to be enrolled in the trials 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 or foreign regulatory agencies to support marketing approval. 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 our 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 or Phase 2 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 suitable 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. Our Phase 2 trial of marzeptacog alpha (activated) is being conducted in twelve patients, and CB

2679d/ISU 304 has been dosed repeatedly in a subcutaneous prophylaxis trial in only five patients. Trials of these product candidates in larger numbers of patients may not have similar efficacy results, and could result in adverse effects that were not observed in the earlier trials with smaller numbers of patients.

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. Any such limitations could adversely affect the value of our product candidates or common stock.

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 is a relatively small number of individuals with hemophilia, that may cause delays in enrollment of clinical trials of marzeptacog alfa (activated) in individuals with hemophilia A and B with an inhibitor or CB 2679d/ISU304 in individuals with hemophilia B. 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.

Risks related to our reliance on third parties

We depend on our collaborative relationship with ISU Abxis for the initial development of CB 2679d/ISU304.

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/ISU304, 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/ISU304, and may have limited or no ability to control such decisions with respect to other product candidates subject to collaboration agreements;
- ISU Abxis may manufacture insufficient amounts or quality of product for a clinical trial, or have difficulty transferring manufacturing of CB 2679d/ISU304 to a CMO if needed for future clinical trials, or may experience delays in either case;
- ISU Abxis may delay clinical trials or, provide insufficient funding 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/ISU304;
- 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/ISU304.

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 marzeptacog alfa (activated) and might also seek collaborators for CB 2689d/ISU304 or our earlier stage programs. In addition, full development efforts on the use of our novel proteases for the treatment of dry AMD will likely involve significant cost, and we do not expect to conduct any such efforts except in collaboration with one or more partners who are willing to pay for such costs.

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 are transitioning manufacturing and clinical activities related to marzeptacog alfa (activated) and CB2679d/ISU304 from Pfizer and ISU Abxis, respectively, to AGC and continuing to optimize the manufacturing processes for these candidates. This process will be lengthy and its outcome uncertain.

Pfizer, through its wholly-owned subsidiary Wyeth, conducted the Phase 1 clinical trial of marzeptacog alfa (activated) pursuant to a research and license agreement. Pfizer terminated this agreement effective June 1, 2015. ISU Abxis conducted the Phase 1/2 clinical trial of CB2679d/ISU 304 and was responsible for manufacturing clinical trial materials for this study.

In March 2016, we engaged AGC to conduct manufacturing development and, upon successful development of the manufacturing process, manufacture the marzeptacog alfa (activated) that we intend to use in our clinical trials on a fee-for-services basis. In addition, in February 2018, we engaged AGC to conduct process transfer and commercial scale manufacturing of CB 2679d/ISU 304 for use in our clinical trials. Manufacturing of biological therapeutics such as marzeptacog alfa (activated) and CB2679d/ISU304 is complex and scale-dependent, and we may need to further optimize the manufacturing process of these product candidates. There can be no assurance that AGC will be able to manufacture sufficient quantities of marzeptacog alfa (activated) to satisfy our clinical trial requirements in a timely manner, within expected budgets or at all. Delays in the manufacture of CB2679d/ISU 304 could delay the start of our anticipated Phase 2b clinical trial.

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 BLA 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 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 or do not have a GMP compliance status acceptable for the FDA, 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 BLA 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.

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. We have previously relied on collaborators, such as Pfizer and ISU Abxis, to contribute to the development of our product candidates, and we are currently working with Mosaic Biosciences to support the development of our dry AMD product candidates. 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 marzeptacog alfa (activated) and might also seek collaborators for CB 2689d/ISU304 or our earlier stage programs. In addition, full development efforts on the use of our novel proteases for the treatment of dry AMD will likely involve significant cost, and we do not expect to conduct any such efforts except in collaboration with one or more partners who are willing to pay for such costs.

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.

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 Medical Officer, Dr. Levy, our Chief Financial Officer, Fletcher Payne, and our Senior Vice President of Technical Operations, Andrew Hetherington. 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-US regulators, to provide accurate information to the FDA and non-US regulators, to comply with healthcare fraud and abuse laws and regulations in the United States and abroad, to report financial information or data accurately or to 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 during 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 management is required to devote substantial time to compliance initiatives, particularly after the completion of a one-year transition period to full compliance.

Upon 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 Catalyst from before the merger 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 have and will continue to 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 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. 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 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 was not 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, 2017, based on the SEC's guidance for reporting over smaller reporting companies. 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 U.S. from a serious disaster.

Our offices are located in the San Francisco Bay Area, which is prone to earthquakes. 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 U.S. 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 U.S. 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 partes* 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 marzeptacog alfa (activated). An opposition proceeding with respect to this patent sustained this patent, and we filed an appeal on November 11, 2016. There can also be no assurance whether or not the claims of such patent would be found to read on marzeptacog alfa (activated) 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 is 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.

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. Marzeptacog alfa (activated) is in a Phase 2 clinical trial, and CB 2679d/ISU 304 has completed the Phase 2 portion of a Phase 2/3 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.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the PPACA, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. The new Presidential Administration and U.S. Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the PPACA. It is uncertain the extent to which any such changes may impact our business or financial condition. In addition, individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product and

medical device pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, in October 2017, California passed a new law, to become effective in January 2019, which will require transparency from biopharmaceutical companies regarding price increases for prescription drugs. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and medical devices to purchase and which suppliers will be included in their prescription drug and other healthcare programs. 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 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 for 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 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 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, results of operations, or cash flows.

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 several 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.

Our product candidates are years away from regulatory approval.

Marzeptacog alfa (activated) and CB 2679d/ISU304 are not expected to be commercially available for several years, if at all. Further, the commercial success of either product candidate will depend upon its acceptance by physicians, individuals, third-party payors and other key decision-makers as a therapeutic and cost-effective alternative to products available at the time, which may include competing products currently under development by others. See “We face substantial competition that may result in others discovering, developing or commercializing products before or more successfully than we do.” If we are unable to successfully develop, obtain regulatory approval for and commercialize marzeptacog alfa (activated) or CB 2679d/ISU304, 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.

Even if the FDA or other regulatory agency approves marzeptacog alfa (activated) or CB 2679d/ISU304, 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 marzeptacog alfa (activated) or CB 2679d/ISU304 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 marzeptacog alfa (activated) or CB 2679d/ISU304 would be limited.

If we are unable to establish sales, marketing and distribution capabilities, we may not be successful in commercializing our product candidates if 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/ISU304 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 sales, marketing and distribution capabilities and enter into additional arrangements with third parties to perform these services, then 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 individuals with inhibitors to Factor VIII or Factor IX and in individuals with Factor VII deficiency and Glanzmann's thrombasthenia, Baxter, which has developed BAX 817, a biosimilar of NovoSeven® that recently completed an intravenous Phase 3 clinical trial and has been filed for marketing approval, Roche, which is developing ACE910/Emicizumab, a recombinant humanized bispecific antibody that binds to activated Factor IX and Factor X and mimics the cofactor function of Factor VIIIa, has been approved by the FDA to treat hemophilia A with inhibitors, Alnylam, which is developing an investigational RNAi therapeutic targeting antithrombin for the treatment of hemophilia, OPKO Biologics, whose recombinant Factor VIIa product that may also be administered subcutaneously is in a Phase 1/2 clinical trial and CSL Behring is developing an albumin–linked Factor VIIa that has an extended half-life. We are also aware of many companies focused on developing gene therapies that may compete with our planned hemophilia B indication, as well as several companies addressing other methods for modifying genes and regulating gene expression.

Our commercial opportunity in different indications could be reduced or eliminated if competitors develop and market products or therapies 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 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 individual registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if we 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 certain 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 pharmaco-economic 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 or 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

The exercise of outstanding warrants will cause dilution.

In April 2017, we issued and sold 1,470,000 shares of common stock at a price to the public of $5.00 per share (including 540,000 shares of common stock sold pursuant to the exercise of the underwriters' overallotment option), 13,350 shares of Series A Preferred Stock, convertible into 2,670,000 shares of common stock, at a price to the public of $1,000.00 per unit, and warrants to purchase 2,070,000 shares of common stock at an exercise price of $5.50 per share (which includes 270,000 sold pursuant to the exercise of the underwriters' overallotment option). As of March 15, 2018, there were outstanding warrants to purchase 45,628 shares of common stock at an exercise of $5.50 per share and no shares of Series A Preferred Stock issued and outstanding. The exercise of these outstanding warrants will cause dilution to holders of our common stock.

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 there have been significant periods of time in which the trading volume of our common stock has been low, which can contribute to volatility in price. 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:

- disclosure of clinical trial results;
- 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.

Sales of a significant number of shares of our common stock in the public markets, or the perception that such sales could occur, could depress the market price of our common stock.

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. We have effective registration statements on Form S-3 that enable us to sell up to $188 million in securities. Any additional sales in the public market of our common stock or other securities under these shelf registration statements could adversely affect prevailing market prices for our common stock. In addition, we have outstanding options to purchase 821,741 shares of common stock at a weighted average exercise price of $13.69. If such options are exercised and the shares are sold into the open market, 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. 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.

We are a smaller reporting company and we cannot be certain if the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are currently a “smaller reporting company” as defined in the Securities Exchange Act of 1934, and are thus allowed to provide simplified executive compensation disclosures in our filings, are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that an independent registered public accounting firm provide an attestation report on the effectiveness of internal control over financial reporting and have certain other decreased disclosure obligations in our SEC filings. We cannot predict whether investors will find our common stock less attractive because of our reliance on any of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

Our corporate headquarters is in South San Francisco, California, where we subleased a portion of a facility that encompasses approximately 12,965 square feet of space. The sublease for this space expired on February 27, 2018. In November 2017, we entered into a new office lease agreement to lease approximately 8,606 rentable square feet of space located in South San Francisco, California. The term of the lease is five years and two months, starting February 16, 2018. We relocated our corporate headquarters to 611 Gateway Blvd., Suite 710, South San Francisco in February 2018.

We believe that our existing facilities are adequate for our current needs. 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 Nasdaq for the quarterly periods indicated:

Year Ended December 31, 2017:	High	Low
First Quarter	$ 15.01	$ 4.73
Second Quarter	8.87	3.74
Third Quarter	5.10	3.19
Fourth Quarter	13.69	4.52

Year Ended December 31, 2016:	High	Low
First Quarter	$ 47.25	$ 24.30
Second Quarter	28.20	18.15
Third Quarter	23.40	17.25
Fourth Quarter	18.30	8.10

Holders of Common Stock

As of March 15, 2018, there were approximately 111 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 references from the discussion responsive thereto under the caption "Stock Based Compensation" in the notes to Financial Statements, and under the caption "Equity Compensation Plan Information" in Item 12. Security Ownership Of Certain Beneficial Owners And Management And Related Stockholder Matters.

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.

ITEM 6. SELECTED FINANCIAL DATA.

Information requested by this Item is not applicable as we are electing scaled disclosure requirements available to Smaller Reporting Companies with respect to this Item.

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 developing novel medicines to address serious medical conditions for individuals who need new or better treatment options. We are focusing our product development efforts in the field of hemostasis (the process that regulates bleeding) and have a mission to develop valuable therapies for individuals with hemophilia. We used a scientific approach to engineer several protease-based therapeutic candidates that regulate bleeding.

Our most advanced program, a highly potent, subcutaneously administered, next-generation coagulation Factor VIIa variant, marzeptacog alfa (activated) ("MarzAA"), is currently enrolling individuals with hemophilia with an inhibitor in a Phase 2/3 subcutaneous dosing trial. The Phase 2 open-label subcutaneous efficacy trial will evaluate the ability of MarzAA to eliminate, or minimize, spontaneous bleeding episodes in individuals with hemophilia A or B with inhibitors. The trial will enroll up to 12 individuals with hemophilia and an inhibitor across up to ten clinical trial sites globally. MarzAA has successfully completed an intravenous Phase 1 clinical trial evaluating the pharmacokinetics, pharmacodynamics and coagulation activity in individuals with severe hemophilia A and B with and without an inhibitor. MarzAA has been granted orphan drug designation by the U.S. Food and Drug Administration ("FDA") for routine prophylaxis to prevent bleeding episodes in individuals with hemophilia A or B with inhibitors. Interim data is expected to be announced in July 2018.

Our next most advanced hemophilia program, a highly potent next-generation coagulation Factor IX variant, CB 2679d/ISU304, has completed enrollment of a Phase 1/2 subcutaneous dosing trial in South Korea, that evaluated the safety and efficacy of CB 2679d/ISU304 in individuals with severe hemophilia B, sponsored by our collaborator, ISU Abxis. The objective of this study was to demonstrate the feasibility of increasing Factor IX activity trough levels from ~1% (severe hemophilia) to >12% (mild hemophilia with a reduced chance of spontaneous joint bleeds) with six daily subcutaneous injections. CB 2679d/ISU304 has been granted orphan drug designation by the FDA and orphan medicinal product designation by the Committee for Orphan Medicinal Products ("COMP") of the European Commission ("EC"). ISU Abxis initiated this trial in June 2017 and top line data was presented on February 9, 2018. Data from Cohorts 1 through 3 (three subjects in each cohort) showed that a single subcutaneous dose of either 75 or 150 IU/kg three days after a single intravenous dose of 75 IU/kg significantly increased the half-life of CB 2679d to 98.7 hours, equivalent to the half-life of extended-half-life intravenous agents. Cohort 4 was omitted as we observed sufficient activity of CB 2679d/ISU304 in cohorts 2 and 3.

In cohort 5, 5 subjects were dosed daily for six days with a subcutaneous dose of 140 IU/kg without a preceding intravenous dose. We observed increased Factor IX activity levels in all five subjects from very low levels after washout of prior therapy to a median Factor IX activity level of 16% (range 11.5-18%), that is well into the mild hemophilia range (5-40%), and is higher than a level required to prevent spontaneous hemarthrosis. The observed increase in Factor IX activity levels after the daily dosing was linear, indicating that continued subcutaneous dosing may achieve high-mild hemophilia Factor IX clotting activity.

Terminal subcutaneous half-life was 63.2 hours (interquartile range 60.2-64 hours) with the result that activity levels were still 4-6.4%, 5 days after the last dose. No inhibitors to CB 2679d/ISU304 or Factor IX were detected to date. One subject had moderate adverse events of pain, erythema and redness after the first 2 injections and mild rating after subsequent injections. Other subjects in cohort 5 reported some of these adverse events, mainly with initial injections. Two subjects had bruising after injection when Factor IX activity levels were low that did not occur with subsequent injections as Factor IX activity levels rose.

The substantially enhanced potency of MarzAA and CB 2679d/ISU304 compared with existing treatment options may allow for effective subcutaneous prophylactic treatment of individuals with hemophilia A or B with an inhibitor or individuals with hemophilia B, respectively, especially in children, and may ultimately deliver substantially better outcomes for individuals with hemophilia.

We believe that subcutaneous dosing of our next-generation factors may result in progressive increases in activity levels until they reach a stable therapeutic target range in the blood (ideally mild hemophilia to normal levels). Conversely, dosing by intravenous infusions results in high initial Factor levels in the blood followed by a rapid fall off in activity to a trough level in a range that is measured as moderate or severe hemophilia and resulting in higher bleeding risk. Stable and higher factor levels could potentially yield a significant improvement in outcomes and have the added benefit of convenience over competing intravenous therapeutics, particularly when administered to children, and where venous access is challenging.

We also have several Factor Xa variants that have demonstrated efficacy in several preclinical models and have the potential to be used as a universal procoagulant. We have delayed initiating further work on our Factor Xa therapeutic program at this time to focus our efforts on the Factor VIIa and Factor IX clinical programs.

Based on industry reports, we estimate annual worldwide sales in 2017 for FDA-approved recombinant protease products for individuals with hemophilia A and B and an inhibitor were approximately $1.2 billion and approximately $2.2 billion when including prothrombin complex concentrate products.

We continue to explore licensing opportunities for our anti-complement programs in dry AMD, however our focus remains on advancing MarzAA and CB 2679d/ISU304 through Phase 2/3 and Phase 2b clinical trials for hemophilia indications, respectively.

In October 2017, we announced a strategic research collaboration with Mosaic Biosciences, Inc. to develop intravitreal anti-complement factor 3 products for the treatment of dry AMD and other retinal diseases. The transaction was reviewed by disinterested members of our board of directors and approved by our audit committee. Expenses related to the collaboration were $0.03 million for the year ended December 31, 2017.

Transactions with related parties, including the transaction referred to above, are reviewed and approved by independent members of our Board of Directors in accordance with our Code of Business Conduct and Ethics.

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. 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. On December 8, 2016, we signed a definitive agreement related to the termination of the Pfizer Agreement. Pursuant to this termination agreement, Pfizer granted us an exclusive license to Pfizer’s proprietary rights for manufacturing materials and processes that apply to Factor VIIa variants, CB 813a and MarzAA. Pfizer also transferred to us the IND application and documentation related to the development, manufacturing and testing of the Factor VIIa products as well as the orphan drug designation.

Pursuant to this agreement, we agreed to make contingent cash payments to Pfizer in an aggregate amount equal to up to $17.5 million, payable upon the achievement of clinical, regulatory and commercial milestones. Following commercialization of any covered product, Pfizer would also receive a single-digit royalty on net product sales on a country-by-country basis for a predefined royalty term. In February 2018, we paid Pfizer a $1 million milestone payment based on the dosing of the first patient in the ongoing Phase 2 study.

In September 2013, we signed 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 manufacturing, preclinical development activities and clinical development through a proof-of-concept Phase 1/2 study in individuals with hemophilia B that was conducted 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. ISU Abxis may exercise its right of first refusal to acquire commercialization rights in South Korea, in which case they would be entitled to profit sharing on worldwide sales. ISU Abxis paid us an up-front fee of $1.75 million and is obligated to pay to us contingent milestone-based payments on the occurrence of certain defined development events, of which two have been achieved as of as of December 31, 2017. Collaboration and license revenue related to the ISU Abxis agreement was $0.3 million and $0.4 million during the years ended December 31, 2017 and 2016 respectively, that reflect the amortization of the up-front fee over the estimated period of our performance obligations, which concluded in February 2018. We received milestone payments from ISU Abxis of $0.9 million and $0 during the years ended December 31, 2017, and 2016, respectively, of which we recognized $0.7 million and $0 for the years ended December 31, 2017 and 2016, respectively, for milestones payments, which are recognized over the estimated remaining period of our performance obligation under the agreement. We had a deferred revenue balance of $0.2 million as of December 31, 2017 related to the ISU Abxis collaboration.

We have no products approved for commercial sale and have not generated any revenue from product sales. From inception to December 31, 2017, we have raised net cash proceeds of approximately $256.6 million, primarily from private placements of convertible preferred stock and the proceeds from our merger with Targacept in addition to issuances of shares of common stock and warrants and payments received from collaboration agreements. The cash proceeds raised do not include the redeemable convertible notes that are offset by 100% restricted cash held in escrow to pay all possible redemptions, and which were redeemed at maturity in February 2018.

We have never been profitable and have incurred significant operating losses in each year since inception. Our net losses were $21.6 million and $16.9 million for years ended December 31, 2017 and 2016, respectively. As of December 31, 2017, we had an accumulated deficit of $173.5 million. Substantially all our operating losses resulted from expenses incurred in our research and development programs and from general and administrative costs associated with our operations.

We expect to incur significant expenses and increasing operating losses for at least the next several years as we continue the preclinical, manufacturing and clinical development, and seek regulatory approval for our drug candidates. In addition, our expenses have increased due to 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.

Recent Developments

On December 20, 2017, we entered into an underwriting agreement with JonesTrading, in connection with a registered firm commitment underwritten public offering of 1,105,263 shares of the Company’s common stock, pursuant to a shelf registration statement that was declared effective by the SEC on April 28, 2016. On December 22, 2017 we sold 1,105,263 shares of common stock at a price to the public of $9.50 per share. The net proceeds to the Company, after deducting the underwriting discounts and commissions and offering expenses payable by us were approximately $9.7 million.

On February 13, 2018, we entered into an underwriting agreement with JonesTrading, in connection with a registered firm commitment underwritten public offering of 2,941,176 shares of common stock, pursuant to a shelf registration statement that was declared effective by the SEC on February 6, 2018. On February 15, 2018 we sold 3,382,352 shares of common stock (including 441,176 shares of common stock sold pursuant to the exercise of the underwriters’ overallotment option) at a price to the public of $34 per share. The net proceeds to us, after deducting the underwriting discounts and commissions and offering expenses payable by us were approximately $106.7 million.

Financial Operations Overview

Contract Revenue

Our contract revenue was generated by recognizing revenue from the amortization of up-front licensee fees and milestone payments for research and development services under our collaboration agreement with 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. ISU Abxis represents 100% of our total contract revenue for the years ended December 31, 2017 and 2016.

Due to the nature of the milestone payments under the remaining collaboration agreement and the nonlinearity of the earnings process associated with certain payments and milestones, we expect that our revenue will fluctuate in future periods, because of 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;
- the cost of acquiring and manufacturing preclinical and clinical materials and developing manufacturing processes;
- clinical trial expenses, including costs of third-party clinical research organizations;
- performing toxicity 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, 2017 and 2016 *(in thousands)*.

	Year Ended December 31,	
	2017	2016
Personnel costs	$ 2,219	$ 4,062
Preclinical research	1,855	2,642
Clinical manufacturing	7,959	3,553
Facility and overhead	814	1,298
Total research and development expenses	$ 12,847	$ 11,555

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 our resources and development efforts on our clinical 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.

On September 3, 2016, our Board of Directors approved reducing our workforce by 10 employees, or approximately 50% of our workforce consistent with a revised strategic plan to reallocate our resources to our hemostasis programs, including our highly potent next-generation Factor VIIa MarzAA, and our highly potent next-generation Factor IX CB 2679d/ISU304. This reduction in force was completed by the fourth quarter 2016 and we recorded restructuring charges of $1.0 million, for the year ended December 31, 2016. In connection with the restructuring, we received proceeds of $0.9 million for property and equipment from the sale of excess equipment and other assets, which are recorded in other income for the year ended December 31, 2016. There were no further restructuring expenses recorded during the year ended December 31, 2017.

Notwithstanding the reduction in force, we expect our aggregate research and development expenses will increase during the next few quarters as we continue the preclinical, manufacturing and clinical development of our product candidates in the United States, particularly the manufacturing and clinical development costs of marzeptacog alfa (activated) and CB 2679d/ISU304. Due to the termination of the research and license agreement with Pfizer, we will incur all costs for the marzeptacog alfa (activated) program. However, the incurrence of such costs is dependent on whether we will pursue the program on our own or sign a new collaboration and license arrangement with another pharmaceutical or biotech company.

On May 20, 2016, we signed a development and manufacturing services agreement with AGC Biologics, Inc. (“AGC”), formerly known as CMC ICOS Biologics, Inc., pursuant to which AGC will conduct manufacturing development manufacture agreed upon product candidates. We will own all intellectual property developed in such manufacturing development activities that are specifically related to our product candidates and will have a royalty-free and perpetual license to use AGC’s intellectual property to the extent reasonably necessary to make these product candidates, including commercial manufacturing. In 2016 we commenced manufacturing activities for MarzAA, and together with AGC we have successfully manufactured marzeptacog alfa (activated) for the Phase 2 portion of a planned Phase 2/3 clinical trial. In February 2018 we entered into a statement of work for AGC for process transfer and clinical scale manufacturing of CB 2679d/ISU 304.

We have agreed to a total of $3.8 million in payments to AGC pursuant to the initial statement of work for MarzAA under the Agreement, and an additional $5.6 million for the statement of work for CB2679d/ISU 304, in each case subject to completion of applicable work stages. In the event that clinical manufacturing batches need to be cancelled or rescheduled, we would be obligated to pay for a portion of AGC’s manufacturing fees less certain fees that AGC is able to mitigate. The initial term of the agreement is ten years or, if later, until all stages under outstanding statements of work have been completed. Either party may terminate the 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 for any reason. In addition, each party may terminate the agreement in the event that the manufacturing development activities cannot be completed for technical or scientific reasons. As of December 31, 2017, we have $0.7 million in payment obligations to AGC remaining under the initial statement of work for MarzAA.

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. Thus, we cannot estimate with any degree of certainty the costs we will incur in the 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 incur expenses associated with operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and Nasdaq Stock Market LLC ("Nasdaq"), insurance expenses, audit expenses, investor relations activities, Sarbanes-Oxley compliance expenses and other administrative expenses and professional services. We expect such expenses to continue.

Interest and Other Income, Net

Interest and other income consists primarily of interest income on our investment portfolio and in 2016 the sale of assets acquired from Targacept in the Merger and changes in fair value of the derivative liability. The accounting for the redeemable convertible notes, which are convertible into shares of our common stock, requires us to bifurcate the derivative liability and account for it as a derivative liability at its estimated fair value upon issuance.

Results of Operations

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

	Year Ended December 31,			
	2017	2016	Change ($)	Change (%)
Contract revenue	$ 1,018	$ 399	$ 619	155%
Operating expenses:				
Research and development	12,847	11,555	1,292	11%
General and administrative	9,993	9,262	731	8%
Total operating expenses	22,840	20,817	2,023	10%
Loss from operations	(21,822)	(20,418)	(1,404)	7%
Interest and other income	261	3,473	(3,212)	(92)%
Net loss	$ (21,561)	$ (16,945)	$ (4,616)	27%

Contract revenue

Contract revenue was $1.0 million and $0.4 million during the years ended December 31, 2017 and 2016, respectively, an increase of $0.6 million, or 155%. The increase was due to the amortization of milestone payments received in 2017 from ISU Abxis under our collaboration agreement.

Research and Development Expenses

Research and development expenses were $12.8 million and $11.6 million during the years ended December 31, 2017 and 2016, respectively, an increase of $1.3 million, or 11%. The increase was due primarily to an increase of $2.6 million related to manufacturing expenses for MarzAA and $1.0 million related to preclinical third-party research and development service contracts, partially offset by a decrease of $1.8 million in personnel-related costs and a decrease of $0.5 million in lab and facility costs, both in connection with the reduction in workforce.

Based on our current programs and related commitments, we expect our research and development expenses for the year ending December 31, 2018 to increase materially compared with 2017s, due primarily to costs associated with clinical trials and manufacturing for MarzAA and CB 2679d/ISU 304. Through the completion of the Phase 1/2 clinical study of CB 2679d/ISU 304, ISU Abxis was responsible for manufacturing and clinical development expenses for this product candidate. Pursuant to our collaboration agreement with ISU Abxis, these expenses are now our responsibility.

General and Administrative Expenses

General and administrative expenses were $10.0 million and $9.3 million during the years ended December 31, 2017 and 2016, respectively, an increase of $0.7 million, or 8%. The increase was due primarily to an increase of $1.0 million in personnel-related costs as a result of increased headcount and stock-based compensation costs and $0.1 million related to facility and other costs; partially offset by a decrease of $0.4 million in professional service costs.

We anticipate that general and administrative expenses for 2018 will be similar to 2017 expenses.

Interest and Other Income

Interest and other income was $0.3 million and $3.5 million during the years ended December 31, 2017 and 2016, respectively, a decrease of $3.2 million, or 92%. The decrease was due primarily to a $2.2 million net gain recognized in 2016, related to the sale of assets in 2016 and $1.2 million gain recognized in 2016, related to the change in fair value of the derivative liability in 2016, partially offset by $0.2 million in interest income.

Recent Accounting Pronouncements

Accounting Pronouncements Recently Adopted

In March 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The new standard involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, accounting for forfeitures, classification of awards as either equity or liabilities and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016. We adopted ASU 2016-09 in 2017 and this guidance did not have a material impact on our financial statements.

In November 2016, the FASB issued ASU 2016-18, Restricted Cash, which requires amounts generally described as restricted cash and restricted cash equivalents be included with cash and cash equivalents when reconciling the total beginning and ending amounts for the periods shown on the statement of cash flows. ASU 2016-08 is effective for fiscal years beginning after December 15, 2017 using a retrospective transition method to each period presented and early adoption is permitted. We adopted ASU 2016-18 in the first quarter of 2018 and this guidance will have a material impact by decreasing our cash flows from financing activities by $14.3 million.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. The standard provides guidance on how certain cash receipts and payments are presented and classified in the statement of cash flows, including beneficial interests in securitization. The standard is intended to reduce current diversity in practice. We adopted ASU 2016-15 in the first quarter of 2018, and this guidance did not have a material impact on our financial statements.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments – Overall (Topic 825-10), which updates certain aspects of recognition, measurement, presentation and disclosure of financial instruments. ASU 2016-01 will be effective for the Company beginning in the first quarter of 2018, and early adoption is not permitted. We adopted ASU 2016-01 in the first quarter of 2018, and this guidance did not have a material impact on our financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), 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. Subsequently, the FASB has issued the following standards related to ASU 2014-09: ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations; ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing; and ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients, (collectively, the “new revenue standards”). We adopted the new revenue standards in the first quarter of 2018, using the modified retrospective method through a cumulative adjustment to equity. While we have

identified that the most significant change relates to our accounting for collaboration arrangements with multiple deliverables, in particular, the ISU Abxis agreement. Under the current guidance, 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. Under the new standard however, the total arrangement consideration is allocated to each performance obligation based on its estimated stand-alone selling price and revenue is recognized as each performance obligation is satisfied. As a result, we anticipate that revenue for this transaction may be recorded in an earlier period than under the existing guidance, resulting in an immaterial increase to our opening balance of retained earnings as of January 1, 2018.

Adopting ASU No. 2014-09, Revenue from Contracts with Customers, or the new revenue standard, will involve significant new estimates and judgments related to the estimates of stand-alone selling prices and the allocation of discounts and variable consideration in allocating the transaction price. We expect that revenue will be recognized earlier under the new standard and may have more variability due to significant estimates involved in the new accounting.

Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which replaces the existing guidance for leases. The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 will be effective for the Company beginning in the first quarter of 2019, but early adoption is permitted. We are currently evaluating the impact of adopting the new lease standard on our consolidated financial statements.

Liquidity and Capital Resources

As of December 31, 2017, we had $32.4 million of cash, cash equivalents and short-term investments, a $21.6 million net loss and $20.0 million cash used in operations. We have an accumulated deficit of $173.5 million as of December 31, 2017. 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.

On March 16, 2016, we entered into a Capital on Demand™ Sales Agreement with JonesTrading. In accordance with the terms of the sales agreement, we were able to offer and sell shares of our common stock having an aggregate offering price up to $6.5 million, subject to certain limitations, from time to time in one or more public offerings of our common stock, with JonesTrading acting as agent, in transactions pursuant to a shelf registration statement that was declared effective by the SEC on April 28, 2016. We sold 479,681 shares of common stock in the open market for net proceeds (net of commissions) of $6.3 million through December 31, 2017, in the Capital on Demand™ program. As of December 31, 2017, we had no common stock available for sale under the Controlled Equity Offering™ program.

On April 6, 2017, our registration statement on Form S-1 relating to an underwritten public offering of our common and preferred stock was declared effective by the SEC. On April 12, 2017, we issued and sold 1,470,000 shares of common stock at a price to the public of $5.00 per share (including 540,000 shares of common stock sold pursuant to the exercise of the underwriters' overallotment option), 13,350 shares of Series A Preferred Stock, convertible into 2,670,000 shares of common stock, at a price to the public of $1,000.00 per unit and warrants to purchase 2,070,000 shares of common stock at an exercise price of $5.50 per share (which includes 270,000 sold pursuant to the exercise of the underwriters' overallotment option). The net proceeds to the Company, after deducting the underwriting discounts and commissions and offering expenses payable by us were approximately $18.6 million.

On December 20, 2017, we entered into an underwriting agreement with JonesTrading, in connection with a registered firm commitment underwritten public offering of 1,105,263 shares of common stock, pursuant to a shelf registration statement that was declared effective by the SEC on April 28, 2016. On December 22, 2017 we sold

1,105,263 shares of common stock at a price to the public of $9.50 per share. The net proceeds to us, after deducting the underwriting discounts and commissions and offering expenses payable by us were approximately $9.7 million.

On February 13, 2018, we entered into an underwriting agreement with JonesTrading, in connection with a registered firm commitment underwritten public offering of 2,941,176 shares of common stock, pursuant to a shelf registration statement that was declared effective by the SEC on February 6, 2018. On February 15, 2018 we sold 3,382,352 shares of common stock (including 441,176 shares of common stock sold pursuant to the exercise of the underwriters' overallotment option) at a price to the public of $34.00 per share. The net proceeds to us, after deducting the underwriting discounts and commissions and offering expenses payable by us were approximately $106.7 million.

We believe that our existing capital resources, including cash, cash equivalents and short-term investments will be sufficient to meet our projected operating requirements for at least the next 12 months from the date of this Annual Report on Form 10-K. 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 asset sales, licensing transactions, 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. Licensing transactions, collaborations or strategic partnerships may result in us relinquishing valuable rights. 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,	
	2017	2016
Cash used in operating activities	$ (19,940)	$ (18,472)
Cash used in investing activities	(11,252)	(1,308)
Cash provided by financing activities	35,400	948
Net increase (decrease) in cash and cash equivalents	$ 4,208	$ (18,832)

Cash Flows from Operating Activities

Cash used in operating activities for the year ended December 31, 2017 was $20.0 million, due primarily to a net loss of $21.6 million, partially offset by the change in our net operating assets and liabilities of $0.6 million due primarily to a $1.3 million increase in accrued compensation and other accrued liabilities, partially offset by a $0.3 million decrease in prepaid expenses, $0.1 million increase in deposits due to our new lease, $0.1 million decrease in accounts payable and a $0.1 million increase in deferred revenue due to the additional milestone fees from our collaborations. Non-cash charges of $0.9 million were recorded for stock-based compensation and $0.2 million for depreciation and amortization.

Cash used in operating activities for the year ended December 31, 2016 was $18.5 million, due primarily to a net loss of $16.9 million. Also included are non-cash gains of $1.0 million related to the change in fair value of the derivative liability, $1.7 million related to the sale of NNR assets, $0.6 million related to the disposal of fixed assets and $0.1 million related to extinguishment of redeemable convertible notes, partially offset by non-cash charges of $0.6 million for stock-based compensation and $0.4 million for depreciation and amortization. Cash used in operating activities also reflect the change in net operating assets of $0.8 million due primarily to a $1.0 million decrease in prepaid expenses and other current assets primarily associated with the prepayment related to our manufacturing agreement and $0.4 million decrease in accounts receivable, partially offset by $0.4 million decrease in deferred revenue due to the recognition of revenue, $0.1 million decrease in accrued compensation and other accrued liabilities and $0.1 million decrease in accounts payable.

Cash Flows from Investing Activities

Cash used in investing activities for the year ended December 31, 2017 was $11.2 million, due primarily to $25.5 million in purchases of investments, partially offset by proceeds from maturities of investments of $14.3 million.

Cash used in investing activities for the year ended December 31, 2016 was $1.3 million, due primarily to $13.4 million in purchases of investments and $0.5 million related to the purchase of property and equipment, partially offset by proceeds from maturities of investments of $10.0 million $1.7 million related to the sale of assets and proceeds from the sale of property and equipment of $0.9 million.

Cash flows from Financing Activities

Cash provided by financing activities for the year ended December 31, 2017 was $35.4 million, due primarily to $18.6 million in net proceeds from the issuance of preferred stock, common stock and warrants related to our underwritten public offering in April 2017, $9.7 million in net proceeds from issuance of common stock related to our underwritten public offering in December 2017, $5.3 million in net proceeds from issuance of common stock in Capital on Demand™ transactions, $1.8 million in proceeds from the exercise of common stock warrants and the release of restricted cash of $14.3 million related to the redemption of some of the redeemable convertible notes which was offset by payments of $14.3 million related to the redemption of such notes..

Cash provided by financing activities for the year ended December 31, 2016 was $0.9 million, due primarily to $0.9 million in net proceeds from issuance of common stock in at-the-market transactions.

Contractual Obligations

The following table summarizes our fixed contractual obligations as of December 31, 2017 *(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]	$ 475	$ 1,500	$ 678	$ —	$ 2,653
AGC Manufacturing obligations[2]	654	—	—	—	654
Total contractual obligations[3][4]	$ 1,129	$ 1,500	$ 678	$ —	$ 3,307

(1) Represents future minimum lease payments under the non-cancelable 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) Represents future payments due under our development and manufacturing services agreement initial statement of work, subject to the completion of applicable work stages, which we expect to occur in less than one year.

(3) 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 uncertain and not estimable, such commitments have not been included in the contractual obligation disclosed above. We may be obligated to pay Pfizer certain milestone payments up to $17.5 million.

(4) We had unrecognized tax benefits in the amount of $1.5 million as of December 31, 2017 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 substantive. As such, we plan to recognize revenue in the period in which the milestone is achieved, only if the milestone is considered 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 because 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 the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

We adopted the new revenue standards in the first quarter of 2018, using the modified retrospective method through a cumulative adjustment to equity. Adopting the new revenue standards, will involve significant new estimates and judgments related to the estimates of stand-alone selling prices and the allocation of discounts and variable consideration in allocating the transaction price. We expect that revenue will be recognized earlier under the new standard and may have more variability due to significant estimates involved in the new accounting.

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 10* to our consolidated financial statements included in this Annual Report on Form 10-K 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, 2017, we had cash and cash equivalents of $32.4 million, which consisted of bank deposits and money market funds, and short-term investments of $18.0 million. The redeemable convertible notes we issued in August 2015 in 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 do 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.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
Catalyst Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Catalyst Biosciences, Inc. (the "Company") as of December 31, 2017 and 2016, and the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2017 and 2016, and the consolidated results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ EisnerAmper LLP

We have served as the Company’s auditor since 2014.

EISNERAMPER LLP
Iselin, New Jersey
March 19, 2018

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

	December 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 14,472	$ 10,264
Short-term investments	17,971	6,800
Restricted cash	5,333	19,468
Prepaid and other current assets	1,309	958
Accounts receivable	24	31
Total current assets	39,109	37,521
Restricted cash, noncurrent	—	125
Deposits, noncurrent	128	—
Property and equipment, net	276	444
Total assets	$ 39,513	$ 38,090
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 747	$ 837
Accrued compensation	1,366	596
Other accrued liabilities	1,322	805
Deferred revenue, current portion	212	283
Deferred rent, current portion	7	41
Redeemable convertible notes	5,085	19,403
Total current liabilities	8,739	21,965
Deferred revenue, noncurrent portion	—	47
Deferred rent, noncurrent portion	—	7
Total liabilities	8,739	22,019
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized; 3,680 and 0 shares issued and outstanding at December 31, 2017 and 2016, respectively	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized; 6,081,230 and 801,756 shares issued and outstanding at December 31, 2017 and 2016, respectively	6	1
Additional paid-in capital	204,262	164,053
Accumulated other comprehensive income (loss)	—	(1)
Accumulated deficit	(173,494)	(147,982)
Total stockholders' equity	30,774	16,071
Total liabilities and stockholders' equity	$ 39,513	$ 38,090

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,	
	2017	2016
Contract revenue	$ 1,018	$ 399
Operating expenses:		
Research and development	12,847	11,555
General and administrative	9,993	9,262
Total operating expenses	22,840	20,817
Loss from operations	(21,822)	(20,418)
Interest and other income, net	261	3,473
Net loss	(21,561)	(16,945)
Deemed dividend for convertible preferred stock beneficial conversion feature	(3,951)	—
Net loss attributable to common stockholders	$ (25,512)	$ (16,945)
Net loss per share attributable to common stockholders, basic and diluted	$ (7.45)	$ (21.75)
Shares used to compute net loss per share attributable to common stockholders, basic and diluted	3,423,901	779,166

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,	
	2017	2016
Net loss	$ (21,561)	$ (16,945)
Other comprehensive income (loss):		
Unrealized (gain) loss on available-for-sale securities	1	(2)
Total comprehensive loss	$ (21,560)	$ (16,947)

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Income	Deficit	Equity
Balance at December 31, 2015	—	$ —	762,005	$ 1	$ 162,460	$ 1	$ (131,037)	$ 31,425
Stock-based compensation expense	—	—	—	—	635	—	—	635
Issuance of common stock, net of issuance costs	—	—	39,743	—	957	—	—	957
Conversion of redeemable convertible notes to common stock	—	—	8	—	1	—	—	1
Unrealized (loss) on available-for-sale securities	—	—	—	—	—	(2)	—	(2)
Net loss	—	—	—	—	—	—	(16,945)	(16,945)
Balance at December 31, 2016	—	—	801,756	1	164,053	(1)	(147,982)	16,071
Stock-based compensation expense	—	—	—	—	863	—	—	863
Issuance of common stock, net of issuance costs	—	—	439,880	—	5,336	—	—	5,336
Issuance of convertible preferred stock, common stock and warrants for follow-on offering, net of issuance costs	13,350	—	1,470,000	2	18,561	—	—	18,563
Issuance of common stock for follow-on offering S-3, net of issuance costs	—	—	1,105,263	1	9,683			9,684
Issuance of common stock upon exercise of warrants	—	—	330,331	—	1,817	—	—	1,817
Conversion of preferred stock to common stock	(9,670)	—	1,934,000	2	(2)	—	—	—
Deemed dividend for preferred stock beneficial conversion feature	—	—	—	—	3,951	—	(3,951)	—
Unrealized gain on available-for-sale securities	—	—	—	—	—	1	—	1
Net loss	—	—	—	—	—	—	(21,561)	(21,561)
Balance at December 31, 2017	3,680	$ —	6,081,230	$ 6	$ 204,262	$ —	$ (173,494)	$ 30,774

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,	
	2017	**2016**
Operating Activities		
Net loss	$ (21,561)	$ (16,945)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	863	635
Depreciation and amortization	173	389
Loss (Gain) on sale of assets	18	(2,231)
Gain on extinguishment of redeemable convertible notes	—	(99)
Change in fair value of derivative liability	—	(1,057)
Changes in operating assets and liabilities:		
Prepaid and other current assets	(351)	956
Accounts receivable	7	461
Deposits	(128)	—
Accounts payable	(90)	(102)
Accrued compensation and other accrued liabilities	1,287	(60)
Deferred revenue	(118)	(400)
Deferred rent	(40)	(19)
Net cash flows used in operating activities	(19,940)	(18,472)
Investing Activities		
Proceeds from maturities of short-term investments	14,300	10,002
Purchase of investments	(25,472)	(13,401)
Proceeds from sale of assets	—	1,674
Change in restricted cash	(57)	(5)
Proceeds from sale of property and equipment	—	890
Purchases of property and equipment	(23)	(468)
Net cash flows used in investing activities	(11,252)	(1,308)
Financing Activities		
Release of restricted cash due to conversion and redemption of redeemable convertible notes	14,318	14,330
Payments for the redemption of redeemable convertible notes	(14,318)	(14,340)
Proceeds from issuance of common stock, net of issuance costs	5,336	958
Proceeds from issuance of preferred stock, common stock and warrants for follow-on offering, net of issuance costs	18,563	—
Proceeds from issuance of common stock under S-3, net of issuance costs	9,684	—
Proceeds from exercise of warrants	1,817	—
Net cash flows provided by financing activities	35,400	948
Net increase (decrease) in cash and cash equivalents	4,208	(18,832)
Cash and cash equivalents at beginning of year	10,264	29,096
Cash and equivalents at end of year	$ 14,472	$ 10,264
Supplemental Disclosure of Non-Cash Investing and Financing Information:		
Deemed dividend for convertible preferred stock beneficial conversion feature	$ 3,951	$ —
Unrealized (Gain) Loss on investments	$ 1	$ (2)

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

1. Nature of Operations

Catalyst Biosciences, Inc. and its subsidiary (the "Company" or "Catalyst") is a clinical-stage biotechnology company focused on developing novel medicines to address hematology indications, including the treatment of hemophilia. Its facilities are in South San Francisco, California and it operates in one segment. Prior to August 20, 2015, the name of the Company was Targacept, Inc. ("Targacept"). On August 20, 2015, Targacept completed its business combination with Catalyst (the "Merger").

Liquidity

The Company had a net loss of $21.6 million for the year ended December 31, 2017 and an accumulated deficit of $173.5 million as of December 31, 2017 and expects to continue to incur losses for the next several years. As of December 31, 2017, the Company had $32.4 million in cash, cash equivalents and short-term investments and used $20.0 million of cash in operating activities for the year ended December 31, 2017. Management believes that the currently available resources, including cash, cash equivalents and short-term investments, will provide sufficient funds to enable the Company to meet its operating plan for at least the next twelve months from the date of this filing.

However, if the Company's anticipated operating results are not achieved in future periods, management believes that planned expenditures can be reduced to extend the time period over which the then-available resources would be able to fund its operations. The Company plans to continue to fund losses from operations and capital funding needs through future equity and/or debt financings, as well as potential additional asset sales, licensing transactions, collaborations or strategic partnerships with other companies. The sale of additional equity or convertible debt could result in additional dilution to its stockholders. The incurrence of indebtedness would result in debt service obligations and could result in operating and financing covenants that would restrict the Company's operations. The Company can provide no assurance that financing will be available in the amounts it needs or on terms acceptable to it, if at all. If the Company is not able to secure adequate additional funding it 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 its business.

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 United States generally accepted accounting principles ("GAAP").

Use of Estimates

The preparation of consolidated financial statements in conformity with 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.

Accounting Pronouncements Recently Adopted

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The new standard involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, accounting for forfeitures, classification of awards as either equity or liabilities and classification on the statement of cash flows. ASU 2016-09 is

effective for fiscal years beginning after December 15, 2016. We adopted ASU 2016-09 in 2017 and elected to account for forfeitures as they occur and this guidance did not have a material impact on our financial statements. Adoption of the standard did not require any cumulative-effect adjustment to the beginning of the year equity

In November 2016, the FASB issued ASU 2016-18, Restricted Cash, which requires amounts generally described as restricted cash and restricted cash equivalents be included with cash and cash equivalents when reconciling the total beginning and ending amounts for the periods shown on the statement of cash flows. ASU 2016-08 is effective for fiscal years beginning after December 15, 2017 using a retrospective transition method to each period presented and early adoption is permitted. We adopted ASU 2016-18 in the first quarter of 2018 and this guidance will have a material impact by decreasing our cash flows from financing activities by $14.3 million.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. The standard provides guidance on how certain cash receipts and payments are presented and classified in the statement of cash flows, including beneficial interests in securitization. The standard is intended to reduce current diversity in practice. We adopted ASU 2016-15 in the first quarter of 2018, and this guidance did not have a material impact on our financial statements.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments – Overall (Topic 825-10), which updates certain aspects of recognition, measurement, presentation and disclosure of financial instruments. ASU 2016-01 will be effective for the Company beginning in the first quarter of 2018, and early adoption is not permitted. We adopted ASU 2016-01 in the first quarter of 2018, and this guidance did not have a material impact on our financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), 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. Subsequently, the FASB has issued the following standards related to ASU 2014-09: ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations; ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing; and ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients, (collectively, the “new revenue standards”). We adopted the new revenue standards in the first quarter of 2018, using the modified retrospective method through a cumulative adjustment to equity. While we have identified that the most significant change relates to our accounting for collaboration arrangements with multiple deliverables, in particular, the ISU Abxis agreement. Under the current guidance, 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. Under the new standard however, the total arrangement consideration is allocated to each performance obligation based on its estimated stand-alone selling price and revenue is recognized as each performance obligation is satisfied. As a result, we anticipate that revenue for this transaction may be recorded in an earlier period than under the existing guidance, resulting in an immaterial increase to our opening balance of retained earnings as of January 1, 2018.

Adopting ASU No. 2014-09, Revenue from Contracts with Customers, or the new revenue standard, will involve significant new estimates and judgments related to the estimates of stand-alone selling prices and the allocation of discounts and variable consideration in allocating the transaction price. We expect that revenue will be recognized earlier under the new standard and may have more variability due to significant estimates involved in the new accounting.

Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which replaces the existing guidance for leases. The new standard establishes a right-of-use (ROU) model that requires a lessee to record

a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 will be effective for the Company beginning in the first quarter of 2019, but early adoption is permitted. We are currently evaluating the impact of adopting the new lease standard on our consolidated financial statements.

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 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).

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.

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.

Derivative Liability

The embedded redemption feature in the redeemable convertible notes, which are convertible into shares of the Company's common stock was bifurcated and 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, as of December 31, 2017 and 2016 the fair value was immaterial.

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 in 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.

The Company adopted the new revenue standards in the first quarter of 2018, using the modified retrospective method through a cumulative adjustment to equity.

While the Company has identified that the most significant change relates to its accounting for collaboration arrangements with multiple deliverables, in particular, the ISU Abxis agreement. Under the current guidance, 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. Under the new standard however, the total arrangement consideration is allocated to each performance obligation based on its estimated stand-alone selling price and revenue is recognized as each performance obligation is satisfied. As a result, the Company anticipates that revenue for this transaction may be recorded in an earlier period than under the existing guidance, resulting in an immaterial increase to its opening balance of retained earnings as of January 1, 2018.

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, 2017 and 2016, the Company recorded a reduction to research and development expenses of $0.1 million and $0.1 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, investments 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.

The Company's accounts receivable at December 31, 2017 was $0.02 million, due from ISU Abxis. 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. Upon adoption of ASU 2016-09, the Company can make an accounting policy election to either estimate the number of share-based awards that are expected to vest, or account for forfeitures when they occur. The Company elected to account for forfeitures when they occur. As such, the Company recognizes stock-based compensation expense, over their requisite service period, based on the vesting provisions of the individual grants.

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, 2017 and 2016, the Company's highly liquid money market funds included within cash equivalents, restricted cash and U.S. government agency securities are valued using Level 1 inputs. The Company classifies its federal agency securities as Level 2. 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 associated with the redeemable convertible notes (see Note 9) and are valued using Level 3 inputs. There were no transfers in or out of Level 3 during the periods presented.

As of December 31, 2017 and December 31, 2016 the fair value of the derivative liability was immaterial. The estimated reporting date fair value-based measurement of the derivative liability was calculated using the Black-Scholes valuation model.

The following tables present the fair value hierarchy for assets and liabilities measured at fair value on a recurring basis as of December 31, 2017 and 2016 (*in thousands*):

	December 31, 2017			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds(1)	$ 14,334	$ —	$ —	$ 14,334
U.S. government agency securities(3)	16,471	$ —	$ —	16,471
Restricted cash (money market funds)(2)	5,333	—	—	5,333
Agency securities(3)	—	1,500	—	1,500
Total financial assets	$ 36,138	$ 1,500	$ —	$ 37,638

(1) Included in cash and cash equivalents on accompanying consolidated balance sheets.
(2) $5.2 million of restricted cash in the Indenture serves as full collateral for the redeemable convertible notes and $0.1 million of restricted cash serves as collateral for the Company's corporate credit card and deposit for its facility lease.
(3) Included in short-term investments on accompanying consolidated balance sheets and are classified as available-for-sale securities.

	December 31, 2016			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds(1)	$ 10,156	$ —	$ —	$ 10,156
U.S. government agency securities(3)	6,800	—	—	6,800
Restricted cash (money market funds)(2)	19,593	—	—	19,593
Total financial assets	$ 36,549	$ —	$ —	$ 36,549

(1) Included in cash and cash equivalents on accompanying consolidated balance sheets.

(2) $19.4 million of restricted cash in the Indenture serves as full collateral for the redeemable convertible notes and $0.1 million of restricted cash serves as collateral for the Company's corporate credit card and deposit for its facility lease.

(3) Included in short-term investments on accompanying consolidated balance sheets and are classified as available-for-sale securities.

4. Financial Instruments

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

December 31, 2017	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$ 14,334	$ —	$ —	$ 14,334
U.S. government agency securities	16,474	—	(3)	16,471
Restricted cash (money market funds)	5,330	3	—	5,333
Agency securities	1,500	—	—	1,500
Total financial assets	$ 37,638	$ 3	$ (3)	$ 37,638
Classified as:				
Cash and cash equivalents				$ 14,334
Short-term investments				17,971
Restricted cash (money market funds)				5,333
				$ 37,638

December 31, 2016	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$ 10,156	$ —	$ —	$ 10,156
U.S. government agency securities	6,802	—	(2)	6,800
Restricted cash (money market funds)	19,593	—	—	19,593
Total financial assets	$ 36,551	$ —	$ (2)	$ 36,549
Classified as:				
Cash and cash equivalents				$ 10,156
Restricted cash (money market funds)				19,593
Short-term investments				6,800
				$ 36,549

As of December 31, 2017, the remaining contractual maturities of available-for-sale securities was less than one year. There have been no material realized gains or losses on available-for-sale securities for the periods presented. The carrying amounts of cash, accounts receivable, other receivables, accounts payable, other payables and redeemable convertible notes approximate their fair values due to the short-term maturity of these instruments.

5. Restructuring Actions

In September 2016, the Company announced a reduction in workforce of 10 employees, or approximately 50% of the Company's workforce, consistent with a revised strategic plan to reallocate our resources to our hemostasis programs, including our highly potent next-generation Factor VIIa variant marzeptacog alfa (activated), and our highly potent next-generation Factor IX CB 2679d/ISU304. The principal objective of the 2016 Restructuring was to enable the Company to focus its efforts and resources on advancing marzeptacog alfa (activated), and CB 2679d/ISU304, through Phase 2/3 and Phase 1/2 clinical trials, respectively.

For the year ended December 31, 2016, the Company recorded restructuring charges of $1.0 million, respectively, in R&D expense, due primarily to $0.9 million employee severance and benefits, and $0.1 million for legal and facility expenses in 2016. The restructuring balance was fully paid by December 31, 2016. There were no such charges recorded for the year ended December 31, 2017. In connection with the 2016 restructuring, the Company received proceeds on the sale of equipment of $0.9 million resulting in a gain of $0.6 million which is reported in interest and other income. There were no such proceeds during 2017.

6. Property and Equipment

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

	Year Ended December 31,	
	2017	2016
Furniture	$ 317	$ 317
Leasehold improvements	1,598	1,613
Computer equipment	237	230
Software	147	144
	2,299	2,304
Less accumulated depreciation and amortization	(2,023)	(1,860)
Property and equipment, net	$ 276	$ 444

Property and equipment depreciation and amortization expense for the years ended December 31, 2017 and 2016 was $0.2 million and $0.4 million, respectively.

In connection with the Restructuring, the amount recorded as a restructuring charge for asset impairment, as presented in "*Note 5 -Restructuring Actions*," was net of the gain on the sale of such assets.

7. Commitments and Contingencies

Operating Leases

The Company leases office and research space under operating leases that expire in February 2018. As a result of the Restructuring, we exited certain facilities in South San Francisco. In November 2017, we entered into a new office lease agreement to lease approximately 8,606 rentable square feet of space located in South San Francisco, California. The term of the lease is five years and two months, starting February 16, 2018. We relocated our corporate headquarters into this new space in February 2018.

The Company's rental expense under its operating leases was $0.8 million and $0.7 million for the years ended December 31, 2017 and 2016.

Future minimum lease payments under all non-cancelable operating leases at December 31, 2017, were as follows (*in thousands*):

2018	$ 475
2019	489
2020	500
2021	511
2022	523
2023	155
Total future minimum lease payments	$ 2,653

Manufacturing Agreements

On May 20, 2016, the Company signed a development and manufacturing services agreement with AGC Biologics, Inc. ("AGC"), formerly known as CMC ICOS Biologics, Inc., pursuant to which AGC will conduct manufacturing development and, and together with AGC the Company has successfully manufactured marzeptacog alfa (activated) for the Phase 2 portion of a planned Phase 2/3 clinical trial. The Company has agreed to a total of $3.8 million in payments to AGC pursuant to the initial statement of work under the Agreement, subject to completion of applicable work stages. As of December 31, 2017, the Company's remaining obligations to AGC were $0.7 million under the agreement.

On February 21, 2018, the Company and AGC entered into a new statement of work under the development and manufacturing services agreement dated May 20, 2016, between the Company and AGC. Under the new statement of work, the Company has engaged AGC for the process transfer and commercial scale cGMP manufacturing of CB 2679d, Catalyst's highly potent next-generation coagulation FIX variant being developed for the treatment of severe hemophilia B. The Company has agreed to a total of approximately $5.6 million in payments pursuant to the new statement of work, including the commercial scale manufacturing of CB 2679d, subject to completion of applicable work stages.

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 12 - Collaborations*), the Company may be obligated to pay ISU Abxis up to $2.0 million in potential milestone payments. At December 31, 2017, 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 up to $17.5 million payable upon the achievement of clinical, regulatory and commercial milestones. Following commercialization of any product, Pfizer would also receive a single-digit royalty on net product sales on a country-by-country basis for a predefined royalty term. In February 2018, the Company paid Pfizer a $1 million milestone payment based on the dosing of the first patient in the ongoing Phase 2 study.

8. Related Parties

On October 24, 2017 the Company announced a strategic research collaboration with Mosaic Biosciences, Inc. ("Mosaic") to develop intravitreal anti-complement factor 3 (C3) products for the treatment of dry AMD and other retinal diseases. According to the agreement the Company and Mosaic will co fund the research. Dr. Usman, our Chief Executive Officer and a member of our board of directors, and Mr. Lawlor, a member of our board of directors, are also members of the board of directors of Mosaic. Expenses related to the collaboration were $0.03 million for the year ended December 31, 2017.

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. The Notes do not bear interest. The principal amount of the Notes is convertible, at the option of each noteholder, into cash or into shares of the Company's common stock at a conversion rate of $137.85 per share, 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 issuance of the Notes, 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 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 Notes into shares of common stock at a conversion price of $137.85 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 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 after the Merger. In addition, changes in the fair value of the derivative liability are being recorded within interest and other income in the consolidated statements of operations. The Company remeasures the derivative liability to fair value until the earlier of the conversion, redemption or maturity of the redeemable convertible notes.

As of December 31, 2017 and December 31, 2016, the fair value of the derivative liability was immaterial. The estimated reporting date fair value-based measurement of the derivative liability was calculated using the Black-Scholes valuation model.

The Company recognized no interest expense for both years ended December 31, 2017 and 2016, related to the amortization of the debt discount on the Company’s consolidated statement of operations as the redeemable convertible notes are immediately fully redeemable at the option of the holders and the entire debt discount was accreted immediately after the Merger.

As of December 31, 2017, the Notes had an outstanding balance of $5.1 million, $31.6 million of the Notes were redeemed and $0.3 million of the Notes were converted into common stock. $14.3 million of the Notes were redeemed during the year ended December 31, 2017. There was $0 and $0.1 million gain on extinguishment when the Notes were redeemed during the years ended December 31, 2017 and 2016, respectively.

On February 19, 2018, the Notes matured and the remaining Notes were repaid in full with cash from the restricted cash indenture. The Company has no outstanding Notes remaining as of February 20, 2018.

10. Stock Based Compensation

The following table summarizes stock option activity under the Company's equity incentive plans 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, 2015	146,634	$ 147.45	5.51	$ 16
Options granted	14,706	$ 23.70		—
Fractional shares written off in connection with the merger(1)	(4)	$ —		
Options canceled	(13,773)	259.05		
Options forfeited	(6,573)	$ 64.95		
Outstanding — December 31, 2016	140,990	$ 128.25	3.93	—
Options granted	742,000	$ 4.56		
Options canceled	(141)	41.91		
Options forfeited	(61,108)	$ 165.63		
Outstanding — December 31, 2017	821,741	$ 13.69	9.17	$ 6,376
Exercisable — December 31, 2017	161,240	$ 45.34		
Vested and expected to vest — December 31, 2017	821,741	$ 13.69		
Shares Available to be granted — December 31, 2017	354,886			

(1) In connection with the merger, the Company assumed stock options covering an aggregate of 94,721 shares of common stock. The Company also assumed 190 shares of Restricted Stock Awards which vested in two equal annual installments beginning on December 31, 2015 and fully vesting on December 31, 2016 and excludes 4 aggregate fractional shares written off as a result of the conversion ratio applied to options assumed in the merger. Total stock-based compensation related to these restricted stock awards was $0.02 million for year ended December 31, 2016.

Valuation Assumptions

The Company estimated the fair value of stock options granted using the Black-Scholes option-pricing formula and a single option award approach. Due to its limited history as a public company and limited number of sales of its common stock, the Company estimated its volatility considering a number of factors including the use of the volatility of comparable public companies. The expected term of options granted under the Plan, all of which qualify as "plain vanilla" per SEC Staff Accounting Bulletin 107, is determined based on the simplified method due to the Company's limited operating history and is 6.03 years based on the average between the vesting period and the contractual life of the option. The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the option. This fair value is being amortized ratably over the requisite service periods of the awards, which is generally the vesting period. The weighted average grant date fair value of employee stock options was $4.01 for the year ended December 31, 2017 and was estimated using the following weighted-average assumptions for the years ended December 31, 2017 and 2016:

	Year Ended December 31,	
	2017	2016
Employee Stock Options:		
Expected term (in years)	6.03	6.14
Risk-free interest rate	2.03%	1.53%
Dividend yield	—	—
Volatility	110.29%	76.59%

Options Granted to Nonemployees

During the years ended December 31, 2017 and 2016, options to purchase 20,000 and 800 shares, respectively, of common stock were issued to consultants that vest over one to four years with a weighted-average exercise price of $4.69 and $20.40 per share, respectively. During the years ended December 31, 2017, and 2016, the Company recorded stock-based compensation expense attributable to these nonemployee stock awards of $0.02 million and $0.05 million, respectively.

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,	
	2017	2016
Non-Employee Stock Options:		
Contractual Life (in years)	9	10
Risk-free interest rate	2.35%	2.39%
Dividend yield	—	—
Volatility	111.55%	101.12%

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

	Year Ended December 31,	
	2017	2016
Research and development	$ 699	$ 185
General and administrative	164	450
Total stock-based compensation	$ 863	$ 635

As of December 31, 2017, 354,886 shares of common stock were available for future grant and 821,741 options to purchase shares of common stock were outstanding. As of December 31, 2017 the Company had unrecognized employee stock-based compensation expense of $3.2 million, related to unvested stock awards, which is expected to be recognized over an estimated weighted-average period of 2.9 years.

11. 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, 2017 and 2016 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, 2017 and 2016 are as follows:

	Year Ended December 31,	
	2017	2016
Tax at statutory federal rate	-34.00%	-34.00%
State Tax (benefit)—net of federal benefit	0.00%	-1.12%
Permanent differences	0.60%	-7.95%
R&D credits	-1.64%	-3.16%
Derecognition due to Sec. 382 and 383 limitations	54.08%	0.00%
Change in valuation allowance	-52.90%	46.66%
Federal tax rate change	33.89%	0.00%
Other	-0.03%	-0.43%
Effective tax rate	—	—

Significant components of the Company's deferred tax assets as of December 31, 2017 and 2016 consist of the following (*in thousands*):

	Year Ended December 31,	
	2017	2016
Deferred tax assets:		
Accruals and reserves	$ 1,112	$ 1,137
Net operating loss carry forwards	11,519	25,944
R&D tax credit carry forwards	3,545	3,174
Fixed and intangible assets	89	114
Valuation Allowance	(16,265)	(30,369)
Net deferred tax assets:	**$ —**	**$ —**

Based on the available objective evidence at December 31, 2017, the Company does not believe it is more likely than not that the net deferred tax assets (DTA) will be realizable. Accordingly, the Company has provided a full valuation allowance against its net deferred tax assets at December 31, 2017 and 2016.

As of December 31, 2017, the Company had federal net operating loss carryforwards of approximately $54.8 million and state net operating loss (NOL) carryforwards of approximately $41.1 million. As of December 31, 2016, the Company had federal net operating loss carryforwards of approximately $68.3 million and state net operating loss carryforwards of approximately $46.6 million. If not utilized, the federal net operating loss carryforwards will begin to expire in 2025 through 2038 and state net operating loss carryforwards will expire from 2028 through 2038.

As of December 31, 2017, the Company also had tax credit carry forwards available to offset future tax liabilities of approximately $0.1 million for federal and $4.4 million for state. If unused, the federal credit will begin to expire in 2037 and 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 carryforwards 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 carryforwards before utilization. As of December 31, 2017, the Company determined that ownership changes occurred December 31, 2007, August 20, 2015, and April 13, 2017. As a result of the ownership changes, approximately $108.9 million and $37.7 million of the NOLs will expire unutilized for federal and California purposes, respectively. As of December 31, 2017, the Company has derecognized NOL related DTAs in the tax affected amounts of $22.9 million and $0 million for federal and California purposes, respectively. The ability of the Company to use its remaining NOL carryforwards may be further limited if the Company experiences a Section 382 ownership change as a result of future changes in its stock ownership.

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 $6.1 million of gross federal R&D credit-related deferred tax assets were derecognized due to the Section 383 limitation.

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 $1.5 million of unrecognized tax benefits as of both December 31, 2017 and 2016. 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, 2016	**$**	**1,314**
Increase/(Decrease) of unrecognized tax benefits taken in prior years		6
Increase/(Decrease) of unrecognized tax benefits related to current year		219
Ending Balance at December 31, 2016	**$**	**1,539**
Increase/(Decrease) of unrecognized tax benefits taken in prior years		(126)
Increase/(Decrease) of unrecognized tax benefits related to current year		62
Ending Balance at December 31, 2017	**$**	**1,475**

Interest and penalties related to unrecognized tax benefits would be included as income tax expense in the Company's consolidated statements of operations. As of December 31, 2017 and 2016, the Company had not recognized any tax-related penalties or interest in its consolidated financial statements.

The Company files income tax returns in the United States federal, California, and New Jersey state jurisdictions. The Company is not currently under examination by income tax authorities in federal, state or other jurisdictions. The Company is subject to United States federal and state income tax examinations by authorities for all tax years due to accumulated net operating losses that are being carried forward for tax purposes.

On December 22, 2017, the United States government approved a bill reforming the U.S. corporate income tax code which will reduce the corporate tax rate from 34% to 21%. The rate reduction would generally take effect on January 1, 2018. The carrying value of our deferred tax assets is also determined by the enacted U.S. corporate income tax rate. Consequently, any changes in the U.S. corporate income tax rate will impact the carrying value of our deferred tax assets. Under the new corporate income tax rate of 21%, deferred income tax assets will decrease by $7.3 million and valuation allowance will decrease by $7.3 million. The net effect of the tax reform enactment on the Company's financial statements is $0 as of December 31, 2017.

12. Collaborations

Pfizer

Pursuant to the termination agreement entered on December 8, 2016, in connection with the termination of a prior license and development agreement, Pfizer granted the Company an exclusive license to Pfizer's proprietary rights for manufacturing materials and processes that apply to Factor VIIa variants, CB 813a and marzeptacog alfa (activated). Pfizer also transferred to the Company the IND application and documentation related to the development, manufacturing and testing of the Factor VIIa products as well as the orphan drug designation. The Company agreed to make contingent cash payments to Pfizer in an aggregate amount equal to up to $17.5 million, payable upon the achievement of clinical, regulatory and commercial milestones. Following commercialization of any covered product, Pfizer would also receive a single-digit royalty on net product sales on a country-by-country basis for a predefined royalty term. No amounts have been paid as of December 31, 2017, under this new agreement. In February 2018, the Company paid Pfizer a $1 million milestone payment based on the dosing of the first patient in the ongoing Phase 2 study.

ISU Abxis

On September 16, 2013, the Company signed 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 manufacturing, preclinical development activities and clinical development through completion of a proof-of-concept Phase 1/2 study in individuals with hemophilia B. The Company has the sole rights and responsibility for worldwide development, manufacture, and commercialization of Factor IX products after Phase 1/2 development. ISU Abxis may exercise its right of first refusal to acquire commercialization rights in South Korea, in which case they would be entitled to profit sharing on worldwide sales. ISU's rights will also terminate if the Company enters into a license agreement with another party to develop, manufacture and commercialize Factor IX products in at the United States, European Union or Asia, subject to ISU's retained rights in South Korea.

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 $0.3 million and $0.4 million for the years ended December 31, 2017 and 2016, respectively, reflects the amortization of the up-front fee over the estimated period of our performance obligations, which concluded in February 2018. In addition, the Company received milestone payments from ISU Abxis of $0.9 million and $0 during the years ended December 31, 2017, and 2016, which are recognized over the estimated remaining period of the Company's performance obligation under the agreement, of which the Company recorded $0.7 million and $0 for the years ended December 31, 2017 and 2016, respectively. The deferred revenue balance related to the ISU Abxis collaboration was $0.2 million and $0.3 million as of December 31, 2017 and 2016, respectively.

13. Interest and Other Income

The following table shows the detail of other income, net for the years ended December 31, 2017 and 2016 *(in thousands)*:

	Year Ended December 31,	
	2017	2016
Gain on sale of assets	$ —	$ 2,231
Change in derivative liability	—	1,156
Other Income, net	261	86
Total Other Income, net	$ 261	$ 3,473

14. Stockholders' Equity

At the Market Issuance Sales Agreement — On March 16, 2016, the Company signed a Capital on Demand™ Sales Agreement with JonesTrading Institutional Services LLC ("JonesTrading"). In accordance with the terms of the sales agreement, the Company was able to offer and sell shares of its common stock having a gross aggregate offering price up to $6.5 million, subject to certain limitations, from time to time in one or more public offerings of the Company's common stock, with JonesTrading acting as agent, in transactions pursuant to a shelf registration statement that was declared effective by the SEC on April 28, 2016.

The Company sold an aggregate of 479,681 shares of common stock in the open market at a weighted-average selling price of $13.55 per share, for net proceeds (net of commissions) of $6.3 million through December 31, 2017, of which $5.5 million were sold in the year ended December 31, 2017, in the Capital on Demand™ program. The Company charged approximately $0.2 million for JonesTrading commission against additional paid-in capital through December 31, 2017. As of December 31, 2017, the Company has no common stock available for sale under the program.

April 2017 Underwritten Public Offering — On April 12, 2017, the Company issued and sold in a registered, underwritten public offering an aggregate of (i) 1,470,000 shares of common stock (including 540,000 shares of common stock sold pursuant to the exercise of the Underwriter's overallotment option), (ii) 13,350 shares of Series A Preferred Stock, each convertible into 200 shares of common stock and (iii) warrants to purchase 2,070,000 shares of common stock at an exercise price of $5.50 per share (including 270,000 sold pursuant to the exercise of the Underwriter's overallotment option). The net proceeds to the Company, after deducting the underwriting discounts and commissions and offering expenses payable by the Company were approximately $18.6 million.

Series A Convertible Preferred Stock — In connection with the closing on April 12, 2017 of the public offering, the Company filed the Certificate of Designation of Preferences, Rights and Limitations of the Series A Preferred Stock (the "Certificate of Designation") with the Secretary of State of the State of Delaware. The Certificate of Designation describes the rights, preferences and privileges of the shares of Series A Preferred Stock. With certain exceptions, the shares of Series A Preferred Stock rank on par with the shares of the Common Stock, in each case, as to dividend rights and distributions of assets upon liquidation, dissolution or winding up of the Company.

Upon its issuance, the Series A Preferred Stock was not considered a liability or temporary equity and as such the Series A Preferred Stock was recorded in permanent equity on the Company's balance sheet.

During the year ended December 31, 2017, 9,670 shares of the Company's Series A Preferred Stock were converted into 1,934,000 shares of common stock of the Company. As of December 31, 2017, there were 3,680 shares of Series A Preferred Stock issued and outstanding.

Beneficial Conversion Feature Series A Preferred Stock (deemed dividend) — Each share of Series A Preferred Stock is convertible into 200 shares of common stock, at any time, at the option of the holder. The net proceeds to the Company of $18.6 million were allocated to the common stock, Preferred A Stock and warrants (see below) based on a relative fair value basis. This resulted in $10.1 million being allocated to the Preferred A Stock and resulted in an effective conversion price of $3.80 per share. On April 12, 2017, the date of issuance of the Series A Preferred Stock, the publicly traded common stock price was $5.28 per share.

Based on the guidance in ASC 470-20-20, the Company determined that a beneficial conversion feature exists, as the effective conversion price for the shares of Series A Preferred Stock at issuance was less than the fair value of the common stock into which the shares of Series A Preferred Stock are convertible. The beneficial conversion feature calculated based on the intrinsic value as of the date of issuance was approximately $4.0 million. This amount was then accreted as a deemed dividend, which is a non-cash transaction. As the conversion rights were 100% effective at the time of issuance, the deemed dividend was immediately charged to accumulated deficit.

Warrants — In connection with the closing on April 12, 2017 of the public offering and the overallotment option, the Company issued warrants to purchase 2,070,000 shares of common stock at an exercise price of $5.50 per share. Upon their issuance, the common stock warrants were determined to be equity instruments under ASC 480 and ASC 815-40. The net proceeds allocated to the warrants based on a relative fair value basis resulted in $5.0 million being allocated to the warrants.

The following is a summary of warrant activity for the year ended December 31, 2016 and 2017:

	Number of Shares Underlying Warrants		Exercise Price
Outstanding — December 31, 2016	12,039	$	145.11
Issued	2,070,000	$	5.50
Exercised	(330,331)	$	5.50
Outstanding — December 31, 2017	1,751,708		

December 2017 Underwritten Public Offering — On December 20, 2017, the Company entered into an underwriting agreement with JonesTrading, in connection with a registered firm commitment underwritten public offering of 1,105,263 shares of the Company's common stock, pursuant to a shelf registration statement that was declared effective by the SEC on April 28, 2016. On December 22, 2017 the Company sold an aggregate of 1,105,263 shares of common stock at a price to the public of at $9.50 per share. The net proceeds to the Company, after deducting the underwriting discounts and commissions and offering expenses payable by the Company were approximately $9.7 million.

February 2018 Underwritten Public Offering — On February 13, 2018, the Company entered into an underwriting agreement with JonesTrading, in connection with a registered firm commitment underwritten public offering of 2,941,176 shares of common stock, pursuant to a shelf registration statement that was declared effective by the SEC on February 6, 2018. On February 15, 2018 the Company sold 3,382,352 shares of common stock (including 441,176 shares of common stock sold pursuant to the exercise of the underwriters' overallotment option) at a price to the public of $34.00 per share. The net proceeds to the Company, after deducting the underwriting discounts and commissions and offering expenses payable by the Company were approximately $106.7 million.

15. Net Loss per Share Attributable to Common Stockholders

The following table sets forth the computation of the basic and diluted net loss per common share during the years ended December 31, 2017 and 2016 *(in thousands, except share and per share data)*:

	Year Ended December 31,	
	2017	2016
Net loss attributable to common stockholders	$ (25,512)	$ (16,945)
Weighted-average number of shares used in computing net loss per share, basic and diluted	3,423,901	779,166
Net loss per share, basic and diluted	$ (7.45)	$ (21.75)

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,	
	2017	2016
Options to purchase common stock	821,741	140,990
Convertible preferred stock(1)	736,000	—
Common stock warrants	1,751,708	12,063
Redeemable convertible notes	36,883	140,743
Total	3,346,332	293,796

(1) As of December 31, 2017, represents 3,680 shares of Series A Preferred Stock on an as converted basis to 0.7 million shares of common stock.

16. Subsequent Events

On February 13, 2018, the Company entered into an underwriting agreement with JonesTrading, in connection with a registered firm commitment underwritten public offering of 2,941,176 shares of common stock, pursuant to a shelf registration statement that was declared effective by the SEC on February 6, 2018. On February 15, 2018 the Company sold 3,382,352 shares of common stock (including 441,176 shares of common stock sold pursuant to the exercise of the underwriters' overallotment option) at a price to the public of $34.00 per share. The net proceeds to the Company, after deducting the underwriting discounts and commissions and offering expenses payable by the Company were approximately $106.7 million.

On February 19, 2018, the Redeemable Convertible notes matured and the remaining Notes were repaid in full with cash from the restricted cash indenture. The Company has no outstanding Notes remaining as of February 20, 2018.

On February 21, 2018, the Company and AGC Biologics ("AGC"), formerly known as CMC ICOS Biologics, Inc. entered into a new statement of work under the development and manufacturing services agreement dated May 20, 2016, between the Company and AGC. Under the new statement of work, the Company has engaged AGC for the process transfer and commercial scale cGMP manufacturing of CB 2679d, Catalyst's highly potent next-generation coagulation FIX variant being developed for the treatment of severe hemophilia B. The Company has agreed to a total of approximately $5.6 million in payments pursuant to the new statement of work, including the commercial scale manufacturing of CB 2679d, subject to completion of applicable work stages.

On March 2, 2018, the Company called all 3,580 outstanding shares of Series A Preferred Stock to be converted into common stock effective as of March 7, 2018. As of March 15, 2018, the Series A Preferred Stock was converted into 716,000 shares of common stock and there were no Series A Preferred Stock outstanding.

On March 5, 2018, the Company called the remaining 254,628 outstanding warrants. As of March 15, 2018, there were 45,628 warrants remaining and approximately $9.3 million proceeds received from warrants exercised during 2018. Warrant holders have until 6:30PM EST on March 19, 2018 to exercise their warrants, after this date the remaining outstanding warrants will be cancelled and the right to exercise such warrants will extinguish.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES

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, 2017. 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, 2017, 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

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 quarter ended December 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our internal control over financial reporting was designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published consolidated financial statements. Internal control over financial reporting is promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel, 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. Internal control over financial reporting, no matter how well designed, has inherent limitations and may not prevent or detect misstatements. Therefore, even effective internal control over financial reporting can only provide reasonable assurance with respect to the financial statement preparation and presentation.

Our management has conducted, with the participation of our CEO and CFO, an assessment, including testing of the effectiveness, of our internal control over financial reporting as of December 31, 2017. Management's assessment of internal control over financial reporting was based on assessment criteria established in the 2013 Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on such evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2017.

Item 9B. Other Information

None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Board of Directors

The members of our Board of Directors as of February 20, 2018, their class, positions and their respective ages on that date are:

Name	Age	Class	Position
Nassim Usman, Ph.D.	58	III	President and Chief Executive Officer
Augustine Lawlor	62	I	Chairman of the Board, Audit Committee Chair and Compensation Committee Member
Andrea Hunt	58	II	Science and Technology Committee Member
Eddie Williams	62	I	Board of Directors
Errol B. De Souza, Ph.D.	64	III	Governance and Nominating Committee, Compensation Committee Member and Science and Technology Committee Chair
Jeff Himawan, Ph.D.	52	II	Compensation Committee and Audit Committee Member
John P. Richard	60	II	Audit Committee Member and Governance and Nominating Committee Chair
Stephen A. Hill, M.D.	59	I	Science and Technology Committee Member

Nassim Usman, Ph.D. served as Chief Executive Officer and a member of the board of directors of Catalyst Bio from February 2006 until the completion of the merger in August 2015. Since the merger, Dr. Usman has served as our President and Chief Executive Officer and as a Class III director. Dr. Usman joined Catalyst Bio from Morgenthaler Ventures, where he is currently a Venture Partner. Prior to joining Morgenthaler in 2005, he was Senior Vice President and Chief Operating Officer at Sirna Therapeutics Inc., which was subsequently acquired by Merck, from 2004 to 2005, and held various R&D positions at both Sirna and Ribozyme Pharmaceuticals, including Vice President of R&D and Chief Scientific Officer, from 1992 to 2004. During his industrial career, Dr. Usman has overseen the entry of several drugs into clinical development, completion of multiple licensing deals with pharmaceutical and biotechnology companies and raised capital in both private and public financings. Prior to moving into the private sector in 1992, Dr. Usman was an NIH Fogarty and NSERC Postdoctoral Fellow and Scientist in the Departments of Biology and Chemistry at the Massachusetts Institute of Technology from 1987 to 1992. He has authored more than 70 scientific articles and is the named inventor in 130 issued patents and patent applications. Dr. Usman serves on the boards of directors of Mosaic Biosciences and Principia Biopharma, is a past director of Osprey Pharmaceuticals, Archemix Corporation and Atugen AG (now Silence Therapeutics) and served on the science advisory boards of RXi Pharmaceuticals and Noxxon Pharma AG. He received his B.Sc. (Honours) and Ph.D. in Organic Chemistry from McGill University. In his doctoral dissertation, he developed a method for the solid-phase synthesis of RNA that is widely used in science and in a marketed RNA product (Macugen™).

Dr. Usman's role as our President and Chief Executive Officer, his prior role as Catalyst Bio's Chief Executive Officer, his prior board service, and extensive experience and innovations in the field of biotechnology, particularly with companies engaged in clinical drug development, enable him to bring a unique perspective to the Board. In addition, Dr. Usman's academic expertise and accomplishments provide the Board with in-depth product and field knowledge.

Augustine Lawlor served as a member of the board of directors of Catalyst Bio from February 2006 until the completion of the merger in August 2015 and as Chairman of the Catalyst Bio board of directors from February 2018. Since the merger, Mr. Lawlor has served on our Board as a Class I director. Since 2015, Mr. Lawlor has served as Chief Operating Officer of Leap Therapeutics, Inc. a Nasdaq-listed oncology company. He has been a Managing Director of HealthCare Ventures since 2000. From 1997 to 2000, he served as Chief Operating Officer of LeukoSite, Inc., a HealthCare Ventures III, IV and V company. Prior to joining LeukoSite, Mr. Lawlor was Chief Financial Officer and Vice President of Corporate Development for Alpha-Beta Technology. He has held similar positions at both BioSurface Technology and Armstrong Pharmaceuticals. Mr. Lawlor was previously a management consultant with KPMG. He is currently a director of biopharmaceutical companies Cardiovascular Systems, Inc., which is listed on Nasdaq, and Mosaic Biosciences, Inc. Mr. Lawlor has previously served as a

director of Human Genome Sciences, which has since been acquired by GlaxoSmithKline and Replidyne, Inc. Mr. Lawlor received his Master's in Public and Private Management from Yale University.

Mr. Lawlor brings an important insight and knowledge to the Board based on his experience as a successful venture capitalist, service on the boards of public and private companies, and roles in commercial and business development in the pharmaceutical and biotechnology industries.

Andrea Hunt has served on our Board as a Class II director since October 2017. Ms. Hunt served as the Vice President of New Product Gene Therapy, Neuroscience, Oncology and Ophthalmology with Shire from June 2016 until June 2017, where she developed and integrated disease area strategies for Shire's gene therapy platform, Neuroscience, Oncology and Ophthalmology franchises. She previously served as the Vice President – Global Franchise Head for Blood Disorders with Baxalta from June 2015 to June 2016 before it was acquired by Shire. From 1988 to 2015, Ms. Hunt served in various roles with Baxter Healthcare, most recently as Vice President – Lead BAX855 and Gene Therapy in the Biosciences division from 2014 to June 2015. Ms. Hunt has served on the board of OX2 Therapeutics since November 2017. Ms. Hunt also served as a board member of the Alliance for Regenerative Medicine from 2016 to 2017 and is an advisor to the Angiogenesis Foundation. Ms. Hunt received an M.B.A. from the University of Michigan at Ann Arbor and a B.S. in Hospital Dietetics and B.A. in Foods & Nutrition from the University of Illinois at Urbana-Champaign.

We believe that Ms. Hunt's breadth of experience with pharmaceutical and biotechnology companies, together with her service as a director for another biopharmaceutical company, make her suited to serve on the Board.

Eddie Williams has served on our Board as a Class I director since January 2018. Mr. Williams was most recently Senior Vice President of biopharmaceuticals at Novo Nordisk Inc., where he was responsible for the general management of all aspects of the biotechnology business for the U.S. in three therapeutic areas, including hemophilia. Prior to Novo Nordisk, Mr. Williams was Vice President of sales in the Respiratory and Dermatology Business Unit at Novartis Pharmaceuticals Corp., where he ran all sales aspects of the respiratory and dermatology businesses. Before joining Novartis, Mr. Williams held numerous sales and marketing positions of increasing responsibility for more than 20 years at Pharmacia & Upjohn Company (acquired by Pfizer in 2002). Mr. Williams served on the board of Biotechnology Innovation Organization (BIO), the National Sales Network, Basic Supply Company, Inc., has been recognized as Industry Leader of the Year by the National Hemophilia Foundation, and chaired fundraising for the Boys & Girls Club of Trenton/Mercer County. Mr. Williams earned his B.S. in biology and chemistry from Marshall University.

We believe that Mr. William's breadth of experience with pharmaceutical and biotechnology companies, together with his service as a director for another biopharmaceutical company, make him suited to serve on the Board.

Errol B. De Souza, Ph.D. served as a member of the board of directors of Targacept from January 2004 until the completion of the merger in August 2015. Since the completion of the merger, Dr. De Souza has served on our Board as a Class III director. Dr. De Souza is currently President, CEO and a member of the Board of Directors of Neuropore Therapies, Inc. a privately held biotechnology company. From March 2010 until January 2016, Dr. De Souza served as President and Chief Executive Officer of Biodel Inc., a specialty pharmaceutical company. From April 2009 to March 2010, Dr. De Souza was a pharmaceutical and biotechnology consultant. From April 2003 to March 2009, he served as President and Chief Executive Officer of Archemix Corporation, a privately held biopharmaceutical company. Dr. De Souza currently serves as Chairman of the board of directors of the publicly-traded company Bionomics Ltd. Within the past five years, he served on the board of directors of each of the publicly-traded companies Biodel, Inc., IDEXX Laboratories, Inc. and Palatin Technologies, Inc. Dr. De Souza brings to the Board substantial experience as an executive in the pharmaceutical industry, having served as President and Chief Executive Officer of Synaptic Pharmaceutical Corp. until its sale to H. Lundbeck A/S, in addition to Biodel and Archemix. Over Dr. De Souza's career, he has also served in a number of high-ranking research and development roles, including Senior Vice President and Head of Global Lead Generation for Hoechst Marion Roussel and Senior Vice President and U.S. head of drug innovation and approval following that company's merger with Rhône-Poulenc to form Aventis (now Sanofi-Aventis) and Co-Founder, Executive Vice President of Research and Development and Director at Neurocrine Biosciences, Inc.

We believe that these experiences, together with his service as a director for other biopharmaceutical companies, will enable Dr. De Souza to contribute valuable insight to the Board regarding pharmaceutical portfolio development and management from both large company and emerging company perspectives.

Jeff Himawan, Ph.D. served as a member of the board of directors of Catalyst Bio from December 2008 until the completion of the merger in August 2015. Since the merger, Dr. Himawan has served as a member of the Board as a Class II director. Dr. Himawan is a Managing Director at Essex Woodlands Health Ventures, a healthcare focused venture capital firm, where he previously served as a Partner from 2001 to 2004 and as an Adjunct Partner from 1999 to 2001. Since 2016, Dr. Himawan has served as a managing director of Park Lane Ventures. He has over 20 years of experience as a scientist, entrepreneur and venture capitalist. Dr. Himawan was a co-founder and Managing Director of Seed-One Ventures, LLC, a venture capital firm that specializes in the initial formation, financing and early operational development of technology-based companies, from 1996 to 2001. From 1983 to 1996, Dr. Himawan was a scientist in academic and industrial settings. He currently serves as a director of MediciNova and Horizon Pharma, two publicly traded companies, as well as Light Sciences Oncology. He has previously served as a director of Iomai, a publicly traded company, as well as Complete Genomics, OMT Therapeutics, Ception Therapeutics and Symphogen. Dr. Himawan received his B.S. from Massachusetts Institute of Technology and his Ph.D. from Harvard University.

We believe Dr. Himawan's extensive experience in the biotechnology industry, considerable service on both public and private boards of directors, and background in corporate finance and raising capital will enable him to contribute important strategic insight to the Board.

John P. Richard served as a member of the board of directors of Targacept from November 2002 until the completion of the merger in August 2015, and he served as Chairman of the Board of Directors of Targacept from January 2014 until the completion of the merger. Since the merger, Mr. Richard has served as a member of the Board as a Class II director. Mr. Richard is the co-founder and head of corporate development at Mereo BioPharma Group plc., and has served as a non-executive director for the life science investment firm Phase4 Partners since March 2011, and has previously served as an Operating Partner and Venture Partner at Phase4 Partners. From 2005 until 2015 he was also a Managing Director of Georgia Venture Partners, a seed venture capital firm that focuses on the biotechnology industry. In addition, Mr. Richard has served as a senior business advisor to a number of biotechnology companies as well as a consultant to portfolio companies of Georgia Venture Partners and Phase4 Ventures. Mr. Richard has been a director of the publicly-traded company Vaxart, Inc. (formerly Aviragen Therapeutics, Inc.) since August 2013. Mr. Richard brings to the Board extensive business development experience, having led that function at three separate life science companies and played a primary role in establishing numerous pharmaceutical alliances.

In addition, we believe the breadth of Mr. Richard's current roles will enable him to view issues that the combined company faces from a variety of perspectives, including as an executive, investor, director and business development professional.

Stephen A. Hill, M.D. served as President and Chief Executive Officer and a member of the board of directors of Targacept from December 2012 until the completion of the merger in August 2015. Since the merger, Dr. Hill has continued to serve on our Board as a Class I director, and in August 2015 Dr. Hill joined Faraday Pharmaceuticals as Chief Executive Officer. From May 2012 to November 2012, Dr. Hill served as President and Chief Executive Officer of QUE Oncology, a start-up biotechnology company, and, from March 2011 to December 2011, he served as President and Chief Executive Officer of 21st Century Biodefense, Inc., a biodefense company. From April 2008 until its acquisition in December 2010, he served as President and Chief Executive Officer of Solvay Pharmaceuticals, Inc., a pharmaceutical company. Prior to Solvay, he served as President, Chief Executive Officer and director of ArQule, Inc., a pharmaceutical company, from April 1999 to March 2008. Dr. Hill is a member of the board of directors of the publicly traded companies Cellectar Biosciences, Inc. (formerly Novelos Therapeutics, Inc.) and Lipocine, Inc. and the private company Faraday Pharmaceuticals. Dr. Hill brings to the Board extensive experience across a range of senior management positions with both pharmaceutical and biotechnology companies. Prior to Solvay and ArQule, Dr. Hill held several leadership positions with F. Hoffmann-La Roche Ltd., including Global Head of Clinical Development, and served for seven years with the National Health Service in the United Kingdom in General and Orthopedic Surgery.

Dr. Hill's prior service as Targacept's Chief Executive Officer, together with his breadth of experience with pharmaceutical and biotechnology companies, make him uniquely suited to serve on the Board.

Executive Officers

Our executive officers as of February 20, 2018, their positions and their respective ages on that date are:

Name	Age	Position
Nassim Usman, Ph.D.	58	President and Chief Executive Officer
Fletcher Payne	55	Chief Financial Officer
Howard Levy, M.B.B.Ch., Ph.D., M.M.M	63	Chief Medical Officer

Our executive officers serve at the discretion of the board of directors, subject to rights, if any, under contracts of employment. There are no family relationships among any of our current directors and executive officers. Biographical information for Dr. Usman is provided above under the heading "Board of Directors."

Fletcher Payne served as Catalyst Bio's Chief Financial Officer from January 2015 until the completion of the merger in August 2015. Since the merger, Mr. Payne has served as our Chief Financial Officer. Mr. Payne joined Catalyst Bio in a consulting capacity through Danforth Advisors LLC, where he worked as a consultant, until April 2015, when he became a Catalyst Bio employee. He has been a consulting Chief Financial Officer of CFP Advisory since November 2011, and from September 2008 to November 2011, Mr. Payne served as Chief Financial Officer of Pathwork Diagnostics. Mr. Payne has also served in senior financial positions at CytomX Therapeutics, Plexxikon Inc., Rinat Neuroscience Corporation, Dynavax Technologies Corporation, Cell Genesys, Abgenix, Sun Micro Systems, and IBM. Mr. Payne has over 20 years of experience helping life science companies achieve their business goals. His life science experience includes successful start-ups, initial public offerings, mergers, spin-outs, financings, business collaborations and working with R&D teams whose efforts have led to four products receiving FDA clearance. Mr. Payne graduated with a B.S. in Finance from the Haas School of Business, University of California, Berkeley.

Howard Levy, M.B. B.Ch., Ph.D., M.M.M., joined us as our Chief Medical Officer in April 2016. Prior to joining us, from 2010 through April 2016, Dr. Levy had served as either a Chief Medical Officer or a consultant with various public and private biotechnology companies on clinical and drug development strategy and execution. In addition, Dr. Levy was the Senior Global Medical Program Director at CSL Bering in 2013, and he was the Senior Vice President and Chief Medical Officer at Inspiration Biopharmaceuticals, a company solely focused on innovation in hemophilia, in 2012. From 2008 to 2011, he served as Chief Medical Officer at Sangart, Inc., which was developing pegylated hemoglobin as an oxygen therapeutic agent and a treatment for sickle cell crisis. Prior to Sangart, from 2006 to 2008, Dr. Levy was Associate Vice President, Clinical Research, Medical and Regulatory Affairs, at Novo Nordisk and was responsible for a number of clinical research programs, including recombinant Factor VIIa. Earlier in his career, Dr. Levy was Clinical Research Physician and Medical Director, Acute Care in the U.S. Medical Division of Eli Lilly and Company supporting post-marketing clinical trials and medical affairs for recombinant Activated Protein C (Xigris) in severe sepsis and antiplatelet agents ReoPro and prasugrel. He was also Chief of Critical Care Medicine at the University of New Mexico in Albuquerque for 11 years. Dr. Levy holds M.B. B.Ch and Ph.D. degrees from University of the Witwatersrand in Johannesburg, South Africa and an M.M.M. from Carnegie Mellon University's H. John Heinz III College.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act of 1934 requires our directors and executive officers, and persons who own more than ten percent of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of common stock and other equity securities of Catalyst. Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of such reports furnished to us and written representations that no other reports were required, during the fiscal year ended December 31, 2017 all Section 16(a) filing

requirements applicable to our officers, directors and greater than ten percent beneficial owners were filed in a timely manner.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all officers, directors and employees. Our Code of Business Conduct and Ethics is available on the investors section of our website (at www.catalystbiosciences.com) under the heading "Governance Highlights." If we make any substantive amendments to our Code of Business Conduct and Ethics or grant any waiver from a provision of the Code of Business Conduct and Ethics to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on the investors section of our website at www.catalystbiosciences.com under the heading "Governance Highlights." We intend to satisfy the disclosure requirements under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics by posting such information on our website at the address and location specified above.

Changes in Governance and Nominating Committee Procedures

There have been no material changes to the procedures by which stockholders may recommend individuals for consideration by the Governance and Nominating Committee as potential nominees for director since such procedures were last described in our Current Report on Form 10-K, filed with the SEC on March 9, 2017.

Audit Committee

We have a separately-designated standing audit committee established in accordance with section 3(a)(58)(A) of the Exchange Act. Our Audit Committee generally assists the Board in its oversight of Catalyst's accounting, financial reporting and internal control functions. The Audit Committee currently consists of Mr. Lawlor, who serves as Chairman, Dr. Himawan and Mr. Richard. As required by Nasdaq rules, the members of the Audit Committee each qualify as "independent" under special standards established for members of audit committees. To qualify as "independent" to serve on the Audit Committee, the Nasdaq rules and the applicable rules of the SEC require that a director does not accept any consulting, advisory, or other compensatory fee from Catalyst, other than for service as a director, or be an affiliated person of the Company. The Board has concluded that the current composition of the Audit Committee meets the requirements for independence under the rules and regulations of Nasdaq and of the SEC. In accordance with SEC rules, the Audit Committee also includes at least one member who is determined by the Board to meet the qualifications of an "audit committee financial expert." Mr. Lawlor and Mr. Richard are the directors who have been determined by the Board to be the audit committee financial experts. The designation does not impose upon Mr. Lawlor or Mr. Richard any duties, obligations or liability that are greater than are generally imposed on each of them as members of the Audit Committee and the Board, and each of their designations as an audit committee financial expert pursuant to this SEC requirement does not affect the duties, obligations or liability of any other member of the Audit Committee or the Board.

Director Independence

Nasdaq's listing standards and Catalyst's Corporate Governance Guidelines require that the Board consist of a majority of independent directors, as determined under the applicable Nasdaq listing standard. The Board, consistent with the determination of its Governance and Nominating Committee, has determined that each of Mr. Lawlor, Ms. Hunt, Mr. Williams, Dr. De Souza, Dr. Himawan and Mr. Richard qualify as an independent director. In addition, as further required by Nasdaq rules, the Board, consistent with the determination of its Governance and Nominating Committee, has made a subjective determination as to each independent director that no relationships exist which, in the opinion of the Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our directors reviewed and discussed information provided by our directors and us with regard to each director's business and personal activities as they may relate to us and our management.

Item 11. EXECUTIVE COMPENSATION

Executive Compensation Table

In this Executive Compensation section of this Annual Report on Form 10-K, we refer to Dr. Usman, Dr. Levy and Mr. Payne, collectively, as our Named Executive Officers. Dr. Usman was our Chief Executive Officer and Mr. Payne and Dr. Levy were our next two highest compensated executive officers serving as of December 31, 2017.

Summary Compensation Table

The following table shows for the years ended December 31, 2017 and 2016 compensation awarded to or paid to our Named Executive Officers.

Name and principal position	Year	Salary ($)	Bonus ($)(1)	Stock Awards ($)(2)	Option Awards ($)(3)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)(4)	Total ($)
Nassim Usman, Ph.D.	2017	464,103	303,417	—	1,062,381	—	5,372	1,835,273
President and Chief Executive Officer	2016	453,200	113,300	—	—	—	3,134	569,634
Fletcher Payne	2017	335,244	152,536	—	289,351	—	2,092	779,223
Chief Financial Officer	2016	325,480	56,960	—	—	—	1,220	383,660
Howard Levy, M.B.B.Ch., Ph.D., M.M.M.(5)	2017	386,250	175,744	—	366,915	—	3,317	932,226
Chief Medical Officer	2016	265,625	46,484	—	100,060	—	1,935	414,104

(1) The amounts in the column titled “Bonus” generally reflect discretionary cash payments made with respect to officer performance during the indicated year but paid during the first quarter of the following year.

(2) The amounts in this column reflect the aggregate grant date fair value of restricted stock awarded during the year calculated in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, Compensation—Stock Compensation, or ASC 718, disregarding the potential for forfeitures, regardless of the period in which the corresponding compensation expense was recorded in accordance with ASC 718.

(3) The amounts in this column reflect for each fiscal year shown the aggregate grant date fair value of stock options granted during the year calculated in accordance with ASC 718, disregarding the potential for forfeitures, regardless of the period in which the corresponding compensation expense was recorded in accordance with ASC 718. The amount in this column for Dr. Levy represents the grant date fair value of an employment inducement option, which was made outside of the Company’s 2015 Stock Incentive Plan, as amended, and is intended to qualify as an employment inducement grant under Nasdaq Listing Rule 5635(c)(4).

(4) The amounts in this column for Drs. Usman and Levy and Mr. Payne for 2017 and 2016 represent payment of life insurance premiums, long-term disability and other insurance-related reimbursements.

(5) Dr. Levy commenced service with the Company on April 18, 2016.

Employment Agreements

Each of our currently serving Named Executive Officers is party to an offer letter (as described below), as well as a standard confidential information and/or inventions assignment agreement, under which each of Dr. Usman, Mr. Payne and Dr. Levy agreed not to disclose our confidential information. On September 19, 2017, we entered into amended and restated employment agreements with Dr. Usman and Mr. Payne. The employment agreements were amended and restated in order to, among other things, harmonize the provisions relating to

(i) severance without cause or as a result of constructive termination; (ii) severance without cause or as a result of constructive termination after a change of control; (iii) the definition of “constructive termination”; and (iv) the

exercise period for vested options in the event of death or disability (collectively, the "Provisions"). Other than as described herein, the material terms of the employment agreements, as previously disclosed by us, have not been revised.

Our board of directors or the compensation committee reviews each NEO's base salary and target bonus opportunity from time to time to ensure compensation adequately reflects the NEO's qualifications, experience, role and responsibilities.

Nassim Usman

Under our amended and restated employment agreement with Dr. Nassim Usman, our President and Chief Executive Officer, Dr. Usman is entitled to an annual base salary, which is currently $480,800, and will also have the opportunity to earn an annual performance-based bonus of 50% of his base salary. Dr. Usman is eligible for our benefits program, including life and disability insurance, medical, dental and vision, and a 401K and Flex Spending account.

The employment agreement provides that if Dr. Usman's employment is terminated without "cause" (as defined in the agreement) or as a result of "constructive termination," (as defined in the agreement) in each case before a "change of control" (as defined in the agreement), he shall be entitled to receive the following:

- severance payments, equal to the rate of his base salary he was receiving at the time of such termination for a period of twelve (12) months; and
- accelerated vesting of the number of shares of common stock subject to options he holds that would otherwise have vested as of the date twelve (12) months after the effective date of his termination.

If Dr. Usman's employment is terminated without "cause" or as a result of "constructive termination," in each case after a "change of control," he shall be entitled to receive the following:

- continued payment of his base salary for twelve (12) months; and
- accelerated vesting as of the time of such termination with respect to all unvested options.

Fletcher Payne

Under our amended and restated employment agreement with Fletcher Payne, our Chief Financial Officer, Mr. Payne is entitled to an annual base salary, which is currently $345,301, and will also have the opportunity to earn an annual performance-based bonus of 35% of his base salary. Mr. Payne is eligible for our benefits program, including life and disability insurance, medical, dental and vision, and 401K plans.

The employment agreement provides that if Mr. Payne's employment is terminated without "cause" (as defined in the agreement) or as a result of "constructive termination," (as defined in the agreement) in each case before a "change of control" (as defined in the agreement), he shall be entitled to receive the following:

- severance payments, equal to the rate of his base salary he was receiving at the time of such termination for a period of six (6) months; and
- accelerated vesting of the number of shares of common stock subject to options he holds that would otherwise have vested as of the date six (6) months after the effective date of his termination.

If Mr. Payne's employment is terminated without "cause" or as a result of "constructive termination," in each case after a "change of control," he shall be entitled to receive the following:

- continued payment of his base salary for nine (9) months; and
- accelerated vesting as of the time of such termination with respect to all unvested options.

Howard Levy

Under our offer letter with Dr. Levy, our Chief Medical Officer, Dr. Levy is entitled to an annual base salary, which is currently $397,838. Dr. Levy will also have the opportunity to earn an annual performance-based bonus of 35% of his base salary. Further, as an inducement to his service with the Company, Dr. Levy was awarded options to purchase 6,666 shares of our common stock at an exercise price per share equal to the fair market value on the date of grant, one quarter of which vested at the one-year anniversary of his April 18, 2016 start date, and the remainder of which is vesting monthly at the rate of 1/48 of the total number of shares per month, subject to acceleration as set forth below. In the event that the Company terminates Dr. Levy's employment for any reason, he will have three months following his termination to exercise the vested portion of these options, except in the case of death or disability, for which he will have one year to exercise such options.

The letter agreement provides that if Dr. Levy's employment is terminated without "cause" (as defined in the agreement) or as a result of "constructive termination," (as defined in the agreement) in each case after the one-year anniversary of his start date and before a "change of control" (as defined in the agreement), he shall be entitled to receive the following:

- severance payments, equal to the rate of his base salary he was receiving at the time of such termination for a period of six (6) months; and
- accelerated vesting of the number of shares of common stock subject to options he holds that would otherwise have vested as of the date six (6) months after the effective date of his termination.

If Dr. Levy's employment is terminated without "cause" or as a result of "constructive termination," in each case after a "change of control," he shall be entitled to receive the following:

- continued payment of his base salary for nine (9) months; and
- accelerated vesting as of the time of such termination with respect to all unvested options.

The letter agreement also provides certain other benefits and perquisites generally made available to similarly situated employees, including the option to participate in certain employee benefit plans and to receive paid time off benefits.

Outstanding Equity Awards at December 31, 2017

The following table provides information regarding unexercised stock options held by each of the Named Executive Officers as of the end of fiscal year 2017.

Name	Grant Date		Number of Securities Underlying Unexercised Option Exercisable(#)	Number of Securities Underlying Unexercised Option Unexercisable(#)		Option Exercise Price($)	Option Expiration Date
Nassim Usman, Ph.D.	1/3/2013	(1)	1,500	—		$ 172.80	1/3/2023
	4/10/2008	(1)	585	—		$ 141.45	4/10/2018
	3/17/2009	(1)	4,074	—		$ 190.95	3/17/2019
	10/22/2015		2,682	2,079	(2)	$ 66.00	10/22/2025
	10/22/2015		5,767	4,471	(2)	$ 66.00	10/22/2025
	7/11/2017		34,375	240,625	(5)	$ 4.63	7/11/2027
Fletcher Payne	1/22/2015	(1)	488	—		$ 114.00	1/22/2025
	1/22/2015	(1)	162	—		$ 114.00	1/22/2025
	5/8/2015	(1)	560	395	(3)	$ 90.45	5/8/2025
	10/22/2015		2,682	2079	(2)	$ 66.00	10/22/2025
	10/22/2015		1,081	823	(2)	$ 66.00	10/22/2025
	7/11/2017		9,375	65,625	(5)	$ 4.63	7/11/2027
Howard Levy M.B.B.Ch., Ph.D., M.M.M.	4/18/2016		2,779	3887	(4)	$ 22.80	4/18/2026
	7/11/2017		11,875	83,125	(5)	$ 4.63	7/11/2027

(1) These stock options were granted by the board of directors of Catalyst Bio on the grant dates listed but were assumed by the Company upon the closing of the merger on August 20, 2015 and converted into options to purchase common stock of the Company as described in the table.

(2) The remaining portion of these options to purchase common stock vest at the rate of 1/48th of the number of total shares subject to the option on the 1st day of each month, with the final tranche vesting on September 1, 2019.

(3) The remaining portion of these options to purchase common stock vest at the rate of 1/48th of the number of total shares subject to the option on the 1st of each month, with the final tranche vesting on August 20, 2019.

(4) A quarter of the shares of common stock underlying this inducement option vested on April 18, 2017 and the remaining portion of the shares of common stock underlying this option shall vest at the rate of 1/48th of the number of total shares subject to the option monthly thereafter, with the final tranche vesting on April 18, 2020.

(5) The remaining portion of these options to purchase common stock vest at the rate of 1/48th of the number of total shares subject to the option on the 15th day of each month, with the final tranche vesting on June 15, 2021.

Director Compensation

Pursuant to our non-employee directors' compensation policy (directors who are employees of the Company will not receive any compensation for their service on the board of directors), our non-employee directors are eligible to receive the following:

- Initial Equity Grants. Each non-employee director who joins the Board will receive an option to purchase 10,000 shares of common stock, which will vest monthly over three years, subject to continued service.

- Annual Retainers. Each non-employee director will receive an annual retainer for service on the Board consisting of an option to purchase 5,000 shares of the common stock, to be awarded at the Company's annual stockholders' meeting and which will vest over one year, in addition to annual cash retainers for service on the Board and committees of the Board, or for service as chair of the Board or such committees (inclusive of retainers for service as a member), as follows:

Additional annual retainer fees for service as member or chair of	Member	Chair
Board of Directors	$ 35,000	$ 25,000
Audit Committee	$ 7,500	$ 15,000
Compensation Committee	$ 5,000	$ 10,000
Governance and Nominating Committee	$ 3,750	$ 7,500
Science and Technology Committee	$ 3,750	$ 7,500

Director Compensation for Fiscal Year 2017

The following table shows for the year ended December 31, 2017 certain information with respect to the compensation of our non-employee directors serving during 2017. For information regarding compensation paid to Dr. Usman, see the "Summary Compensation Table" on page 103.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)(2)	Total ($)
Augustine Lawlor	50,000	35,086	85,086
Andrea Hunt(3)	6,505	38,346	44,851
Eddie Williams(4)	—	—	—
Errol B. De Souza	51,250	35,086	86,336
Harold E. Selick, Ph.D.	73,750	35,086	108,836
Jeff Himawan, Ph.D.(5)	—	—	—
John P. Richard	50,000	35,086	85,086
Stephen A. Hill	38,750	35,086	73,836

(1) The amounts in this column reflect the aggregate grant date fair value of stock options granted during fiscal 2017 calculated in accordance with ASC 718, disregarding the potential for forfeitures.

(2) The following table sets forth the aggregate number of option awards held by each non-employee director serving in 2017 as of December 31, 2017:

NAME	Aggregate Number of Option Awards
Augustine Lawlor	11,500
Andrea Hunt	10,000
Eddie Williams	—
Errol B. De Souza	13,577
Harold E. Selick, Ph.D.	11,697
Jeff Himawan, Ph.D.	—
John P. Richard	13,577
Stephen A. Hill	11,500

(3) Andrea Hunt joined Catalyst as a director on October 26, 2017.

(4) Eddie Williams joined Catalyst as a director on January 1, 2018.

(5) Dr. Himawan has declined to receive any compensation for his service as a director, in accordance with the policies of the investment fund for which he serves as Managing Director.

Compensation Committee Interlocks and Insider Participation

None of the directors who served on our Compensation Committee during 2017, was an officer within the meaning of Rule 3b-2 under the Securities Exchange Act of 1934, or an employee of the Company during or prior to fiscal year 2017 nor did any of such directors have any relationship during the past year that would have been required to be disclosed pursuant to Item 404 of Regulation S-K. None of our executive officers currently serve, or in the past year have served, as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more executive officer serving on our Board or Compensation Committee.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of February 20, 2018, for:

(1) each person or group of affiliated persons known by us to be the beneficial owner of more than 5% of our common stock;

(2) each of our named executive officers;

(3) each of our directors; and

(4) all current executive officers and directors as a group.

Applicable percentage ownership is based on 10,741,273 shares of common stock outstanding at February 20, 2018. We have determined beneficial ownership in accordance with SEC rules. The information does not necessarily indicate beneficial ownership for any other purpose. Under these rules, the number of shares of common stock deemed outstanding includes shares issuable upon exercise of options or warrants, or the conversion of convertible notes, held by the respective person or group that may be exercised or converted within 60 days after February 20, 2018. For purposes of calculating each person's or group's percentage ownership, stock options and warrants exercisable, and notes convertible, within 60 days after February 20, 2018 are included for that person or group, but not the stock options of any other person or group.

Unless otherwise indicated and subject to applicable community property laws, to our knowledge, each stockholder named in the following table possesses sole voting and investment power over the shares listed. Unless otherwise noted below, the address of each person listed in the table is c/o Catalyst Biosciences, Inc., 611 Gateway Blvd., Suite 710, S. San Francisco, CA 94080.

Name	Number of Shares Owned and Nature of Beneficial Ownership	Percent of Class
5% or Greater Stockholders		
Deerfield Entities	1,185,000(1)	11.03%
780 Third Avenue, 37th Floor		
New York, NY 10017		
Directors and Named Executive Officers		
Nassim Usman, Ph.D.	87,782 (2)	*
Fletcher Payne	24,527 (3)	*
Howard Levy, M.B.B.Ch., Ph.D., M.M.M.	25,190 (4)	*
Augustine Lawlor	80,944(5)(6)	*
Andrea Hunt	1,389(7)	*
Eddie Williams	961(8)	*
Errol B. De Souza	12,016(9)	*
Jeff Himawan, Ph.D.	81,762(10)	*
John P. Richard	12,039 (11)	*
Stephen A. Hill, M.D.	11,078 (12)	*
All Directors and Executive Officers as a Group (10 persons)	**337,688 (13)**	**3.14%**

* Indicates less than 1% of class.

(1) The information reported is based on a Schedule 13G filed with the SEC on February 15, 2018 which reports that, as of February 15, 2018, (i) Deerfield Partners, L.P. (“Deerfield Partners”) directly holds 859,307 shares and (ii) Deerfield Special Situations Fund, L.P. (“Deerfield Fund”) directly holds 325,693 shares, Deerfield Mgmt., L.P. (“Deerfield LP”) is the general partner of Deerfield Partners and Deerfield Fund and may be deemed to have shared dispositive and voting power over the 1,185,000 shares held by Deerfield Partners and Deerfield LP. Deerfield Management Company, L.P. (“Deerfield Management”) is the investment advisor for Deerfield Partners and Deerfield Fund and may be deemed to have shared dispositive and voting power with respect to the 1,185,000 shares held by Deerfield Partners and Deerfield LP. James Flynn may also be deemed to have shared dispositive and voting power with respect to the 1,185,000 shares held by Deerfield Partners and Deerfield Fund.

(2) Consists of (i) 4,056 shares and 1 share issuable upon the exercise of warrants within 60 days held by the Usman Family Trust, of which Dr. Usman is a co-trustee with Susan L. Usman, (ii) 5,225 shares and (iii) 78,500 shares issuable upon the exercise of options within 60 days.

(3) Consists of (i) 1,668 shares held by Charles and Nancy Payne 2000 Trust, of which Mr. Payne is a trustee and (ii) 22,859 shares issuable upon the exercise of options within 60 days.

(4) Consists of 25,190 shares issuable upon the exercise of options within 60 days.

(5) Consists of 9,698 shares issuable upon the exercise of options within 60 days.

(6) The information reported is based on a Schedule 13D filed with the SEC on August 31, 2015 which reports that, as of August 20, 2015, Healthcare Ventures VIII, L.P. (“HCVVIII”) directly beneficially owns 71,247 shares which include 1,846 shares that may be purchased upon the exercise of warrants within 60 days. Each of James H. Cavanaugh, Ph.D., Harold R. Werner, John W. Littlechild, Christopher Mirabelli, Ph.D., and Augustine Lawlor are the managing directors of HealthCare Ventures VIII, LLC (“HCPVIIILLC”), the general partner of HealthCare Partners VIII, L.P. (“HCPVIII”), which is the

general partner of HCVVIII. HCPVIIILLC and HCPVIII may be deemed to indirectly beneficially own 71,247 shares, which include 1,846 shares that may be purchased upon the exercise of warrants within 60 days. Each of Drs. Cavanaugh and Mirabelli and Messrs. Werner, Littlechild and Lawlor may be deemed to indirectly beneficially own 71,247 shares, which include 1,846 shares that may be purchased upon the exercise of warrants within 60 days. HCVVIII, HCPVIII, HCPVIIILLC. Drs. Cavanaugh and Mirabelli and Messrs. Werner, Littlechild and Lawlor share the power to vote and direct the vote and to dispose of and direct the disposition of the shares beneficially owned by HCVVIII.

(7) Consists of 1,389 shares issuable upon the exercise of options within 60 days.

(8) Consists of (1) 128 shares and (ii) 833 shares issuable upon the exercise of options within 60 days.

(9) Consists of (i) 241 shares, and (ii) 11,775 shares issuable upon the exercise of options within 60 days.

(10) The information reported is based on a Schedule 13D filed with the SEC on August 31, 2015 which reports that, as of August 20, 2015, (i) Essex Woodlands Health Ventures Fund VIII, L.P. (“Essex VIII”) directly holds 74,103 shares, which include 2,850 shares issuable upon the exercise of warrants within 60 days, (ii) Essex Woodlands Health Ventures Fund VIII-A, L.P. (“Essex VIII-A”) directly holds 5,342 shares which include 255 shares issuable upon the exercise of warrants within 60 days), and (iii) Essex Woodlands Health Ventures Fund VIII-A, L.P. (“Essex VIII-B”) directly holds 2,322 shares, which include 89 shares issuable upon the exercise of warrants within 60 days. Essex Woodlands Health Ventures VIII, L.P. (the “GP Partnership”) is the general partner of Essex VIII, Essex VIII-A, and Essex VIII-B. Essex Woodlands Health Ventures VIII, LLC (“Essex VIII LLC”) is the general partner of the GP Partnership. Essex VIII LLC, as the general partner of the GP Partnership, may be deemed to have sole voting investment power with respect to 81,767 shares comprising of (i) 78,623 shares and (ii) 3,144 shares that may be purchased upon the exercise of warrants within 60 days. Essex VIII LLC disclaims beneficial ownership to 81,767 shares comprising of (i) 78,623 shares and (ii) 3,144 shares that may be purchased upon the exercise of warrants within 60 days, except to the extent of its pecuniary interest. Dr. Jeff Himawan, Marty Sutter, Petri Vainio, Immanuel Thangaraj, Ron Eastman, Steve Wiggins, and Guido Neels (the “Managers”) may also be deemed to have shared dispositive power and voting power with respect to 81,767 shares comprising of (i) 78,623 shares and (ii) 3,144 shares that may be purchased upon the exercise of warrants within 60 days. The GP Partnership disclaims beneficial ownership of the shares except to the extent of its pecuniary interest therein.

(11) Consists of (i) 264 shares, and (ii) 11,775 shares issuable upon the exercise of options within 60 days.

(12) Consists of (i) 1,380 shares, and (ii) 9,698 shares issuable upon the exercise of options within 60 days.

(13) Includes (i) 14,069 shares, and (ii) 158,224 shares of subject to options exercisable within 60 days.

Equity Compensation Plan Information

The Company's equity compensation plans consist of the Catalyst Biosciences, Inc. 2015 Stock Incentive Plan (as amended and restated effective October 14, 2015), as amended (the "2015 Plan"), the Targacept, Inc. 2006 Stock Incentive Plan (the "2006 Plan") and the Targacept, Inc. 2000 Equity Incentive Plan (the "2000 Plan"), each of which was approved by the Company's stockholders, as well as the Catalyst Biosciences, Inc. 2004 Stock Plan (the "2004 Plan"), which was approved by Catalyst Bio's stockholders and assumed in connection with the merger, and a plan that relates solely to an inducement stock option grant for 100,000 shares that was awarded in 2016. No further grants may be made under any of these plans, other than the 2015 Plan. The Company also granted a standalone inducement stock option to Dr. Howard Levy in April 2016, another standalone inducement stock option in December 2012, and assumed in connection with the merger, standalone options granted to certain service providers of Catalyst Bio in February 2014, February 2015 and May 2015. The following table sets forth certain information as of December 31, 2017 with respect to the Company's equity compensation plans and standalone options.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options Warrants and Rights (A)	Weighted-Average Exercise Price of Outstanding Options (B)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (A)) (C)
Equity compensation plans approved by security holders(1)	798,054	$ 11.03	354,886
Equity compensation plans not approved by security holders(2)	23,687	$ 103.37	—
Total	821,741	$ 13.69	354,886

(1) Includes shares issued or issuable upon the exercise of stock option, restricted stock or other stock-based awards under the 2015 Plan and 2006 Plan.

(2) Includes options to purchase 14,653 shares, at a weighted average exercise price of $139.85, which were granted under the 2004 Plan. No further grants may be made under the 2004 Plan. Includes an aggregate of 2,368 shares issuable upon the exercise of standalone options with a weighted average exercise price of $104.50, issued to Dr. Hansoo Keyoung and Fletcher Payne, our Chief Financial Officer, by Catalyst Bio and assumed in connection with the merger. Also includes 6,666 shares issuable upon the exercise of a standalone option with an exercise price of $22.80, issued to Dr. Levy, as a material inducement to the decision of Dr. Levy to accept employment as Chief Medical Officer of the Company (both of such inducement grants were approved by both the Compensation Committee and the Board and are subject to anti-dilution adjustment in connection with splits, reports, and other nonreciprocal corporate transactions).

As of February 20, 2018, the maximum aggregate number of shares available for future grants under all the Company-administered equity compensation plans was 126,986 shares. In addition, at that time, the aggregate number of shares subject to unvested outstanding full value awards was zero, and the aggregate number of shares subject to outstanding options, including standalone options, was 1,049,641 shares. The weighted average exercise price of these options was $13.94 and the weighted average remaining term was 6.03 years as of December 31, 2017. On February 20, 2018, the closing sales price of the common stock as reported on Nasdaq was $29.50 per share.

Item 13. CERTAIN RELATIONSHIPS, RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Described below are the transactions and series of similar transactions since January 1, 2016 in which:

- transactions in which the amount involved exceeds the lesser of $120,000 or one percent of the average of the smaller reporting company's total assets at year-end for the last two completed fiscal years; and
- any of the directors, executive officers, holders of more than 5% of capital stock (sometimes referred to as “5% stockholders” below) of the Company or any member of their immediate family had or will have a direct or indirect material interest.

Executive Compensation and Employment Arrangements

Please see “Executive Compensation” for information on compensation arrangements with our executive officers, the inducement grant made to Dr. Levy and agreements with, and offer letters to, our executive officers containing compensation and termination provisions, among others.

Indemnification Agreements

The Company has entered into indemnification agreements with each of its directors and with each executive officer. Pursuant to the indemnification agreements, the Company has agreed to indemnify and hold harmless these directors and officers to the fullest extent permitted by the Delaware General Corporation Law. The agreements generally cover expenses that a director or officer incurs or amounts that a director or officer becomes obligated to pay because of any proceeding to which he or she is made or threatened to be made a party or participant by reason of his or her service as a current or former director, officer, employee or agent of the Company. The agreements also provide for the advancement of expenses to the directors and officers subject to specified conditions. There are certain exceptions to the Company’s obligation to indemnify the directors and officers, including any intentional malfeasance or act where the director or officer did not in good faith believe he or she was acting in the Company’s best interests, with respect to “short-swing” profit claims under Section 16(b) of the Exchange Act and, with certain exceptions, with respect to proceedings that he or she initiates.

Policies and Procedures Regarding Related Party Transactions

The Board has adopted a written policy pursuant to which each actual or proposed financial transaction, arrangement or relationship (including any indebtedness or guarantee of indebtedness) or series of similar financial transactions, arrangements or relationships, other than specified employment and compensatory matters, in which (i) the Company was or would be a participant, (ii) the amount involved exceeds $120,000 and (iii) a “related person” (as defined under Item 404 of Regulation S-K) has a direct or indirect material interest, is submitted to the Audit Committee for its review and approval or, if applicable, ratification. These transactions, arrangements or relationships are known as “related person transactions.”

Under the policy, our Chief Financial Officer and outside counsel consult regarding any proposed transaction, arrangement or relationship that is identified as a possible related person transaction. If they determine the Company desires to proceed with the proposed transaction, arrangement or relationship and the outside counsel determines, based on available information, that the proposed transaction may constitute a related person transaction, it is submitted to the Audit Committee for its consideration. The Audit Committee is to consider all available relevant facts and circumstances, including the benefits to the Company, the impact on a director’s independence in the event the related person is a director (or a family member or entity affiliated with a director), the availability of other sources for comparable products or services, the proposed terms and the terms available to or from parties that are not related persons. Absent special circumstances, the Audit Committee may approve only those related person transactions that it determines to be in or not contrary to the best interests of the Company and its stockholders. No member of the Audit Committee may participate in any review, consideration or approval of any related person transaction with respect to which the member or any of his or her immediate family members is the related person.

Strategic Research Collaboration with Mosaic Biosciences, Inc. ("Mosaic")

On October 24, 2017, the Company announced a strategic research collaboration with Mosaic to develop intravitreal anti-complement factor 3 (C3) products for the treatment of dry AMD and other retinal diseases. According to the agreement the Company and Mosaic will co-fund the research and the Company will pay Mosaic a portion of any proceeds received from any license of products resulting from the collaboration. Dr. Usman, our Chief Executive Officer and a member of our board of directors, and Mr. Lawlor, a managing director of HealthCare Ventures VIII, L.P. and a member of our board of directors, are members of the board of directors of Mosaic. Mr. Lawlor may be deemed to indirectly beneficially own all of the shares of Mosaic held by Healthcare Ventures VIII, L.P. The transaction was reviewed by disinterested members of our board of directors and approved by our audit committee.

Director Independence

For a discussion of the independence of our directors, please see Part III-Item 10-"Directors, Executive Officers and Corporate Governance—Director Independence" above.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Current Independent Registered Public Accounting Firm Fees

The following table sets forth the fees for professional services rendered by EisnerAmper LLP, the Company's independent registered public accounting firm, in connection with the audits of our annual financial statements for the years ended December 31, 2017 and 2016 and for other services rendered by EisnerAmper LLP during those periods. All fees described below were approved by the audit committee.

	Fiscal 2017	Fiscal 2016
Audit Fees(1):	$ 282,974	$ 208,250
Audit-Related Fees:	—	—
Tax Fees:	—	—
All Other Fees:	—	—
Total Fees:	$ 282,974	$ 208,250

(1) Audit Fees include fees billed for the applicable year for services: (a) in connection with the audit of the Company's financial statements included in its annual report on Form 10-K, quarterly reports on Form 10-Q and registration statements on Forms S-1, S-3 and S-8.

Audit Committee Pre-Approval Policy

The Audit Committee has adopted a policy that requires the Audit Committee to approve all audit and permissible non-audit services to be provided by the independent registered public accounting firm prior to its engagement to provide such services. The Audit Committee has established a pre-approval policy for certain audit and non-audit services, up to a specified amount for each identified service that may be provided by the independent registered public accounting firm. In addition, the Chairman of the Audit Committee, or any member of the Audit Committee designated by the Chairman, may specifically approve any service that is not a prohibited non-audit service if the fees for such service are not reasonably expected to exceed $10,000. Any such approval by the Chairman or his designee must be reported to the Audit Committee at its next scheduled meeting. The pre-approved services of the independent registered public accounting firm, and corresponding maximum fees, are reviewed annually by the Audit Committee.

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. See LIST OF EXHIBITS

(b) See LIST OF EXHIBITS

Item 16. FORM 10-K SUMMARY

None.

LIST OF EXHIBITS

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 Fourth 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	Second Certificate of Amendment to the Fourth 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 February 10, 2017)
3.4	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)
3.5	Certificate of Designation of Preferences, Rights and Limitations, filed with the Delaware Secretary of State on April 10, 2017, with respect to the Series A Preferred Stock (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on April 13, 2017)
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)
4.3	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)
4.4	Warrant to Purchase Stock of Catalyst Biosciences, Inc., issued to Silicon Valley Bank on March 3, 2005 (incorporated by reference to Exhibit 4.3 to the Company's Form 10-K, filed with the SEC on March 9, 2016)
4.5	Form of Warrant to Purchase Stock of Catalyst Biosciences, Inc., issued to purchasers of Series E Preferred Stock (incorporated by reference to Exhibit 4.4 to the Company's Form 10-K, filed with the SEC on March 9, 2016)
4.6	Form of Warrant to Purchase Stock of Catalyst Biosciences, Inc., issued to purchasers of convertible promissory notes (incorporated by reference to Exhibit 4.5 to the Company's Form 10-K, filed with the SEC on March 9, 2016)
4.7	Form of Indenture (incorporated by reference to Exhibit 4.5 to the Company's Form S-3 (Reg No. 333-222644), as filed with the SEC on January 22, 2018)
4.8	Form of Warrant to be Issued in Offering (incorporated by reference to Exhibit 4.5 to the Company's Amendment No. 2 to Form S-1 (Reg. No. 333-21663), as filed with the SEC on April 4, 2017)
10.1**	Catalyst Biosciences, Inc. (formerly Targacept, Inc.) 2015 Stock Incentive Plan (as Amended and Restated Effective June 9, 2016) (incorporated by reference to Appendix A to the Company's Definitive Proxy Statement (File No. 000-51173), filed with the SEC on April 25, 2016)
10.2**	Catalyst Biosciences, Inc. 2016 Inducement Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on April 20, 2016)
10.3**	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)

Exhibit Number	Description
10.4**	Form of Incentive Stock Option Award Notice (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on July 14, 2017)
10.5**	Form of Non-qualified Stock Option Award Notice (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on July 14, 2017)
10.6**	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)
10.7**	Amended and Restated Employment Agreement, dated as of September 19, 2017, by and between Catalyst Biosciences, Inc. and Dr. Nassim Usman, Ph.D. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on September 22, 2017)
10.8**	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)
10.9**	Amended and Restated Employment Agreement, dated as of September 19, 2017, by and between Catalyst Biosciences, Inc. and Fletcher Payne (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on September 22, 2017)
10.10**	Offer Letter, executed April 27, 2012, by and between Catalyst and Dr. Harold E. Selick (incorporated by reference to Exhibit 10.34 to the Company's Form S-4 (Reg. No. 333-204423), filed with the SEC on May 22, 2015)
10.11**	Offer Letter, executed April 15, 2016, by and between Catalyst and Dr. Howard Levy
10.12**	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))
10.13**	Consulting Agreement, dated January 14, 2015, by and between the Company 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)
10.14**	Form of Indemnification Agreement between the Company and each of its directors and members of executive management, other than the Indemnification Agreement by and between the Company and Fletcher Payne (incorporated by reference to Exhibit 10.14 to the Company's Form 10-K, filed with the SEC on March 8, 2017)
10.15**	Indemnification Agreement, dated January 14, 2015, by and between the Company and Fletcher Payne (incorporated by reference to Exhibit 10.33 to the Company's Form S-4 (Reg. No. 333-204423), filed with the SEC on May 22, 2015)
10.16(a)**	Stock Option Agreement—Early Exercise, No. 427, dated January 22, 2015, by and between Catalyst and Fletcher Payne (incorporated by reference to Exhibit 10.40(a) to the Company's Form S-4 (Reg. No. 333-204423), filed with the SEC on May 22, 2015)
10.16(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)
10.16(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(c) to the Company's Form S-4 (Reg. No. 333-204423), filed with the SEC on May 22, 2015)
10.17**	Separation Agreement, dated September 14, 2016, between the Company and Edwin Madison (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on September 16, 2016)
10.18(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)
10.18(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)

Exhibit Number	Description
10.19+	Development and Manufacturing Services Agreement, by and between CMC ICOS Biologics, Inc. and the Company, dated as of May 20, 2016 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 4, 2016)
10.20+	Termination Agreement, dated December 8, 2016, between the Company and Wyeth LLC, a wholly-owned subsidiary of Pfizer Inc. (incorporated by reference to Exhibit 10.16 to the Company's Form 10-K, as filed with the SEC on March 8, 2017)
10.21	Capital on Demand™ Sales Agreement, dated March 16, 2016, by and between the Company and JonesTrading Institutional Services LLC (incorporated by reference to Exhibit 1.1 to the Company's Form S-3 (Reg No. 333-210248), as filed with the SEC on March 16, 2016)
10.22	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)
10.23	Lease Agreement, dated November 8, 2017 by and between BXP 611 Gateway Center, LP and the Company (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on November 17, 2017)
21.1	List of subsidiaries of the Company (incorporated by reference to Exhibit 21.1 to the Company's Form 10-K, filed with the SEC on March 9, 2016)
23.1*	Consent of EisnerAmper LLP, Independent Registered Public Accounting Firm
24.1	Power of Attorney (included as part of the signature pages hereto)
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, 2017, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets as of December 31, 2017 and December 31, 2016; (ii) the Consolidated Statement of Operations for the years ended December 31, 2017, 2016 and 2015; (iii) the Consolidated Statements of Comprehensive Income for the years ended December 31, 2017, 2016 and 2015; (iv) the Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit as of December 31, 2017; (v) the Consolidated Statements of Cash Flows for the twelve months ended December 31, 2017, 2016 and 2015; and (vi) the Notes to Consolidated Financial Statements

* Filed herewith.

** 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.

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 19, 2018

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 19, 2018
/s/ Fletcher Payne **Fletcher Payne**	Chief Financial Officer (*Principal Financial and Accounting Officer*)	March 19, 2018
/s/ Augustine Lawlor **Augustine Lawlor**	Chairman of the Board of Directors	March 19, 2018
/s/ Errol B. De Souza, Ph.D. **Errol B. De Souza, Ph.D.**	Director	March 19, 2018
/s/ Jeff Himawan, Ph.D. **Jeff Himawan, Ph.D.**	Director	March 19, 2018
/s/ Andrea Hunt **Andrea Hunt**	Director	March 19, 2018
/s/ Eddie Williams **Eddie Williams**	Director	March 19, 2018
/s/ John P. Richard **John P. Richard**	Director	March 19, 2018
/s/ Stephen A. Hill, M.D. **Stephen A. Hill, M.D.**	Director	March 19, 2018

CATALYST BIOSCIENCES, INC.
260 Littlefield Avenue
South San Francisco, CA 94080
P 650.871.0761
W catalystbiosciences.com
NASDAQ: CBIO

Nassim Usman, Ph.D.
Chief Executive Officer

14 April 2016

Howard Levy, M.D., Ph.D., M.M.M.
65 Van Dyke Road
Hopewell, New Jersey 08525

Dear Dr. Levy:

I am pleased to confirm our offer to you to serve as Chief Medical Officer of Catalyst Bio, Inc. (the "**Company**"). In this role, you will report directly to Nassim Usman, President and Chief Executive Officer. We look forward to your joining us on or before 18 April 2016.

While employed by the Company, you agree to perform your duties faithfully and to the best of your abilities and to devote your full business efforts and time to the Company. Except upon the prior written consent of the Board of Directors, you will not, during your employment with the Company, (i) accept any other employment, or (ii) engage, directly or indirectly, in any other business activity (whether or not pursued for pecuniary advantage) that might interfere with your duties and responsibilities as Chief Medical Officer or create a conflict of interest with the Company. This consent will not be unduly withheld. Notwithstanding the foregoing, the Company acknowledges and approves of the continuation of your current advisory activities to Hillhurst Biopharmaceuticals and ZZ Biotech, so long as such activities do not interfere with your duties and responsibilities to the Company.

Your initial base compensation will be $31,250 per month ($375,000, annualized), paid periodically in accordance with normal Company payroll practices and subject to the usual, required withholding. You will be eligible for a review of your salary in January, 2017. You will also have the opportunity to earn an annual performance-based bonus up to 35% of your annual salary (pro-rated for 2016 based on your date of hire). Any annual bonus that is earned will be paid no later than March 15th of the year following the year to which the bonus relates.

It is anticipated that you will work primarily from your home in Hopewell, NJ, with occasional travel to the Company's offices and for other business meetings as required.

During your employment with the Company, you will be eligible to participate in the Company's employee benefit plans including, but not limited to, Life, Disability, Medical, Dental and Vision Insurance, 401(k), Section 125 Flexible Spending Accounts. The Company reserves the right to cancel or change the benefit plans and programs it offers to its employees at any time.

As a full-time employee, you will be eligible for paid time off benefits, which include sick leave and vacation time, in accordance with the Company's policies for similarly situated employees.

Subject to the approval of the Board of Directors or Compensation Committee of the Board of Directors of Catalyst Biosciences, Inc., you will receive stock options to purchase 100,000 shares of common stock of Catalyst Biosciences, Inc. The exercise price of your stock options will be equal to the closing price of the common stock on the grant date of the options, which will be the later of (i) your start date and (ii) the date on which the Board of Directors or Compensation Committee of the Board of Directors approves of the grant of such stock options. Your options will vest over four years, with 25% vesting on the one-year anniversary of your start date, and 1/48 of the total number of shares vesting monthly thereafter. Your option will be granted as an "inducement option" outside of the Company's 2015 Stock Incentive Plan pursuant to Nasdaq rules and regulations, but will have terms and conditions similar to options granted pursuant to the Catalyst Biosciences, Inc. 2015 Stock Incentive Plan, as will be set forth in the applicable stock option agreement.

In the event your employment with us is terminated for any reason other than death or Disability (as defined in the 2015 Stock Incentive Plan), you will have three months following the termination of employment to exercise the vested portion of your initial option grant. In the event your employment with us is terminated due to your death or Disability, the vested portion of your initial option grant may be exercised within the one-year period following the termination of your employment. In no event may your initial option grant be exercised after the expiration of its ten-year term. As a condition of accepting this offer of employment, you will be required to complete, sign and return the Company's standard form of confidential information and/or inventions assignment agreement, if you have not already done so.

You should be aware that your employment with the Company is for no specified period and constitutes "at will" employment. As a result, you are free to terminate your employment at any time, for any reason or for no reason. Similarly, the Company is free to terminate your employment at any time, for any reason or for no reason. The at-will employment policy can only be changed by a written document approved by the Board and signed on behalf of the Board.

Should your employment with the Company be terminated without Cause or as a result of Constructive Termination in each case after the one year anniversary of your Start Date and before a Change of Control (each as defined below), (i) you shall be eligible to receive severance payments, equal to the rate of base salary which you were receiving at the time of such termination, during the period from the date of your termination until the date that is six (6) months after the effective date of the termination (the "Severance Period"), which payments shall be paid during the Severance Period (or applicable shorter period) in accordance with the

Company's standard payroll practice following the effective date of the release described below and which shall be subject to applicable withholding taxes, and (ii) accelerated vesting as of the time of such termination with respect to the unvested options held by you that would have vested during the Severance Period.

Should your employment with the Company be terminated without Cause or as a result of Constructive Termination in each case after a Change of Control, (i) you shall be eligible to receive severance payments, equal to the rate of base salary which you were receiving at the time of such termination, during the period from the date of your termination until the date that is nine (9) months after the effective date of the termination (the "Post-COC Severance Period"), which payments shall be paid during the Post-COC Severance Period (or applicable shorter period) in accordance with the Company's standard payroll practice following the effective date of the release described below and which shall be subject to applicable withholding taxes, and (ii) 100% percent of any unvested options held by you will vest as of the time of such termination.

Any severance benefits under this Agreement are conditioned upon (a) your execution of a release of claims in a form provided by the Company, and any severance payments shall commence on the 60th day following your separation, so long as you have signed a release that has become irrevocable during such period, with the initial payment including payments that otherwise would have been made during the sixty day period, and (b) your agreement not to compete with the Company, or its successors or assigns, during the period in which you are receiving these severance payments. If you engage in any business activity competitive with the Company or its successors or assigns during this period, all severance payments shall cease immediately.

Notwithstanding anything to the contrary in this offer letter, any cash severance payment due to you under this offer letter or otherwise will not be paid during the six (6) month period following your termination of employment unless the Company determines, in its good faith judgment, that paying such amounts at the time or times indicated above would not cause you to incur an additional tax under Section 409A of the Internal Revenue Code and any temporary or final treasury regulations and internal revenue service guidance thereunder ("**Section 409A**"). If the payment of any amounts are delayed as a result of the previous sentence, any cash severance payments due to you pursuant to this offer letter or otherwise during the first six (6) months after your termination will accrue during such six month period and will become payable in a lump sum payment on the date six (6) months and one (1) day following the date of your termination. Thereafter, payments will resume in accordance with the applicable schedule set forth in this offer letter. You agree to work in good faith with the Company to consider amendments to this offer letter which are necessary or appropriate to avoid imposition of any additional tax or income recognition under Section 409A prior to the actual payment to you of payments or benefits under this offer letter. Notwithstanding the foregoing, this offer letter will be deemed amended, without any consent required from you, to the extent necessary to avoid imposition of any additional tax or income recognition pursuant to Section 409A prior to actual payments to you under this offer letter. You and the Company agree to cooperate with each other and to take reasonably necessary steps in this regard.

This Agreement is intended to comply with the requirements of Section 409A, including the exceptions thereto, and shall be construed and administered in accordance with such intent.

Notwithstanding any other provision of this Agreement, payments provided under this Agreement may only be made upon an event and in a manner that complies with Section 409A or an applicable exemption. Any payments under this Agreement that may be excluded from Section 409A either as separation pay due to an involuntary separation from service or as a short-term deferral shall be excluded from Section 409A to the maximum extent possible. For purposes of Section 409A, each installment payment provided under this Agreement shall be treated as a separate payment. Any payments to be made under this Agreement in connection with a termination of employment shall only be made if such termination of employment constitutes a "separation from service" under Section 409A. To the extent that reimbursements or other in-kind benefits under this Agreement constitute "nonqualified deferred compensation" for purposes of Section 409A, (i) such expenses or other reimbursements hereunder shall be made on or prior to the last day of the taxable year following the taxable year in which such expenses were incurred, (ii) no right to such reimbursement or in-kind benefits shall be subject to liquidation or exchange for another benefit, and (iii) no such reimbursement, expenses eligible for reimbursement, or in-kind benefits provided in any taxable year shall in any way affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year. Notwithstanding the foregoing, the Company makes no representations that the payments and benefits provided under this Agreement comply with Section 409A and in no event shall the Company, any Company affiliates, or their respective employees, officers, directors, agents and representatives (including, without limitation, legal counsel) be liable for all or any portion of any taxes, penalties, interest or other expenses that may be incurred by you on account of non-compliance with Section 409A.

"**Cause**" shall mean (i) your failure to perform your assigned duties or responsibilities as an employee of the Company after notice thereof from the Company describing your failure to perform such duties or responsibilities, (ii) your engaging in any act of dishonesty, fraud or misrepresentation, (iii) your violation of any federal or state law or regulation applicable to the Company's business, (iv) your breach of any confidentiality agreement or invention assignment agreement between you and the Company, or (v) your being convicted of or entering a plea of *nolo contendere* to, any crime or committing any act of moral turpitude.

"**Constructive Termination**" shall be deemed to occur if, without your written consent, within 90 days following any of the conditions below, you terminate your employment in accordance with this provision: (A) the Company's material breach of this Agreement resulting from the failure of the Company to require any successor to the Company upon a Change of Control to assume the Company's obligations under this offer letter, (B) a material reduction or other adverse change in your job duties, reporting relationships, responsibilities and requirements inconsistent with your position with the Company and prior duties, reporting relationships, responsibilities and requirements, provided that neither a mere change in title alone nor reassignment following a Change of Control to a position that is substantially similar to the position held prior to the Change of Control in terms of job duties, responsibilities or requirements shall constitute a material reduction in job responsibilities, or (C) the request by the Company or its successor to relocate the principal place for performance of your Company duties to a location more than thirty (30) miles from your then-current principal business location; provided that (i) you have provided written notice of your intent to terminate employment on the basis of a Constructive Termination within sixty (60) days after the Constructive Termination condition first occurs, and (ii) the

Company fails to correct the Constructive Termination within thirty (30) days after receipt of your written notice.

In the event that the severance and other payments or benefits provided for in this offer letter or otherwise payable to you (i) constitute "parachute payments" within the meaning, of Section 280G of the Code, and (ii) but for this paragraph would be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then your benefits under this offer letter shall be either

A. delivered in full, or

B. delivered as to such lesser extent which would result in no portion of such benefits being subject to the Excise Tax,

whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the Excise Tax, results in the receipt by you on an after tax basis, of the greatest amount of benefits, notwithstanding that all or some portion of such benefits may be taxable under Section 4999 of the Code. If a reduction is requiredand no parachute payments constitute nonqualified deferred compensation under Section 409A, you shall be able to select which payments and/or benefits are reduced and the order of reduction. If a reduction is required and any parachute payments constitute nonqualified deferred compensation under Section 409A, the reduction shall occur in the following order: (i) options whose exercise price exceeds the fair market value of the optioned equity, (ii) Full Credit Payments (as defined below) that are payable in cash, (iii) non-cash Full Credit Payments that are taxable, (iv) non-cash Full Credit Payments that are not taxable (v) Partial Credit Payments (as defined below) and (vi) non-cash employee welfare benefits. In each case, reductions shall be made in reverse chronological order such that the payment or benefit owed on the latest date following the occurrence of the event triggering the excise tax will be the first payment or benefit to be reduced (with reductions made pro-rata in the event payments or benefits are owed at the same time). The term "Full Credit Payment" means a payment or benefit that if reduced in value by one dollar reduces the amount of the parachute payment (as defined in Section 280G of the Code) by one dollar. "Partial Credit Payment" means any payment or benefit that is not a Full Credit Payment.
You understand and agree that by accepting this offer of employment, you represent to the Company that your performance will not breach any other agreement to which you are a party and that you have not, and will not during the term of your employment with the Company, enter into any oral or written agreement in conflict with any of the provisions of this letter or the Company's policies. You are not to bring with you to the Company, or use or disclose to any person associated with the Company, any confidential or proprietary information belonging to any former employer or other person or entity with respect to which you owe an obligation of confidentiality under any agreement or otherwise. The Company does not need and will not use such information. Also, we expect you to abide by any obligations to refrain from soliciting any person employed by or otherwise associated with any former employer.

This offer letter and the confidential information and/or inventions assignment agreement between you and the Company that you will be required to execute upon commencement of your employment hereunder, if you have not already done so, represent the entire agreement and understanding between you and the Company concerning your employment relationship with the

Company, and supersede in their entirety any and all prior agreements and understandings concerning your employment relationship with the Company, whether written or oral. Except as specifically provided in this offer letter, this offer letter can only be amended in a writing approved by the Board and signed by you and a duly authorized officer of the Company. Any waiver of a right under this offer letter must be in writing. The Company will require any successor to all or substantially all of its assets or businesses to assume this Agreement and perform the Company's obligations hereunder. This offer letter will be governed by California law.

For purposes of federal immigration laws, you will be required to provide to the Company documentary evidence of your identity and eligibility for employment in the United States. Such documentation must be provided within three (3) business days of the effective date of your employment, or your employment relation hip with the Company may be terminated.

Please sign below to indicate your acceptance and agreement to the terms set forth in this offer letter and return the signed offer letter to me no later than 18 April 2016.

I am pleased to welcome you to the Company, and I look forward to your participation in the Company's future success. Please call me at (650) 266-8674 if you have any questions.

Sincerely,

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

Accepted and agreed to this
15 day of APR, 2016

Howard Levy, M.D., Ph.D., M.M.M.

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. on Form S-1 (No. 333-216663), Form S-1MEF (No. 333-217186), Form S-8 (Nos. 333-133882, 333-189143, 333-133881, 333-160331, 333-185888, 333-206523, 333-206526, 333-212345, and 333-219301), and Form S-3 (Nos. 333-210248 and 333-222644) of our report dated March 19, 2018, on our audits of the consolidated financial statements as of December 31, 2017 and 2016, and for each of the years then ended, which report is included in this Annual Report on Form 10-K to be filed on or about March 19, 2018.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Iselin, New Jersey
March 19, 2018

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 19, 2018

/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 19, 2018

/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, 2017 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 19, 2018

/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, 2017 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 19, 2018

/s/ Fletcher Payne

Fletcher Payne
Chief Financial Officer