

**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, 2018

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  
(State or Other Jurisdiction of  
Incorporation or Organization)  
611 Gateway Blvd. Suite 710  
South San Francisco, California  
(Address of Principal Executive Offices)

56-2020050  
(I.R.S. Employer  
Identification No.)

94080  
(Zip Code)

(650) 871-0761

(Registrant's Telephone Number, Including Area Code)

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

Title of each class  
Common stock, par value \$0.001 per share

Name of each exchange on which registered  
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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

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 4, 2019 was 11,970,042. The aggregate market value of the voting stock held by non-affiliates of the registrant as of June 30, 2018, was \$137,450,357.

**CATALYST BIOSCIENCES, INC.**  
**Annual Report on Form 10-K**  
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## Forward-Looking Statements and Market Data

This Annual Report on Form 10-K and the documents incorporated by reference herein contain 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, as amended (the “Exchange Act”). All statements, other than statements of historical facts, included or incorporated by reference in this Annual Report on Form 10-K regarding our strategy, future results of operations, future financial condition, future revenues, projected costs, prospects, plans, intentions and objectives of management, as well as the assumptions that underlie these statements, are forward-looking statements. 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, although not all forward-looking statements contain these identifying words. Such forward-looking statements are based on our management’s assumptions and assessments in light of information currently available to our management, its experience and its perception of historical trends, current conditions, expected future developments and other factors our management believes to be appropriate.

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 scope, duration, progress or outcomes of the development of product candidates or programs;
- the timelines, progress and potential results of our current and future clinical studies and trials;
- the competitiveness of our products candidates against other competing products;
- 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, statements of belief and any statement of assumptions underlying any of the foregoing;
- 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, partnerships 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 the U.S. Food and Drug Administration (“FDA”) and other government regulations on our business;
- uncertainties associated with obtaining and protecting patents and other intellectual property rights, as well as avoiding the intellectual property rights of others;
- products and companies that will compete with the products we license to third-party collaborators;
- the possibility we may commercialize our own products and build up our commercial, sales and marketing capabilities and other required infrastructure;
- our employees, including the number of employees and the continued service of key management, technical and scientific personnel;
- our future performance and 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, as well as our plans for obtaining and ability to obtain such 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.

Any such forward-looking statements are not guarantees of future performance and are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in or contemplated by such forward-looking statements. Factors that might cause such a difference include, but are not limited to, the risks and uncertainties described in this Annual Report on Form 10-K, including those risks described in Part I, Item 1A, “Risk Factors,” as well as others that we may consider immaterial or do not anticipate at this time. The risks and uncertainties described in this report, including in Part I, Item 1A, “Risk Factors,” are not exclusive and further information concerning our company and our businesses, including factors that potentially could materially affect our operating results or financial condition, may emerge from time to time. All 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 (the “SEC”).

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 Organization.”

**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 blood clotting.

Our most advanced program, a subcutaneously administered, next-generation engineered coagulation Factor VIIa, marzeptacog alfa (activated) (“MarzAA”), has completed enrollment of the Phase 2 portion of a Phase 2/3 subcutaneous dosing trial in individuals with hemophilia with an inhibitor. The Phase 2 open-label subcutaneous efficacy portion was designed to evaluate the ability of MarzAA to eliminate, or minimize, spontaneous bleeding episodes in individuals with hemophilia A or B with inhibitors and was initiated in December 2017. The trial has completed enrollment of 11 individuals with hemophilia and an inhibitor across six clinical trial sites globally. MarzAA has also 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. We will also initiate a subcutaneous Phase 1 pharmacokinetics, pharmacodynamics study in the second quarter of 2019 and expect the study to conclude in the fourth quarter of 2019. 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.

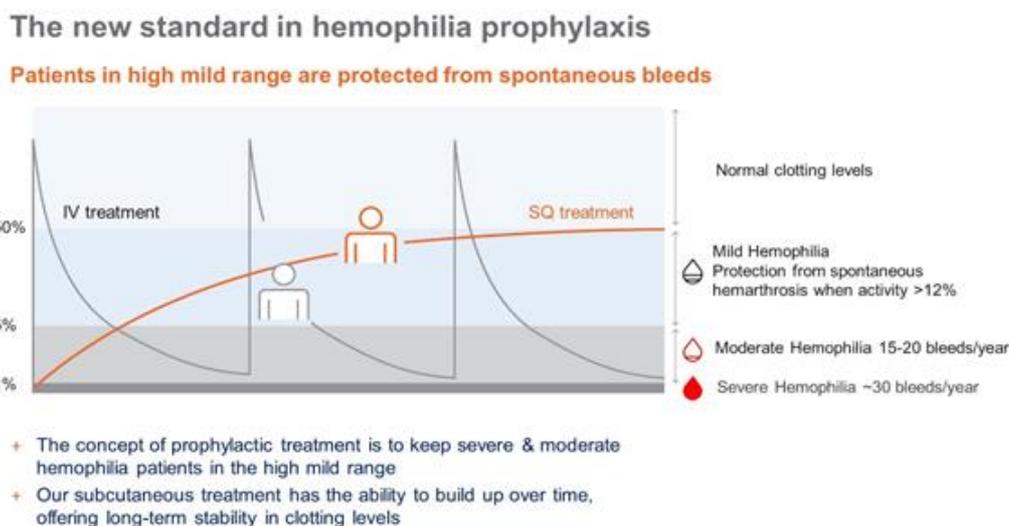
As of February 8, 2019, 11 subjects were enrolled with a mean annualized bleed rate (“ABR”) of 18.2; range of 12.2-26.7. One subject revoked consent after single intravenous and subcutaneous doses. Two subjects were dosing. Of the seven subjects that have completed dosing, all had clinically significant reductions in ABR. Five subjects had completed the study with no bleeding at 30 µg/kg and two subjects with no bleeding at 60 µg/kg. One subject with severe hypertension experienced a fatal serious adverse event that was not related to study drug on day 11.

Pharmacokinetics analysis has shown that MarzAA’s intravenous half-life of 3.9 hours increased to 13.1 hours when dosed subcutaneously. No anti-drug antibodies to MarzAA or thrombotic events have been detected to date, and only a single moderately severe injection site reaction has been reported after more than 450 injections. We expect to complete the Phase 2 open-label subcutaneous efficacy trial in the second half of 2019 and plan to conduct a global Phase 3 clinical study in 2020 assessing reductions in ABR in 20-40 patients with hemophilia with pre-dosing observation and six months of daily subcutaneous dosing of MarzAA.

Our next most advanced hemophilia program, a next-generation engineered coagulation Factor IX, Dalcinonacog alfa (“Dalca”) (formerly CB 2679d/ISU304), has completed a Phase 1/2 subcutaneous dosing trial in South Korea, that evaluated the safety and efficacy of Dalca 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 daily subcutaneous injections. Dalca 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. Following the positive data from the multi-dose cohort 5, the Korean Ministry of Food and Drug Safety (“MFDS”) approved the addition of a sixth cohort to the Phase 1/2 trial of Dalca in individuals with severe hemophilia B in April 2018. Cohort 6 enrolled two previously treated subjects from cohort 5. Both subjects had a nadir of 20% activity level after an initial IV dose and following 9 days of daily subcutaneous dosing reached greater than 30% activity before being reduced by neutralizing antibodies (nAb), one of which was transient. Both nAbs waned over time and did not cross react with their wildtype FIX treatments to which they returned without issue. We completed a comprehensive investigation of the cause of the nAb in December 2018 and concluded that the immunogenic potential of Dalca was low and similar to that of commercial FIX products. Based on the results of the investigations and discussions with clinicians and regulatory experts, we concluded that we should continue development of Dalca. We plan to initiate a Phase 2b trial that will include 28 days of daily subcutaneous dosing in six subjects in the first quarter of 2019 and we expect the Phase 2b trial to be completed in the second half of 2019. Based on the efficacy data that we have previously shown in which subjects achieved high mild hemophilia FIX activity, we believe that Dalca has the potential to provide a conveniently-dosed subcutaneous prophylactic treatment option for those suffering from hemophilia B.

The enhanced potency of MarzAA and Dalca 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 deliver substantially better outcomes for individuals with hemophilia.

We have demonstrated that subcutaneous dosing of our next-generation coagulation factors results in progressive increases in activity levels until they reach a stable therapeutic target range in the blood. Conversely, dosing by intravenous infusions results in high initial factor activity levels in the blood followed by a rapid fall off in factor activity levels to a low trough level 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. This concept is illustrated in the diagram below.



We also have several engineered Factor Xa proteases that have demonstrated efficacy in preclinical bleeding 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 MarzAA and Dalca clinical programs.

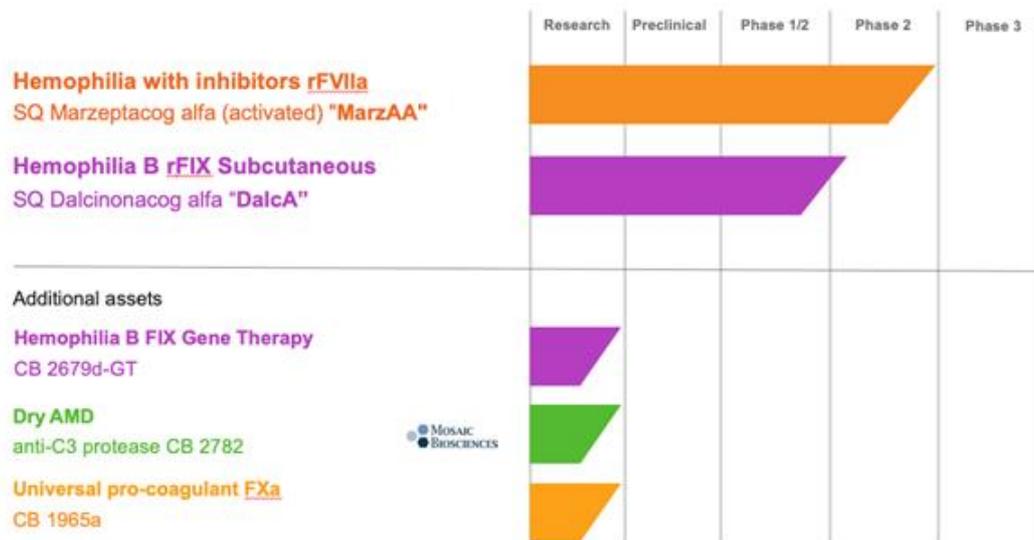
Finally, we have developed novel protease molecules that target the complement cascade, a series of naturally occurring molecular processes that play a central role in the body's inflammatory and immune response. In October 2017, we announced a strategic research collaboration with Mosaic Biosciences, Inc. to develop intravitreal anti-complement factor three (C3) products for the treatment of dry AMD and other retinal diseases. In December 2018, we amended our collaboration agreement with Mosaic to, among other things, include certain additional products.

Based on industry reports and company reported sales, we estimate the 2018 global market opportunity for MarzAA and Dalca to be approximately \$2.2 billion and \$1.5 billion, respectively. Annual worldwide sales in 2018 for FDA-approved recombinant protease products for individuals with hemophilia A or B and an inhibitor were approximately \$1.2 billion and approximately \$2.2 billion when including prothrombin complex concentrate and bispecific antibody products. We remain focused on advancing the MarzAA and Dalca clinical trials.

## Our Product Candidate Pipeline

We are currently focused on the clinical development of our improved, next-generation enhanced potency Factor VIIa (MarzAA) and Factor IX variants (DalcA) for subcutaneous prophylaxis. We have three additional assets, a FIX gene therapy construct CB 2679d-GT that has demonstrated 3-fold higher activity and 4-5 fold faster clotting time in a preclinical hemophilia B model compared with the Padua variant of FIX that is in clinical development by others, a Factor Xa pro-coagulant and a novel anti-C3 protease program for dry AMD, CB 2782 for which we have a strategic research collaboration with Mosaic and 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 males 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 Factor IX 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 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 outside research and sales data, we estimate worldwide sales of all Factor IX-containing products for the treatment of hemophilia B in 2018 were at least \$1.5 billion, including approximately \$0.6 billion as reported by Pfizer, Inc. for its BeneFIX® product and our internal estimate of \$0.5 billion by Swedish Orphan Biovitrum for their Alprolix® product and \$0.4 billion from CSL Behring for their Idelvion® 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 TAKADA/Shire and Hemlibra®, produced by Roche. NovoSeven RT 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 2018, were \$1.2 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 and sales data, had 2018 sales of \$0.75 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 in 2018 were estimated by industry sources to be \$0.2 billion.

#### *Hemophilia with Inhibitors—Factor VIIa (“MarzAA”) Program*

Our most advanced product candidate is MarzAA, a potent, subcutaneously administered, next-generation Factor VIIa variant, 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 MarzAA in severe hemophilia A and B with and without inhibitors. MarzAA is being developed for the prophylactic treatment of individuals with severe hemophilia A or 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 anticipate completion of the Phase 2 trial by the end of 2019. We plan to conduct a global Phase 3 clinical study assessing reductions in ABR in 20-40 patients with hemophilia with six months of daily subcutaneous dosing of MarzAA. MarzAA has received orphan drug designation in the United States from the FDA.

In the Phase 1 clinical trial of intravenous MarzAA 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 four cohorts of six 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 MarzAA were well tolerated and there were no instances of bleeding or thrombosis. MarzAA 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 published in *Journal of Thrombosis and Haemostasis* 2018, vol 16, 1984-1993.

We designed MarzAA 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 MarzAA can treat or prevent bleeding when dosed intravenously. The next step required to develop MarzAA 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. Daily subcutaneous dosing in dogs for 6 days reduced the whole blood clotting time towards normal. Stable blood levels of MarzAA were seen after the 4<sup>th</sup> dose onwards (European Association Haemophilia and Allied Disorders 2017).

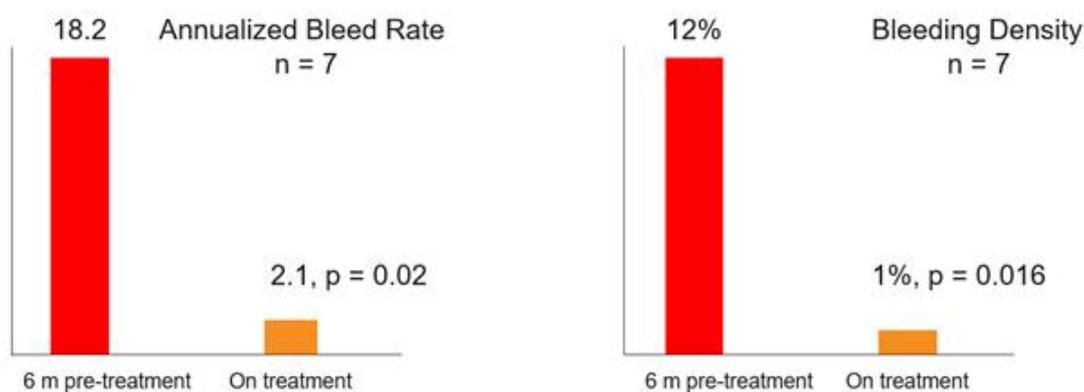
During the past 12 months, we have presented data at scientific conferences demonstrating that daily subcutaneous administration in humans had clinically significant reductions in annualized bleed rate (ABR).

In the Phase 2 portion of the Phase 2/3 trial of MarzAA for the treatment of hemophilia A or B with inhibitors:

- Seventeen patients were consented and eleven subjects were enrolled (mean annualized bleed rate of 18.2; range of 12.2-26.7).
- Of the seven subjects that have completed dosing, all had clinically significant reductions in annualized bleed rate (ABR).
- As of March 7, 2019, two subjects are currently dosing.
- After more than 450 subcutaneous injections, no antidrug antibodies have been detected, and only one injection site reaction of swelling and 5 mild or moderate redness that stopped after the patient rotated injection to other injection sites, and all resolved without sequelae.

Results are summarized in the chart below.

### MarzAA reduces annualized bleed rate (ABR) and percentage of days with bleeding



Levy et al. EAHAD 2019

The average percentage of days of bleeding in the pre-treatment period was 12.2% (standard deviation 5.2%) [median 11.0%]. In the treatment period, these percentages were reduced to 1.0% (standard deviation 5.2%) [median 1.0%]. The analysis of these pairwise differences by a randomization paired t-test yields  $p=0.016$ .

## *Hemophilia B - Factor IX (“DalcA”) Subcutaneous Program*

Our next most advanced product candidate is DalcA, 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 have completed a DalcA Phase 1/2 subcutaneous dosing trial in South Korea sponsored by our collaborator, ISU Abxis, that evaluated the safety and efficacy of DalcA in individuals with severe hemophilia B. 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 daily subcutaneous injections. DalcA has been granted orphan drug designation by the FDA and orphan medicinal product designation by the COMP of the EC.

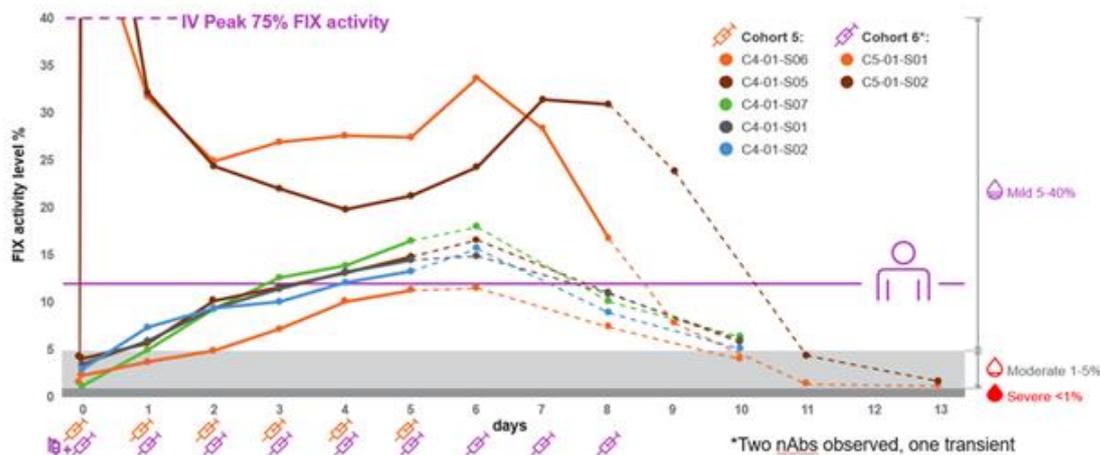
ISU Abxis initiated this trial in June 2017 and top line data was presented on February 9, 2018. Data from Cohorts 1 through 3 (three subjects in each cohort) showed that a single subcutaneous dose of either 70 or 140 IU/kg three days after a single intravenous dose of 70 IU/kg significantly increased the half-life of DalcA 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 DalcA in cohorts 2 and 3. In cohort 5, five subjects were dosed daily for six days with a subcutaneous dose of 140 IU/kg without an 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 the 12% level required to prevent spontaneous hemarthrosis. According to the World Federation of Hemophilia, patients with Factor IX levels between 5% and 40% are considered to have mild hemophilia. The observed increase in Factor IX activity levels after daily dosing in cohort 5 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 for subjects in cohort 5 (interquartile range 60.2-64 hours) with the result that activity levels were still 4-6.4%, five days after the last dose. In cohorts one through five, no inhibitors to DalcA or Factor IX were detected. One subject had moderate adverse events of pain, erythema and redness after the first two 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.

In April 2018, the MFDS approved the addition of a sixth cohort to the Phase 1/2 trial of DalcA in individuals with severe hemophilia B following the positive data from the multi-dose cohort 5. Each individual received a single intravenous dose of 70 IU/kg, followed by nine daily subcutaneous doses of 140 IU/kg DalcA. The intravenous dose was administered 30 minutes before the first subcutaneous dose.

ISU Abxis enrolled two patients out of a planned three to five in cohort 6, and DalcA showed efficacy in both subjects. During the treatment period, Factor IX activity levels always remained above 20% after the single intravenous dose in both patients. The first patient then had a progressive increase in trough Factor IX activity level to 34% and the second patient achieved a trough activity level of 31%. However, both subjects in cohort 6 developed neutralizing antibodies (“nAbs”) to DalcA and a reduction in Factor IX activity levels was observed. Blood testing revealed that the nAb was transient in one subject and was below the level of quantification at a follow up visit. The nAb in the second subject fell below one Bethesda Unit (“BU”) at a follow up visit. A BU reflects the percentage reduction in Factor IX activity from the standard control of 100%, with one BU being 50% reduction; two BU being 75% reduction and three BU being 87.5% reduction. Importantly, from a safety perspective, the absence of binding to wildtype Factor IX allowed both patients to successfully resume treatment with their prescribed intravenous Factor IX prophylaxis therapies. Prior to cohort 6, no DalcA neutralizing antibodies had been detected in any of the patients treated with DalcA, including both patients in cohort 6 who had also participated in cohort 5. Subsequent to the detection of the nAbs, the investigator treating the two subjects determined that these subjects were cousins and had the identical Factor IX gene defect, however their human leukocyte antigen (“HLA”) profiles were not identical. The HLA system is a gene complex encoding major histocompatibility complex (“MHC”) proteins in humans. These cell-surface proteins are responsible for the regulation of the immune system in humans and allow the immune system to identify foreign proteins within the body. HLA type determines the range of possible immune responses to exogenous proteins and whether antibodies can be made.

## Dalca Phase 1/2 clinical trial FIX activity results



We conducted a comprehensive analysis to assess the cause and impact of the antibody observations prior to deciding whether to initiate a Phase 2b study. The comprehensive immunogenicity risk assessment to investigate the development of neutralizing antidrug antibodies in Cohort 6 of the Phase 1/2 program concluded:

- The Dalca drug product does not appear to be inherently immunogenic.
- *In silico, in vitro* and *ex vivo* analyses indicated that the immunogenicity risk for Dalca is similar to commercial wildtype recombinant FIX products.
- The Dalca drug product quality is similar to marketed FIX products.
- 7-day subcutaneous non-human primate toxicology studies showed that Dalca subcutaneous injections were well tolerated.

The results of our extensive Dalca immunogenicity risk assessment revealed a similar low immunogenicity potential compared with BeneFIX and other commercial wildtype FIXs products; therefore, we will be moving forward with the clinical development of Dalca. We plan to initiate a Phase 2b trial that will include 28 days of daily subcutaneous dosing in six subjects in the first quarter of 2019 and expect the Phase 2b trial to be completed in the second half of 2019. Based on the efficacy data that we have previously shown in which subjects achieved high mild hemophilia FIX activity, we believe that Dalca has the potential to provide a conveniently-dosed subcutaneous prophylactic treatment option for those suffering from hemophilia B.

In December 2018, we entered into an amended and restated license agreement with ISU Abxis (the “A&R ISU Abxis Agreement”), which amended and restated in full our previous license and collaboration agreement with ISU Abxis entered into in September 2013 (as subsequently amended in October 2014 and December 2016). Under the A&R ISU Abxis Agreement, ISU Abxis will receive commercialization rights in South Korea to Dalca and we will receive clinical development and commercialization rights in the rest of world (excluding South Korea) and manufacturing development and manufacturing rights worldwide (including South Korea). The A&R ISU Abxis Agreement eliminates the profit-sharing arrangement in the Original ISU Abxis Agreement and provides for a low single-digit royalty payment to ISU Abxis, on a country-by-country basis, for net product sales of Dalca by us or our affiliates in each country other than South Korea. Pursuant to the A&R ISU Abxis Agreement, the Company will also make up to an aggregate of \$19.5 million in milestone payments to ISU Abxis, inclusive of \$2.5 million in regulatory and development milestone payments and up to \$17 million in commercial milestone payments, if the applicable milestones are met.

## **Hemophilia B – Factor IX Gene Therapy Program**

Use of the Factor IX Padua variant transgene (Factor IX-R338L) has demonstrated a 5-10 fold greater potency over Factor IX-WT in pre-clinical and clinical gene therapy studies. Pfizer/Spark (fidanacogene elaparovec) and uniQure (AMT-061) use the Padua variant as the transgene in their AAV based gene therapy clinical programs and both have demonstrated encouraging Factor IX levels in their respective Phase 1/2 and Phase 2/3 studies with median Factor IX levels of ~30%.

We have demonstrated in a hemophilia B mouse study that AAV gene therapy delivery using our CB 2679 gene sequence (FIX-R318Y/R338E/T343R) demonstrated significantly improved clotting activity and a four-fold reduction of bleeding time when compared with Factor IX Padua. This improvement is supported by the observed 22-fold greater clinical potency of DalcA over BeneFIX in a Phase 1/2 clinical trial.

## **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 GlobalData, AMD affects approximately 11 million people in the United States of which over 1 million are late stage dry AMD, with the potential size of the dry AMD market worldwide estimated at over \$3 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, a cyclic peptide that binds Complement Factor 3) announced positive statistically significant results from a randomized Phase 2 trial that APL-2 reduces geographic atrophy (GA) lesion growth associated with dry AMD using 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 unmodified 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 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 MarzAA and DalcA through Phase 2/3 and Phase 1/2 clinical trials, respectively. In December 2018, we amended our collaboration agreement with Mosaic to, among other things, include certain additional products. In collaboration with Mosaic we have created an extended half-life version of our anti-C3 protease CB 2782 with a 40 kDa linear PEG. This Pegylated CB 2782 has indistinguishable enzymatic activity inactivating C3 at the same rate as unmodified CB 2782. We have successfully completed an *in vivo* intravitreal Rabbit PK study comparing Pegylated CB 2782 with CB 2782 and will report the results of the study at a scientific conference in 2019.

## 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, MarzAA, for the prophylactic treatment of 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 MarzAA into the Phase 2/3 subcutaneous dosing clinical efficacy trial and anticipate completion of the Phase 2 trial by the end of this year. We plan to conduct a global Phase 3 clinical study assessing reductions in ABR in 20-40 patients with hemophilia with six months of daily subcutaneous dosing of MarzAA. In addition, we are advancing Dalca, our next-generation Factor IX drug candidate in individuals with severe hemophilia B, into a Phase 2b 28-day subcutaneous dosing clinical study in the first quarter of 2019 and we expect the Phase 2b trial to be completed in the second half of 2019.
- **Build a Hemostasis Franchise:** We intend to build on our recent clinical success of our Factor VIIa and Factor IX candidates by completing a Phase 2/3 clinical efficacy trial of our Factor VIIa program starting in 2019 and initiating a Phase 2b trial of our Factor IX product candidate in the first quarter of 2019. 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.
- **Explore options for the Factor IX Gene Therapy Construct:** We intend to explore a path forward for our Factor IX gene therapy program which may include research and/or development collaboration(s).
- **Find a partner for the C3 dry AMD program:** We intend to continue developing our C3 dAMD program towards a pre-clinical candidate (including demonstrating PK/PD efficacy in a NHP model) and find a development and commercialization partner.

## Collaborations

### Pfizer

On June 29, 2009, we entered into a Research and License agreement with Wyeth Pharmaceuticals, Inc., which was 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, recorded as an R&D expense.

On December 13, 2018, we entered into an Amended and Restated License Agreement (the “A&R ISU Abxis Agreement”), effective as of December 17, 2018, with ISU Abxis, which amends and restates in full our License and Collaboration Agreement with ISU Abxis, dated as of September 16, 2013, as subsequently amended on October 31, 2014 and on December 7, 2016 (the “Original ISU Abxis Agreement”). Pursuant to the A&R ISU Abxis Agreement, ISU Abxis will receive commercialization rights in South Korea to DalcA and the Company will receive clinical development and commercialization rights in the rest of world (excluding South Korea) and manufacturing development and manufacturing rights worldwide (including South Korea). The A&R ISU Abxis Agreement eliminates the profit-sharing arrangement in the Original ISU Abxis Agreement and provides for a low single-digit royalty payment to ISU Abxis, on a country-by-country basis, for net product sales of DalcA by the Company or its affiliates in each country other than South Korea. Pursuant to the A&R ISU Abxis Agreement, the Company will also make up to an aggregate of \$19.5 million in milestone payments to ISU Abxis, inclusive of \$2.5 million in regulatory and development milestone payments and up to \$17 million in commercial milestone payments, if the applicable milestones are met.

Under the Original ISU Abxis Agreement, ISU Abxis paid us a non-refundable upfront signing fee of \$1.75 million. ISU Abxis was also obligated, under the Original ISU Abxis Agreement, 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 were achieved for a total of \$2.65 million as of December 31, 2018.

The A&R ISU Abxis Agreement contains customary representations, warranties, covenants and indemnification provisions. The A&R ISU Abxis Agreement may be terminated by either party, subject to applicable notice and/or cure periods, upon a material breach by or an event of bankruptcy relating to the other party or by mutual consent of both parties.

As of December 31, 2018, the cumulative aggregate payments received and recognized by us under the Original ISU Abxis Agreement were \$2.65 million and we had made reimbursements of \$0.2 million to ISU Abxis, associated with certain preclinical studies in 2018. The adoption of the new revenue standards resulted in a \$0.2 million cumulative adjustment to the Company’s opening balance of accumulated deficit as of January 1, 2018. We had no deferred revenue balance as of December 31, 2018 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 December 31, 2018, our patent portfolio included approximately 161 patents; including 15 issued U.S. patents and 146 foreign granted and accepted patents, and 5 U.S. patent applications, plus an additional 20 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, Israel, Mexico, Russia, South Korea and Ukraine) that includes a claim that may read on MarzAA. 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 MarzAA 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 MarzAA 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. Members of the 4902 family, directed to screening methods (4 patents, including 2 of the issued U.S. patents) are jointly owned with the Torrey Pines Institute for Molecular Studies, which licensed its interest to us. Our current patents and patent applications include:

- 69 patents, including 3 issued U.S. patents, and 4 patent applications, including 1 pending U.S. patent application, covering modified Factor VII polypeptides, such as our lead product candidate, MarzAA, 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.

- 18 patents, including 3 issued U.S. patents, and 10 patent applications, including 2 U.S. patent applications, covering modified Factor IX polypeptides, such as our clinical candidate DalcA. The U.S. patents and patent applications, including patent term adjustment, expire, or are expected to expire, respectively, in 2030-2032 and 2038, and the foreign patents and patent applications, if granted, expire, or are expected to expire, respectively, in 2031.
- 15 patents, including 2 issued U.S. patents, and 6 patent applications, covering improved Factor Xa variants and methods of production of improved Factor Xa variants. The issued patents and patent applications, if granted, including patent term adjustment, expire, or are expected to expire in 2033.
- 56 patents, including 5 issued U.S. patents, and 5 patent applications, including 2 U.S. patent applications, covering novel proteases. The U.S. patents and patent applications, including patent term adjustment, expire, or are expected to expire, respectively in 2025-2029 and 2038-2039, 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.

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 not act 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 MarzAA, DalcA, 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 MarzAA for clinical trials pursuant to our license and collaboration agreement with Pfizer.

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 of 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 MarzAA for the Phase 2 portion of a planned Phase 2/3 clinical trial. ISU Abxis was responsible for manufacturing DalcA, our next-generation Factor IX drug candidate, through the completion of the Phase 1/2 clinical trials, after which we will be responsible for manufacturing this product candidate. In February 2018 we entered into a statement of work for AGC for process transfer and clinical scale manufacturing of DalcA.

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 DalcA, 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, 2018, we have \$0.3 million in payment obligations to AGC remaining under the initial statement of work for MarzAA and \$3.4 million in payment obligations related to DalcA.

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 MarzAA 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 MarzAA for our Phase 2/3 clinical trial.

## **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 DalcA in South Korea and our anti-C3 dry AMD program, we 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 hemophilia strategy outside of the United States. At this time, we intend to partner our anti-C3 dry AMD program for global development and commercialization.

## **Competition**

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 RT is a recombinant Factor VIIa indicated for treatment of bleeding episodes. NovoSeven RT 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. Takeda'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 RT such as rEVO Biologics LF769, which has completed a Phase 3 clinical trial, Alnylam is developing an investigational RNAi therapeutic targeting antithrombin for the treatment of hemophilia which 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 may 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 in mid-stage clinical 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 2018 revenues of \$0.6 billion. In addition, Alprolix, a Factor IX-Fc fusion product was approved in 2014 and is marketed by Sanofi Aventis and Swedish Orphan Biovitrum (SOBI - in Europe, Russia, North Africa and the Middle East) with 2018 revenues of \$0.5 billion. CSL Behring announced that their biologics license application (BLA) for their Idelvion (rFIX) product was approved by the FDA on March 4, 2016 and we estimate their 2018 sales to be \$0.4 billion. Novo Nordisk's glycopegylated-Factor IX product Rebinyn<sup>®</sup> was approved by the FDA on May 31, 2017 but is not indicated for routine prophylaxis.
- **FIX Gene Therapy Competition:** While there are no currently approved Factor IX gene therapy treatments for Hemophilia B, several companies, notably uniQure, Pfizer/Spark and Freeline are developing Factor IX gene therapy treatments and are in late stage clinical studies. Both uniQure and Pfizer/Spark (each use the Padua variant transgene) are in Phase 3 studies and Freeline (using a novel 2 mutation variant transgene, one of which is the Padua mutation) is in a Phase 2/3 study.
- **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 Phase 3 (Apellis) or Phase 2 (Ophthotech and Novartis) studies. Of note, Apellis' APL-2 (cyclic peptide that binds C3) 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. We are initiating proof-of-concept NHP primate studies in the first half of 2019.

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 product candidate 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 product candidate 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 candidate 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. MarzAA 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. MarzAA 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 four 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 \$21.5 million and \$12.8 million for the years ended December 31, 2018 and 2017, 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, 2018, we had 21 full-time employees, 4 of whom have Ph.D. or M.D. degrees. Of these full-time employees, 10 employees are engaged in manufacturing and clinical development activities and 11 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 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](http://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](http://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 \$30.1 million and \$21.6 million for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, we had an accumulated deficit of \$203.3 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 MarzAA;
- continue clinical development of DalcA (formerly 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.

In connection with the Amended and Restated License Agreement (the “A&R ISU Abxis Agreement”) with ISU Abxis, the Company will also make up to an aggregate of \$19.5 million in milestone payments to ISU Abxis, inclusive of \$2.5 million in regulatory and development milestone payment and up to \$17 million in commercial milestone payment, if the applicable milestones are met. 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, regarding the MarzAA manufacturing development project, we have agreed to a total of \$3.8 million in payments to AGC, of which \$3.5 million has been paid as of December 31, 2018, subject to the completion of work. We have also agreed to pay AGC approximately \$5.6 million the process transfer and commercial scale cGMP manufacturing of DalcA, of which \$2.2 million has been paid cumulatively as of December 31, 2018. See *Item 1—Business—Manufacturing*” 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 may 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 MarzAA and DalcA, 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 may need to raise substantial additional capital to complete the development and commercialization of MarzAA, DalcA, 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 MarzAA and DalcA;
- 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 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 "January 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 \$34.00 per share, for net proceeds to us, after deducting underwriting discounts and offering expenses payable by us, of approximately \$106.8 million. Pursuant to the January 2018 Registration Statement, we may sell up to approximately \$35 million in additional securities in one or more offerings. In addition, in December 2018, we filed a shelf registration statement with the SEC, which registration statement was declared effective on February 14, 2019, and allows us to offer up to \$200 million of securities from time to time in one or more offerings (the "December 2018 Registration Statement").

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.

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

**We are substantially dependent upon the success of MarzAA and DalcA.**

The failure of MarzAA or DalcA to achieve successful clinical trial endpoints, delays in clinical development, unanticipated adverse side effects, the cessation of clinical development or any other adverse developments or information related to MarzAA or DalcA would significantly harm our business, its prospects and the value of the company's common stock. We expect to complete enrollment of a Phase 2/3 subcutaneous dosing trial of MarzAA in individuals with hemophilia A and B inhibitors this year. We plan to advance DalcA into a Phase 2b study. There is no guarantee that the results of further clinical trials of MarzAA or DalcA will be positive or will not generate unanticipated safety concerns. The Phase 1 clinical trial of MarzAA 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 MarzAA in individuals who received the product candidate. While so far none of the patients in the Phase 2/3 subcutaneous dosing trial of MarzAA developed any inhibitory antibodies, there can be no assurance that such antibodies or other adverse events will not be observed in the future. Neutralizing antibodies have been observed in clinical trials of DalcA. If additional neutralizing antibodies or other adverse events in patients receiving either MarzAA or DalcA lead to concerns about patient safety, the long-term efficacy, or commercial viability of either product candidate, development of such product candidate could be halted. Even if the trials of MarzAA and DalcA are positive, each product candidate may require substantial additional trials and other testing before being approved for marketing.

MarzAA and DalcA 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 MarzAA and DalcA, 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 MarzAA or DalcA, 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 MarzAA or DalcA 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 MarzAA or DalcA would be limited.

**DalcA has caused and MarzAA may cause the generation of neutralizing antibodies, which could prevent their further development.**

Both MarzAA and DalcA are protein molecules which may cause the generation of antibodies in individuals who receive them. The Phase 1 clinical trial of MarzAA 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 MarzAA in individuals who received the product candidate. While no antibodies to MarzAA have been observed in a multi-dose subcutaneous Phase 2 portion of a Phase 2/3 trial, there can be no assurance such antibodies will not be observed in the future. Two patients who received DalcA subcutaneously following intravenous dosing developed neutralizing antibodies that inhibit the activity of DalcA. There can be no assurance that such antibodies will not be observed in the future, either in the patients who have already received DalcA or MarzAA, or in new patients. If clinical trials demonstrate a treatment-related neutralizing immunological response in individuals that causes safety concerns or would limit the efficacy of either product candidate, development of the product candidate could be halted.

**MarzAA and DalcA 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.**

MarzAA is in a Phase 2/3 clinical trial and DalcA has completed a Phase 1/2 clinical trial. 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 or intolerance 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 MarzAA is being conducted in twelve patients, and DalcA 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 MarzAA in individuals with hemophilia A and B with an inhibitor or Dalca 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 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 MarzAA and might also seek collaborators for Dalca 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 MarzAA and DalcA 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 MarzAA 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 DalcA 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 MarzAA 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 DalcA for use in our clinical trials. Manufacturing of biological therapeutics such as MarzAA and DalcA 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 MarzAA to satisfy our clinical trial requirements in a timely manner, within expected budgets or at all. Delays in the manufacture of DalcA could delay the start of future clinical trials of DalcA, if any.

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

All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including any contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with GMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a biologics license application (“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 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 MarzAA and might also seek collaborators for DalcA 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. Nassim Usman, our Chief Medical Officer, Dr. Howard Levy, our Chief Financial Officer, Fletcher Payne, our Senior Vice President of Technical Operations, Andrew Hetherington and our Vice President of Translational Research, Dr. Grant Blouse. 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 costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives.**

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. Pursuant to Section 404 of the Sarbanes-Oxley Act, our independent registered public accounting firm is required to deliver an attestation report on the effectiveness of our internal control over reporting. 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 MarzAA. 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 MarzAA 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 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. MarzAA is in a Phase 2 part of a Phase 2/3 clinical trial, and DalcA has completed a Phase 1/2 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. In addition, the FDA review and approval process could be delayed by any future shutdown of the U.S. government, and our development activities could be harmed or delayed as a result. 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 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 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, and there may be, 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. These changes could result from a number of different reasons, for example, a change in the U.S. Presidential Administration, and we cannot predict what these changes will be or their impact on our development and marketing activities or our operations or financial performance.

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, which became 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 or any future shutdown of the U.S. government, including the FDA, 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 intravenous NovoSeven RT 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 subcutaneous efficacy and potential advantages compared with alternative treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of subcutaneous 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.**

MarzAA and DalcA 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 in a timely manner (including due to reasons that are beyond our control such as changes in regulations or a shutdown of the federal government, including the FDA) for and commercialize MarzAA or DalcA, 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 MarzAA or DalcA, 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 MarzAA or DalcA 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 MarzAA or DalcA 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' rights to commercialize Dalca 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 to 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 RT, 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 RT that recently completed an intravenous Phase 3 clinical trial and has filed for marketing approval, Roche, which is marketing Hemlibra ACE910/Emicizumab, a recombinant humanized bispecific antibody that binds to activated Factor IX and Factor X mimicking the cofactor function of Factor VIIIa, that has been approved by the FDA to treat hemophilia A with inhibitors and is administered subcutaneously, Alnylam/Sanofi, which is developing an investigational subcutaneously administered RNAi therapeutic targeting antithrombin III, fitusiran, for the treatment of hemophilia and OPKO Biologics, whose recombinant Factor VIIa product that may also be administered subcutaneously has completed a part 1 of a planned Phase 1/2 clinical trial. There are numerous marketed factor IX-based products that are used to replace Factor IX intravenously. CSL Behring is developing its marketed product Idelvion an albumin-linked Factor IX for subcutaneous administration. 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. Alnylam/Sanofi is developing an investigational RNAi therapeutic targeting antithrombin III, fitusiran and Pfizer, Novo Nordisk, Green Cross and Bayer are developing antibodies that inhibit Tissue Factor Pathway inhibitor ("TFPI"), and Apcintex has a serpine directed against Activated Protein C, all for the treatment of all forms of hemophilia.

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 earlier 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 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 \$268 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 1,361,977 shares of common stock at a weighted average exercise price of \$12.04 as of December 31, 2018. 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 have been a “smaller reporting company” as defined in the Securities Exchange Act of 1934, and thus have been allowed to provide simplified executive compensation disclosures in our filings. We have also had certain other decreased disclosure obligations in our SEC filings. We cannot predict whether investors 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 lease approximately 13,232 rentable square feet of space. The term of the lease is five years and two months, starting February 16, 2018.

We believe that our existing facilities are adequate for our current needs.

**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.

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

Catalyst Biosciences, Inc. 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:

<b>Year Ended December 31, 2018:</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 35.60	\$ 14.18
Second Quarter	28.88	9.11
Third Quarter	12.44	9.35
Fourth Quarter	11.28	6.59
<b>Year Ended December 31, 2017:</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 15.01	\$ 4.73
Second Quarter	8.87	3.74
Third Quarter	5.10	3.19
Fourth Quarter	13.69	4.52

**Holders of Common Stock**

As of March 4, 2019, there were approximately 65 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 blood clotting.

Our most advanced program, a subcutaneously administered, next-generation engineered coagulation Factor VIIa, MarzAA, has completed enrollment of the Phase 2 portion of a Phase 2/3 subcutaneous dosing trial in individuals with hemophilia with an inhibitor. The Phase 2 portion of the open-label subcutaneous efficacy trial was designed to evaluate the ability of MarzAA to eliminate, or minimize, spontaneous bleeding episodes in individuals with hemophilia A or B with inhibitors and was initiated in December 2017. The trial has completed enrollment of 11 individuals with hemophilia and an inhibitor across six clinical trial sites globally. MarzAA has also 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. We will also initiate a subcutaneous Phase 1 pharmacokinetics, pharmacodynamics study in the second quarter of 2019 and expect the study to conclude in the fourth quarter of 2019. MarzAA has been granted orphan drug designation by the FDA for routine prophylaxis to prevent bleeding episodes in individuals with hemophilia A or B with inhibitors. We expect to complete the Phase 2 open-label subcutaneous efficacy trial in the second half of 2019 and plan to conduct a global Phase 3 clinical study in 2020 assessing reductions in ABR in 20-40 patients with hemophilia with pre-dosing observation and six months of daily subcutaneous dosing of MarzAA.

Our next most advanced hemophilia program, a next-generation engineered coagulation Factor IX, DalcA (formerly CB 2679d/ISU304), has completed a Phase 1/2 subcutaneous dosing trial in South Korea, that evaluated the safety and efficacy of DalcA 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 daily subcutaneous injections. DalcA has been granted orphan drug designation by the FDA and orphan medicinal product designation by the COMP of the EC. We plan to initiate a Phase 2b trial that will include 28 days of daily subcutaneous dosing in six subjects in the first quarter of 2019 and we expect the Phase 2b trial to be completed in the second half of 2019. Based on the efficacy data that we have previously shown in which subjects achieved high mild hemophilia FIX activity, we believe that DalcA has the potential to provide a conveniently-dosed subcutaneous prophylactic treatment option for those suffering from hemophilia B.

We are currently focused on the clinical development of our improved, next-generation enhanced potency Factor VIIa (MarzAA) and Factor IX variants (DalcA) for subcutaneous prophylaxis. We have three additional assets, a FIX gene therapy construct CB 2679d-GT that has demonstrated 3-fold higher activity and 4-5 fold faster clotting time in a preclinical hemophilia B model compared with the Padua variant of FIX that is in clinical development by others, a Factor Xa pro-coagulant and a novel anti-C3 protease program for dry AMD, CB 2782 for which we have a strategic research collaboration with Mosaic and intend to out-license.

The lead Factor Xa pro-coagulant molecule has demonstrated efficacy in preclinical bleeding 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.

The novel anti-C3 protease targets the complement cascade, a series of naturally occurring molecular processes that play a central role in the body's inflammatory and immune response. In October 2017, we announced a strategic research collaboration with Mosaic, a related party, to develop intravitreal anti-complement factor three (C3) products for the treatment of dry AMD and other retinal diseases. In December 2018, we amended our collaboration agreement with Mosaic to, among other things, include certain additional products. The transaction was reviewed by disinterested members of our board of directors and approved by our audit committee. Expenses related to the collaboration were \$1.3 million and \$0.03 million for the years ended December 31, 2018 and 2017, respectively. We intend to find a partner for this program.

Based on industry reports and company reported sales, we estimate the 2018 global market opportunity for MarzAA and DalcA to be approximately \$2.2 billion and \$1.5 billion, respectively. Annual worldwide sales in 2018 for FDA-approved recombinant protease products for individuals with hemophilia A or B and an inhibitor were approximately \$1.2 billion and approximately \$2.2 billion when including prothrombin complex concentrate and bispecific antibody products. We are focused on advancing MarzAA through Phase 2/3 and DalcA through Phase 2b and potential Phase 3 clinical trials.

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., which was 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, recorded as an R&D expense.

On December 13, 2018, we entered into an Amended and Restated License Agreement (the "A&R ISU Abxis Agreement"), effective as of December 17, 2018, with ISU Abxis, which amends and restates in full our License and Collaboration Agreement with ISU Abxis, dated as of September 16, 2013, as subsequently amended on October 31, 2014 and on December 7, 2016 (the "Original ISU Abxis Agreement"). Pursuant to the A&R ISU Abxis Agreement, ISU Abxis will receive commercialization rights in South Korea to DalcA and the Company will receive clinical development and commercialization rights in the rest of world (excluding South Korea) and manufacturing development and manufacturing rights worldwide (including South Korea). The A&R ISU Abxis Agreement eliminates the profit-sharing arrangement in the Original ISU Abxis Agreement and provides for a low single-digit royalty payment to ISU Abxis, on a country-by-country basis, for net product sales of DalcA by the Company or its affiliates in each country other than South Korea. Pursuant to the A&R ISU Abxis Agreement, the Company will also make up to an aggregate of \$19.5 million in milestone payments to ISU Abxis, inclusive of \$2.5 million in regulatory and development milestone payment and up to \$17 million in commercial milestone payment, if the applicable milestones are met.

Under the Original ISU Abxis Agreement, ISU Abxis paid us a non-refundable upfront signing fee of \$1.75 million. ISU Abxis was also obligated, under the Original ISU Abxis Agreement, 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 were achieved for a total of \$2.65 million as of December 31, 2018.

The A&R ISU Abxis Agreement contains customary representations, warranties, covenants and indemnification provisions. The A&R ISU Abxis Agreement may be terminated by either party, subject to applicable notice and/or cure periods, upon a material breach by or an event of bankruptcy relating to the other party or by mutual consent of both parties.

As of December 31, 2018, the cumulative aggregate payments received and recognized by us under the Original ISU Abxis Agreement were \$2.65 million and we had made reimbursements of \$0.2 million to ISU Abxis, associated with certain preclinical studies in 2018. The adoption of the new revenue standards resulted in a \$0.2 million cumulative adjustment to the Company's opening balance of accumulated deficit as of January 1, 2018. We had no deferred revenue balance as of December 31, 2018 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, 2018, we have raised net cash proceeds of approximately \$373.0 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 ("Notes") which matured on February 19, 2018 and the remaining Notes were repaid in full with cash from the restricted cash indenture and an immaterial amount were converted to common stock. The Company has no outstanding Notes remaining as of December 31, 2018.

We have never been profitable and have incurred significant operating losses in each year since inception. Our net losses were \$30.1 million and \$21.6 million for years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, we had an accumulated deficit of \$203.3 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 21, 2018, we filed a shelf registration statement with the SEC, which registration statement was declared effective on February 14, 2019, and allows us to offer up to \$200 million of securities from time to time in one or more offerings.

### **Financial Operations Overview**

#### ***Contract Revenue***

We enter 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, product supplies, and royalties on any future sales of commercialized products that result from the collaborations. We have not generated any revenue from commercial product sales to date. ISU Abxis represents 100% of our total contract revenue for the year ended December 31, 2018 and 2017.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under our agreements, we perform the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when we satisfy each performance obligation.

### 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;
- The cost of acquiring comparator drugs for our research studies;
- 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, 2018 and 2017 (*in thousands*).

	Year Ended December 31,	
	2018	2017
Personnel costs	\$ 4,366	\$ 2,219
Preclinical research	3,457	1,855
Clinical manufacturing	12,745	7,959
Facility and overhead	906	814
Total research and development expenses	<u>\$ 21,474</u>	<u>\$ 12,847</u>

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 two clinical stage programs. Our internal resources, employees and infrastructure are not directly tied to individual product candidates or development programs. As such, we do not maintain information regarding these costs incurred for these research and development programs on a project-specific basis.

We expect our aggregate research and development expenses will increase during the next year as we continue the preclinical, manufacturing and clinical development of our product candidates, particularly the manufacturing and clinical development costs of MarzAA and DalcA. While ISU has previously been responsible for clinical and development expenses for DalcA under our agreement with them, their funding obligations have expired, and we are assuming responsibility for these expenses in the future.

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 MarzAA 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 DalcA.

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 DalcA, 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, 2018, we have \$0.3 million in payment obligations to AGC remaining under the initial statement of work for MarzAA and \$3.4 million in payment obligations related to DalcA.

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 consist primarily of interest income on our investment portfolio and milestone payments received under an agreement associated with neuronal nicotinic receptor (“NNR”) assets sold in 2016.

## Results of Operations

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

	Year Ended December 31,		Change (\$)	Change (%)
	2018	2017		
Contract revenue	\$ 6	\$ 1,018	\$ (1,012)	(99)%
Operating expenses:				
Research and development	21,474	12,847	8,627	67%
General and administrative	12,354	9,993	2,361	24%
Total operating expenses	33,828	22,840	10,988	48%
Loss from operations	(33,822)	(21,822)	(12,000)	55%
Interest and other income	3,767	261	3,506	1343%
Net loss	<u>\$ (30,055)</u>	<u>\$ (21,561)</u>	<u>\$ (8,494)</u>	<u>39%</u>

### Contract revenue

Contract revenue was \$0.01 million and \$1.0 million during the years ended December 31, 2018 and 2017, respectively, a decrease of \$1.0 million, or 99%. The decrease 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 \$21.5 million and \$12.8 million during the years ended December 31, 2018 and 2017, respectively, an increase of \$8.6 million, or 67%. The increase was due primarily to an increase of \$5.7 million related to DalcA expenses, \$1.4 million anti-complement dry AMD expense, \$2.1 million personnel related expenses as a result of increased employees and non-cash stock-based compensation costs. The increase was partially offset by a decrease of \$0.6 million in MarzAA expense.

Based on our current programs and related commitments, we expect our research and development expenses for the year ending December 31, 2019 to increase materially compared with 2018, due primarily to costs associated with clinical trials and manufacturing for MarzAA and DalcA. Through the completion of the Phase 1 clinical study of DalcA, ISU Abxis was responsible for manufacturing and clinical development expenses for this product candidate. Pursuant to our collaboration agreement with ISU Abxis, we are responsible for the Phase 2b trial that is expected to start in the first quarter of 2019.

### General and Administrative Expenses

General and administrative expenses were \$12.4 million and \$10.0 million during the years ended December 31, 2018 and 2017, respectively, an increase of \$2.4 million, or 24%. The increase was due primarily to an increase in personnel-related costs as a result of increased employees and non-cash stock-based compensation costs.

### Interest and Other Income

Interest and other income were \$3.8 million and \$0.3 million during the years ended December 31, 2018 and 2017, respectively, an increase of \$3.5 million, or 1,343%. The increase was due primarily to a \$2.0 million increase in interest income resulting from a higher cash balance resulting from our 2018 financing of \$111.3 million, and a \$1.5 million increase in miscellaneous income from a milestone payment received from the sale of NNR asset.

## Recent Accounting Pronouncements

### *Accounting Pronouncements Recently Adopted*

In November 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 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. We adopted ASU 2016-18 effective January 1, 2018, using a retrospective transition method to each period presented. The adoption of this ASU changed previously reported amounts in the condensed consolidated statement of cash flows for the year ended December 31, 2017, by increasing our cash flows from financing activities by \$5.3 million as compared to previously reported amounts for the prior year period.

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 effective January 1, 2018 and this guidance did not have a material impact on our consolidated 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. Subsequently, in February 2018, the FASB issued ASU No. 2018-03, Technical Corrections and Improvements to Financial Instruments - Overall (Topic 825-10), which includes provisions to accounting for equity investments, financial liabilities under the fair value option and presentation and disclosure requirements for financial instruments. The amended guidance requires equity securities, except for those accounted for under the equity method of accounting, with determinable fair values to be measured at fair with changes in fair value recognized in net income (loss). We adopted ASU 2016-01 and 2018-03 effective January 1, 2018, and this guidance did not have a material impact on our financial statements, as we only have debt securities.

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. We adopted the new revenue standards effective January 1, 2018, using the modified retrospective method through a cumulative adjustment to equity. While we have identified that the most significant change relates to its accounting for collaboration arrangements with multiple deliverables, in particular, the ISU Abxis agreement. Under the old 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 current 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, revenue for this transaction may be recorded in an earlier period than under the old guidance, resulting in an \$0.2 million increase to our opening balance of accumulated deficit as of January 1, 2018.

Adopting ASU No. 2014-09, Revenue from Contracts with Customers, or the new revenue standard, involved 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.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) (“ASU 2016-02”), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. Originally, entities were required to adopt ASU 2016-02 using a modified retrospective approach at the beginning of the earliest comparative period presented in the financial statements and the recognition of a cumulative-effect adjustment to the opening balance of retained earnings. The FASB subsequently issued ASU No. 2018-10 and 2018-11 in July 2018, which provide clarifications and improvements to ASU 2016-02 (collectively, the “new lease standard”).

ASU No. 2018-11 also provides the optional transition method which allows companies to apply the new lease standard at the adoption date instead of at the earliest comparative period presented and continue to apply the provisions of the previous lease standard in its annual disclosures for the comparative periods. The new lease standard requires lessees to present a right-of-use asset and a corresponding lease liability on the balance sheet. Lessor accounting is substantially unchanged compared to the current accounting guidance. Additional footnote disclosures related to leases will also be required.

On January 1, 2019, we adopted the new lease standard using the optional transition method. The comparative financial information will not be restated and will continue to be reported under the previous lease standard in effect during those periods. In addition, the new lease standard provides a number of optional practical expedients in transition. We elected the package of practical expedients. As such, we will not reassess whether expired or existing contracts are or contain a lease; will not need to reassess the lease classifications or reassess the initial direct costs associated with expired or existing leases. We did not elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter not being applicable to us.

The new lease standard also provides practical expedients for an entity's ongoing accounting. We elected the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, we will not recognize right of use assets or lease liabilities, and this includes not recognizing right of use assets or lease liabilities for existing short-term leases of those assets in transition. We elected the practical expedient to not separate lease and non-lease components for certain classes of assets.

On January 1, 2019, we expect to recognize right of use assets of \$2.5 million and lease liabilities of \$2.3 million. We do not expect the adoption of the new lease standard to impact our consolidated statement of operations or our consolidated statement of cash flows.

In June 2018, the FASB issued ASU No. 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. The ASU aligns the measurement and classification guidance for share-based payments to nonemployees with the guidance for share-based payments to employees, with certain exceptions. Under the new standard, equity-classified share-based payment awards issued to nonemployees will be measured on the grant date, instead of the current requirement to remeasure the awards through the performance completion date. We adopted ASU 2018-07 effective January 1, 2019 and this guidance did not have a material impact on our financial statements.

### **Liquidity and Capital Resources**

As of December 31, 2018, we had \$120.1 million of cash, cash equivalents and short-term investments. During the year ended December 31, 2018, we had a \$30.1 million net loss and \$28.6 million cash used in operating activities. We have an accumulated deficit of \$203.3 million as of December 31, 2018. Our primary uses of cash are to fund operating expenses, including research and development expenditures and general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in its outstanding accounts payable and accrued expenses.

We believe that our existing capital resources, 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*):

	<u>Year Ended December 31,</u>	
	<u>2018</u>	<u>2017</u>
Cash used in operating activities	\$ (28,553)	\$ (19,940)
Cash used in investing activities	(71,321)	(11,195)
Cash provided by financing activities	111,332	21,082
Net increase (decrease) in cash and cash equivalents	<u>\$ 11,458</u>	<u>\$ (10,053)</u>

#### ***Cash Flows from Operating Activities***

Cash used in operating activities for the year ended December 31, 2018 was \$28.6 million, due primarily to a net loss of \$30.1 million, partially offset by non-cash charges of \$2.6 million were recorded for stock-based compensation, the change in our net operating assets and liabilities of \$1.4 million due primarily to a \$2.9 million increase in prepaid and other current assets, \$0.9 million increase in accrued compensation and other accrued liabilities and \$0.5 million increase in accounts payable.

Cash used in operating activities for the year ended December 31, 2017 was \$19.9 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 \$0.4 million decrease in prepaid and other current assets. Non-cash charges of \$0.9 million were recorded for stock-based compensation.

#### ***Cash Flows from Investing Activities***

Cash used in investing activities for the year ended December 31, 2018 was \$71.3 million, due primarily to \$198.9 million in purchases of investments and 0.4 million purchase of property and equipment, partially offset by proceeds from maturities of investments of \$128.0 million.

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 flows from Financing Activities***

Cash provided by financing activities for the year ended December 31, 2018 was \$111.3 million, due primarily to \$106.8 million in net proceeds from the issuance of common stock related to our underwritten public offering in February 2018, \$9.5 million in proceeds from the exercise of common stock warrants, partially offset by \$5.1 million payments for the redemption of the redeemable convertible notes.

Cash provided by financing activities for the year ended December 31, 2017 was \$21.1 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 and \$1.8 million in proceeds from the exercise of common stock warrants which was offset by payments of \$14.3 million related to the redemption of such notes.

## Contractual Obligations

The following table summarizes our fixed contractual obligations as of December 31, 2018 (*in thousands*):

	Payments due by period				Total
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	
<b>Contractual Obligations:</b>					
Operating lease obligations <sup>(1)</sup>	\$ 571	\$ 1,809	\$ 209		\$ 2,589
AGC Manufacturing obligations <sup>(2)</sup>	3,716				3,716
Total contractual obligations <sup>(3)(4)</sup>	\$ 4,287	\$ 1,809	\$ 209	\$ —	\$ 6,305

- (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 Pfizer certain milestone payments up to \$17.5 million. We may be obligated to pay ISU Abxis \$19.5 million. Timing and certainty are unknown and therefore not included here.
- (4) We had unrecognized tax benefits in the amount of \$1,573 million as of December 31, 2018 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 Policies 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

Effective January 1, 2018, we adopted Accounting Standards Codification (“ASC”) 606 using the modified retrospective method through a cumulative adjustment to equity, which resulted in an immaterial \$0.2 million decrease to our opening balance of accumulated deficit as of January 1, 2018. We enter 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, product supplies, and royalties on any future sales of commercialized products that result from the collaborations.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its agreements, we perform the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when we satisfy each performance obligation.

At the inception of each arrangement that includes variable consideration such as development milestone payments, we evaluate whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price which is then allocated to each relevant performance obligation. Milestone payments that are not within our control or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received.

As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the timing of recognition and the stand-alone selling price for each performance obligation identified in the contract. We use key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

Estimated selling prices for licenses are calculated using the residual approach if we have not yet established a price for such license and the license has not previously been sold on a standalone basis. Otherwise, selling prices for licenses are determined using an income approach model and include key assumptions such as: development timeline, revenue forecast, commercialization expenses, discount rate and probabilities of technical and regulatory success. To estimate selling prices for research services and product supply, we use a cost-plus margin approach.

### ***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 forfeited awards. We elected to account for forfeitures when they occur. 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 9* 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, 2018, we had cash and cash equivalents of \$31.2 million, which consisted of bank deposits and money market funds, and short-term investments of \$88.9 million.

CATALYST BIOSCIENCES, INC.

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

**Opinion on the Consolidated Financial Statements**

We have audited the accompanying consolidated balance sheets of Catalyst Biosciences, Inc. (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, comprehensive loss, 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, 2018 and 2017, and the consolidated results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), and our report dated March 7, 2019 expressed an unqualified opinion.

**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 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. 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 7, 2019

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

	December 31, 2018	December 31, 2017
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 31,213	\$ 14,472
Short-term investments	88,914	17,971
Restricted cash	50	5,333
Prepaid and other current assets	3,814	1,333
Total current assets	123,991	39,109
Other assets, noncurrent	543	128
Property and equipment, net	386	276
<b>Total assets</b>	<b>\$ 124,920</b>	<b>\$ 39,513</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,248	\$ 747
Accrued compensation	1,495	1,366
Other accrued liabilities	2,043	1,322
Deferred revenue, current portion	—	212
Deferred rent, current portion	15	7
Redeemable convertible notes	—	5,085
Total current liabilities	4,801	8,739
Deferred rent, noncurrent portion	174	—
Total liabilities	4,975	8,739
Stockholders' equity:		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized; 0 and 3,680 shares issued and outstanding at December 31, 2018 and 2017, respectively	—	—
Common stock, \$0.001 par value, 100,000,000 shares authorized; 11,954,528 and 6,081,230 shares issued and outstanding at December 31, 2018 and 2017, respectively	12	6
Additional paid-in capital	323,279	204,262
Accumulated other comprehensive loss	(4)	—
Accumulated deficit	(203,342)	(173,494)
Total stockholders' equity	119,945	30,774
<b>Total liabilities and stockholders' equity</b>	<b>\$ 124,920</b>	<b>\$ 39,513</b>

*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)

	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Contract revenue	\$ 6	\$ 1,018
Operating expenses:		
Research and development	21,474	12,847
General and administrative	12,354	9,993
Total operating expenses	33,828	22,840
Loss from operations	(33,822)	(21,822)
Interest and other income, net	3,767	261
Net loss	(30,055)	(21,561)
Deemed dividend for convertible preferred stock beneficial conversion feature	-	(3,951)
Net loss attributable to common stockholders	\$ (30,055)	\$ (25,512)
Net loss per share attributable to common stockholders, basic and diluted	\$ (2.68)	\$ (7.45)
Shares used to compute net loss per share attributable to common stockholders, basic and diluted	11,213,884	3,423,901

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

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

	<u>Year Ended December 31,</u>	
	<u>2018</u>	<u>2017</u>
Net loss	\$ (30,055)	\$ (21,561)
Other comprehensive income (loss):		
Unrealized (loss) gain on available-for-sale securities	(4)	1
Total comprehensive loss	<u>\$ (30,059)</u>	<u>\$ (21,560)</u>

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

**Catalyst Biosciences, Inc.**  
**Consolidated Statements of Stockholders' Equity**  
(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
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, 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	—	—	0	—	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
Opening balance adjustment - adoption of ASC 606	—	—	—	—	—	—	207	207
Balance at January 1, 2018	3,680	—	6,081,230	6	204,262	—	(173,287)	30,981
Stock-based compensation expense	—	—	—	—	2,606	—	—	2,606
Issuance of common stock for follow-on offering, net of issuance costs	—	—	3,382,352	4	106,758	—	—	106,762
Issuance of common stock upon exercise of warrants	—	—	1,735,419	2	9,543	—	—	9,545
Conversion of preferred stock to common stock	(3,680)	—	736,000	—	—	—	—	—
Issuance of common stock from stock grants and exercise of stock options (1)	—	—	19,506	—	107	—	—	107
Conversion of redeemable convertible notes to common stock	—	—	21	—	3	—	—	3
Unrealized loss on available-for-sale securities	—	—	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	—	—	(30,055)	(30,055)
Balance at December 31, 2018	—	\$ —	11,954,528	\$ 12	\$ 323,279	\$ (4)	\$ (203,342)	\$ 119,945

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

(1) Includes 6,790 shares of stock grants board member elected to receive in lieu of cash compensation for the board of director fees.

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

	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>Operating Activities</b>		
Net loss	\$ (30,055)	\$ (21,561)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,606	863
Depreciation and amortization	149	173
Loss on disposal of property and equipment	116	18
Changes in operating assets and liabilities:		
Prepaid and other current assets	(2,895)	(351)
Accounts receivable	—	7
Deposits	—	(128)
Accounts payable	500	(90)
Accrued compensation and other accrued liabilities	850	1,287
Deferred revenue	(6)	(118)
Deferred rent	182	(40)
Net cash flows used in operating activities	<u>(28,553)</u>	<u>(19,940)</u>
<b>Investing Activities</b>		
Proceeds from maturities of short-term investments	127,967	14,300
Purchase of short-term investments	(198,912)	(25,472)
Purchases of property and equipment	(376)	(23)
Net cash flows used in investing activities	<u>(71,321)</u>	<u>(11,195)</u>
<b>Financing Activities</b>		
Payments for the redemption of redeemable convertible notes	(5,082)	(14,318)
Proceeds from issuance of common stock, net of issuance costs	—	5,336
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 for follow-on offering, net of issuance costs	106,762	9,684
Proceeds from exercise of stock options and issuance of stock grants	107	—
Proceeds from exercise of warrants	9,545	1,817
Net cash flows provided by financing activities	<u>111,332</u>	<u>21,082</u>
Net increase (decrease) in cash and cash equivalents	11,458	(10,053)
Cash, cash equivalents and restricted cash at beginning of the period	19,805	29,858
Cash, cash equivalents and restricted cash at end of the period(a)	<u>\$ 31,263</u>	<u>\$ 19,805</u>

**Supplemental Disclosure of Non-Cash Investing and Financing Activities:**

Deemed dividend for convertible preferred stock beneficial conversion feature	\$ —	\$ 3,951
Adoption of ASC 606	\$ 207	\$ —
Conversion of redeemable convertible notes to common stock	\$ 3	\$ —
Unrealized loss/gain on investments	\$ 4	\$ 1

(a) The following table provides a reconciliation of cash and restricted cash to amounts reported within the condensed consolidated balance sheets:

Cash and cash equivalents	\$ 31,213	\$ 14,472
Restricted cash	50	5,333
Total cash and restricted cash	<u>\$ 31,263</u>	<u>\$ 19,805</u>

*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”).

**2. Liquidity**

The Company had a net loss of \$30.1 million for the year ended December 31, 2018 and an accumulated deficit of \$203.3 million as of December 31, 2018 and expects to continue to incur losses for the next several years. As of December 31, 2018, the Company had \$120.1 million in cash, cash equivalents and short-term investments and used \$28.6 million of cash in operating activities for the year ended December 31, 2018. 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.

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.

**3. Summary of Significant Accounting Policies**

***Basis of Presentation***

The accompanying consolidated financial statements include the accounts of the Company and its subsidiary. 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 November 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 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. We adopted ASU 2016-18 effective January 1, 2018, using a retrospective transition method to each period presented. The adoption of this ASU changed previously reported amounts in the condensed consolidated statement of cash flows for the year ended December 31, 2017, by increasing our cash flows from financing activities by \$5.3 million as compared to previously reported amounts for the prior year period.

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. The standard is intended to reduce current diversity in practice. The Company adopted ASU 2016-15 effective January 1, 2018, and this guidance did not have an impact on the Company’s 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. Subsequently, in February 2018, the FASB issued ASU No. 2018-03, Technical Corrections and Improvements to Financial Instruments - Overall (Topic 825-10), which clarifies certain aspects of ASU 2016-01, which includes provisions to accounting for equity investments, financial liabilities under the fair value option and presentation and disclosure requirements for financial instruments. The amended guidance requires equity securities, except for those accounted for under the equity method of accounting, with determinable fair values to be measured at fair value with changes in fair value recognized in net income (loss). The Company adopted ASU 2016-01 and 2018-03 effective January 1, 2018, and this guidance did not have a material impact on the Company’s financial statements, as the Company only has debt securities.

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”). The Company adopted the new revenue standards effective January 1, 2018, using the modified retrospective method through a cumulative adjustment to equity. 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 old guidance, such deliverables and consideration must be accounted for under a single unit of accounting along with other arrangement deliverables and consideration that does not have stand-alone value and are recognized as revenue over the estimated period that the performance obligations are to be performed. Under the current 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, revenue for this transaction is recorded in an earlier period than under the old guidance, resulting in a \$0.2 million increase to the Company’s opening balance of accumulated deficit as of January 1, 2018.

Adopting ASU No. 2014-09, Revenue from Contracts with Customers, or the new revenue standard, involved 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. The Company recognized revenue earlier under the current new standard and may have more variability due to significant estimates involved under the new accounting guidance.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) (“ASU 2016-02”), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. Originally, entities were required to adopt ASU 2016-02 using a modified retrospective approach at the beginning of the earliest comparative period presented in the financial statements and the recognition of a cumulative-effect adjustment to the opening balance of retained earnings. The FASB subsequently issued ASU No. 2018-10 and ASU No. 2018-11 in July 2018, which provide clarifications and improvements to ASU 2016-02 (collectively, the “new lease standard”).

ASU No. 2018-11 also provides the optional transition method which allows companies to apply the new lease standard at the adoption date instead of at the earliest comparative period presented and continue to apply the provisions of the previous lease standard in its annual disclosures for the comparative periods. The new lease standard requires lessees to present a right-of-use (“ROU”) asset and a corresponding lease liability on the balance sheet. Lessor accounting is substantially unchanged compared to the current accounting guidance. Additional footnote disclosures related to leases will also be required.

On January 1, 2019, the Company adopted the new lease standard using the optional transition method. The comparative financial information will not be restated and will continue to be reported under the previous lease standard in effect during those periods. In addition, the new lease standard provides a number of optional practical expedients in transition. The Company elected the package of practical expedients. As such, the Company will not reassess whether expired or existing contracts are or contain a lease; will not need to reassess the lease classifications or reassess the initial direct costs associated with expired or existing leases. The Company did not elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter not being applicable to the Company.

The new lease standard also provides practical expedients for an entity’s ongoing accounting. The Company elected the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, the Company will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. The Company elected the practical expedient to not separate lease and non-lease components for certain classes of assets.

On January 1, 2019, the Company expects to recognize ROU assets of \$2.5 million and lease liabilities of \$2.3 million. The Company does not expect the adoption of the new lease standard to impact its consolidated statement of operations or its consolidated statement of cash flows.

#### ***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 at December 31, 2018 consists of a certain certificate of deposit account that is pledged as collateral for the Company’s corporate credit card program. Restricted cash at December 31, 2017 consisted 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 4 – 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.

***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 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 were convertible into shares of the Company’s common stock was bifurcated and was accounted for as a derivative liability at its estimated fair value. The derivative was 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. These notes were repaid in 2018. The Company adjusted the liability for changes in fair value until the earlier of the conversion, redemption or maturity of the redeemable convertible notes. At December 31, 2017 the fair value was \$0.

### ***Revenue Recognition***

Effective January 1, 2018, the Company adopted Accounting Standards Codification (“ASC”) 606 using the modified retrospective method through a cumulative adjustment to equity, which resulted in an immaterial \$0.2 million decrease to our opening balance of accumulated deficit as of January 1, 2018. 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, product supplies, and royalties on any future sales of commercialized products that result from the collaborations.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when the Company satisfies each performance obligation.

At the inception of each arrangement that includes variable consideration such as development milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price which is then allocated to each relevant performance obligation. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received.

As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the timing of recognition and the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

Estimated selling prices for licenses are calculated using the residual approach if the Company has not yet established a price for such license and the license has not previously been sold on a standalone basis. Otherwise, selling prices for licenses are determined using an income approach model and include key assumptions such as: development timeline, revenue forecast, commercialization expenses, discount rate and probabilities of technical and regulatory success. To estimate selling prices for research services and product supply, the Company uses a cost-plus margin approach.

### ***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, 2018 and 2017, the Company recorded a reduction to research and development expenses of \$0.05 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 restricted cash. 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, included in prepaid and other current assets, at December 31, 2018 was \$0.01 million, due from ISU Abxis, see Note 12. 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.

**4. Fair Value Measurements**

For a description of the fair value hierarchy and our fair value methodology, see "Note 3 – Summary of Significant Accounting Policies". As of December 31, 2018 and 2017, the Company's highly liquid money market funds included within cash equivalents, restricted cash and U.S. Treasury 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. US Treasury securities are bonds issued by the U.S. government and are fully backed by the U.S. government. Given the frequency at which U.S. Treasury securities trade and the accessibility of observable, quoted prices for such assets in active markets, they are recognized as Level 1 assets. Federal agency securities are bonds and notes issued by government-sponsored enterprises, including Fannie Mae, Freddie Mac and the Federal Home Loan Bank. Since federal agency securities typically do not trade as U.S. Treasury securities and no exchange exists to price such investments, they are recognized as Level 2 assets.

At December 31, 2017 the fair value of the derivative liability was \$0. 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, 2018 and 2017 (in thousands):

	December 31, 2018			Total
	Level 1	Level 2	Level 3	
<b>Financial assets:</b>				
Money market funds(1)	\$ 29,090	\$ —	\$ —	\$ 29,090
Federal agency securities(1)	—	999	—	999
Restricted cash (2)	50	—	—	50
U.S. Treasury securities(3)	74,139	—	—	74,139
Federal agency securities(3)	—	14,775	—	14,775
<b>Total financial assets</b>	<b>\$ 103,279</b>	<b>\$ 15,774</b>	<b>\$ —</b>	<b>\$ 119,053</b>

- (1) Included in cash and cash equivalents on accompanying consolidated balance sheets.
- (2) \$0.05 million of restricted cash serves as collateral for the Company's corporate credit card.
- (3) Included in short-term investments on accompanying consolidated balance sheets and are classified as available-for-sale securities.

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December 31, 2017

	Level 1	Level 2	Level 3	Total
<b>Financial assets:</b>				
Money market funds(1)	\$ 14,334	\$ —	\$ —	\$ 14,334
U.S. Treasury securities(3)	16,471	—	—	16,471
Restricted cash(2)	5,333	—	—	5,333
Federal agency securities(3)	—	1,500	—	1,500
<b>Total financial assets</b>	<b>\$ 36,138</b>	<b>\$ 1,500</b>	<b>\$ —</b>	<b>\$ 37,638</b>

- (1) Included in cash and cash equivalents on accompanying consolidated balance sheets.
- (2) \$5.3 million of restricted cash in the Indenture (see Note 9) serves as full collateral for the redeemable convertible notes.
- (3) Included in short-term investments on accompanying consolidated balance sheets and are classified as available-for-sale securities.

**5. Financial Instruments**

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

<b>-December 31, 2018</b>	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds (cash equivalents)	\$ 29,090	\$ —	\$ —	\$ 29,090
Agency securities (cash equivalents)	999	—	—	999
Restricted cash	50	—	—	50
U.S. government agency securities	74,144	1	(6)	74,139
Agency securities	14,774	1	—	14,775
<b>Total financial assets</b>	<b>\$ 119,057</b>	<b>\$ 2</b>	<b>\$ (6)</b>	<b>\$ 119,053</b>
<b>Classified as:</b>				
Cash and cash equivalents				\$ 30,089
Short-term investments				88,914
Restricted cash				50
				<b>\$ 119,053</b>

<b>December 31, 2017</b>	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	\$ 14,334	\$ —	\$ —	\$ 14,334
U.S. government agency securities	16,473	—	(2)	16,471
Restricted cash	5,330	3	—	5,333
Agency securities	1,500	—	—	1,500
<b>Total financial assets</b>	<b>\$ 37,637</b>	<b>\$ 3</b>	<b>\$ (2)</b>	<b>\$ 37,638</b>
<b>Classified as:</b>				
Cash and cash equivalents				\$ 14,334
Short-term investments				17,971
Restricted cash				5,333
				<b>\$ 37,638</b>

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As of December 31, 2018, 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, other assets, other receivables, accounts payable and other payables approximate their fair values due to the short-term maturity of these instruments.

**6. Property and Equipment**

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

	Year Ended December 31,	
	2018	2017
Furniture	\$ 226	\$ 317
Leasehold improvements	84	1,598
Computer equipment	222	237
Software	139	147
	671	2,299
Less accumulated depreciation and amortization	(285)	(2,023)
Property and equipment, net	<u>\$ 386</u>	<u>\$ 276</u>

Property and equipment depreciation and amortization expense for the years ended December 31, 2018 and 2017 was \$0.1 million and \$0.2 million, respectively.

**7. Commitments and Contingencies**

**Operating Leases**

In November 2017, the Company 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. On August 10, 2018, the Company entered into an amendment to the existing office lease agreement to lease an additional approximately 4,626 rentable square feet. The lease amendment will be coterminous with the original lease term above.

The Company's rental expense under its operating leases was \$0.4 million and \$0.8 million for the years ended December 31, 2018 and 2017.

Future minimum lease payments under all non-cancelable operating leases at December 31, 2018, were as follows (*in thousands*):

2019	\$ 571
2020	587
2021	605
2022	617
2023	209
Total future minimum lease payments	<u>\$ 2,589</u>

### **Manufacturing Agreements**

On May 20, 2016, the Company signed a development and manufacturing services agreement (the “Agreement”) with AGC Biologics, Inc. (“AGC”), formerly known as CMC ICOS Biologics, Inc., pursuant to which AGC will conduct manufacturing development. Together with AGC, the Company has successfully manufactured MarzAA 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, 2018, the Company’s remaining obligations to AGC were \$0.3 million under the Agreement.

On February 21, 2018, the Company and AGC entered into a new statement of work under the 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 DalcA. 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 DalcA, subject to completion of applicable work stages. As of December 31, 2018, the Company’s remaining obligations to AGC were \$3.4 million under the new statement of work.

### **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, 2018, no such milestones have been achieved.

In December 2018, the Company entered into an amended and restated license agreement with ISU Abxis (the “A&R ISU Abxis Agreement”), which amended and restated in full its previous license and collaboration agreement with ISU Abxis entered into in September 2013 (as subsequently amended in October 2014 and December 2016). The A&R ISU Abxis Agreement eliminates the profit-sharing arrangement in the Original ISU Abxis Agreement and provides for a low single-digit royalty payment to ISU Abxis, on a country-by-country basis, for net product sales of DalcA by the Company or its affiliates in each country other than South Korea. Pursuant to the A&R ISU Abxis Agreement, the Company will make up to an aggregate of \$19.5 million in milestone payments to ISU Abxis, inclusive of \$2.5 million in regulatory and development milestone payments and up to \$17 million in commercial milestone payments, if the applicable milestones are met.

Pursuant to the termination agreement entered on December 8, 2016, 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. With the termination agreement, the Company recovered worldwide exclusive license for research, development, manufacturing and commercialization to all company’s original FVIIa programs, including CB 813d.

**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. On December 21, 2018, the Company amended its collaboration agreement with Mosaic to, among other things, include certain additional products. According to the Mosaic collaboration agreement, as amended, 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 \$1.3 million and \$0.03 million for the years ended December 31, 2018 and 2017.

**9. Redeemable Convertible Notes**

The Company has no outstanding Notes remaining as of December 31, 2018.

On August 19, 2015, immediately prior to the Merger, the Company issued to Targacept stockholders non-interest bearing redeemable convertible notes (the “Notes”) in the aggregate principal amount of \$37.0 million, which matured on February 19, 2018. The Notes did not bear interest. The principal amount of the Notes was 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. On February 19, 2018, the Notes matured, and the remaining Notes were repaid in full with cash from the restricted cash indenture and an immaterial amount were converted to common stock.

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 were the Company’s secured obligation, and the Indenture did not limit its other indebtedness, secured or unsecured.

The conversion to common stock feature of the Notes was determined to be a derivative liability requiring bifurcation and separate accounting. 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 were being recorded within interest and other income in the consolidated statements of operations. The Company remeasured the derivative liability to fair value until the earlier of the conversion, redemption or maturity of the redeemable convertible notes.

As of December 31, 2018, there was no derivative liability and as of December 31, 2017, 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, 2018 and 2017, related to the amortization of the debt discount as the redeemable convertible notes were immediately fully redeemable at the option of the holders and the entire debt discount was expensed immediately after the Merger.

**10. Stock Based Compensation**

**2018 Omnibus Incentive Plan**

In June 2018, stockholders of the Company approved the Company’s 2018 Omnibus Incentive Plan (the “2018 Plan”). The 2018 Plan had previously been approved by the Company’s Board of Directors (the “Board”) and the Compensation Committee of the Board, subject to stockholder approval. The 2018 Plan became effective on June 13, 2018 and provided an additional 1,500,000 stock options, following receipt of the requisite stockholder approval. The 2018 Plan replaces the Company’s 2015 Stock Incentive Plan, as amended (the “2015 Plan”). All awards outstanding under the 2015 Plan will remain in effect in accordance with their respective terms.

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, 2016	140,990	\$ 128.25	3.93	—
Options granted	742,000	\$ 4.56		
Options forfeited	(61,249)	\$ 165.63		
Outstanding — December 31, 2017	821,741	\$ 13.69	9.17	\$ 6,376
Options granted	612,050	\$ 13.13		
Options exercised	(12,716)	\$ 4.17		\$ 213
Options canceled/forfeited	(43,315)	\$ 7.76		
Options expired	(15,783)	\$ 158.81		
Outstanding — December 31, 2018	<u>1,361,977</u>	\$ 12.04	8.71	\$ 2,294
Exercisable — December 31, 2018	<u>414,584</u>	\$ 17.98		
Vested and expected to vest — December 31, 2018	<u>1,361,977</u>	\$ 12.04		
Shares available to be granted — December 31, 2018	<u>1,295,144</u>			

**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 6.04 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 \$9.97 and \$4.01 for the years ended December 31, 2018 and 2017, respectively, and was estimated using the following weighted-average assumptions for the years ended December 31, 2018 and 2017:

	Year Ended December 31,	
	2018	2017
<b>Employee Stock Options:</b>		
Expected term (in years)	6.04	6.03
Risk-free interest rate	2.67%	2.03%
Dividend yield	—	—
Volatility	92.61%	110.29%

**Options Granted to Nonemployees**

During the year ended December 31, 2018, no options were issued to consultants. During the year ended December 31, 2017, options to purchase 20,000 shares of common stock were issued to consultants that vest over one to four years with a weighted-average exercise price of \$4.69 per share. During the years ended December 31, 2018, and 2017, the Company recorded stock-based compensation expense attributable to these nonemployee stock awards of \$0.09 million and \$0.02 million, respectively.

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

	Year Ended December 31,	
	2018	2017
<b>Non-Employee Stock Options:</b>		
Contractual Life (in years)	N/A	9
Risk-free interest rate	N/A	2.35%
Dividend yield	N/A	—
Volatility	N/A	111.55%

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

	Year Ended December 31,	
	2018	2017
Research and development	\$ 590	\$ 164
General and administrative <sup>(1)</sup>	1,990	699
<b>Total stock-based compensation</b>	<b>\$ 2,580</b>	<b>\$ 863</b>

(1) 2018 includes \$0.1 million in modification stock-based compensation expense related to a Board member’s separation agreement.

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As of December 31, 2018, the Company had unrecognized employee stock-based compensation expense of \$6.5 million, related to unvested stock option awards, which is expected to be recognized over an estimated weighted-average period of 2.78 years.

**2018 Employee Stock Purchase Plan**

In June 2018, the Company’s stockholders approved the 2018 Employee Stock Purchase Plan (the “ESPP”). The 2018 ESPP had previously been approved by the Board and the Compensation Committee of the Board, subject to stockholder approval which became effective as of June 13, 2018. Under the ESPP, employees meeting certain specific employment qualifications are eligible to participate and can purchase shares of common stock semi-annually on February 9<sup>th</sup> and August 9<sup>th</sup> of each year, through payroll deductions. The purchase price is 85% of the lower of the fair market value of the stock at the commencement or end of the offering period. The ESPP permits eligible employees to purchase shares of common stock through payroll deductions for up to 15% of qualified compensation.

A total of 120,000 shares of common stock may be granted in accordance with the terms of the ESPP. As of December 31, 2018, no shares of common stock have been issued to employees participating in the ESPP and 120,000 shares are available for issuance under the ESPP. Compensation expense, using Black-Scholes, for the ESPP was \$0.03 million as of December 31, 2018.

**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, 2018 and 2017 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, 2018 and 2017 are as follows:

	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Tax at statutory federal rate	-21.00%	-34.00%
State Tax (benefit)—net of federal benefit	-0.03%	0.00%
Permanent differences	0.68%	0.60%
R&D credits	-0.76%	-1.64%
Derecognition due to Sec. 382 and 383 limitations	-20.16%	54.08%
Change in valuation allowance	39.33%	-52.90%
Federal tax rate change	0.00%	33.89%
Other	1.94%	-0.03%
Effective tax rate	—	—

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Significant components of the Company's deferred tax assets as of December 31, 2018 and 2017 consist of the following (*in thousands*):

	Year Ended December 31,	
	2018	2017
<b>Deferred tax assets:</b>		
Accruals and reserves	\$ 751	\$ 1,112
Net operating loss carry forwards	23,559	11,519
R&D tax credit carry forwards	3,772	3,545
Fixed and intangible assets	3	89
Valuation Allowance	(28,085)	(16,265)
<b>Net deferred tax assets:</b>	<b>\$ —</b>	<b>\$ —</b>

Based on the available objective evidence at December 31, 2018, the Company does not believe it is more likely than not that the net deferred tax assets will be realizable. Accordingly, the Company has provided a full valuation allowance against its net deferred tax assets at December 31, 2018 and 2017.

As of December 31, 2018, after consideration of certain limitations (see below), the Company had approximately \$112.1 million federal and \$64.6 million state net operating loss carryforwards ("NOL") available to reduce future taxable income which, if unused, will begin to expire in 2032 for federal and 2028 for state tax purposes.

As of December 31, 2018, the Company also had tax credit carry forwards available to offset future tax liabilities of approximately \$0.2 million for federal and \$4.5 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. The Company determined that ownership changes occurred December 31, 2007, August 20, 2015, April 13, 2017, and February 15, 2018. Approximately \$80.1 million and \$14.2 million of the NOLs will expire unutilized for federal and California purposes, respectively. The Company has derecognized NOL related deferred tax assets in the tax affected amounts of \$16.8 million and \$0.0 million for federal and California purposes, respectively.

All of the federal R&D credits could expire unutilized, 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. 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.

***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.

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The Company had approximately \$1.6 million and \$1.5 million of unrecognized tax benefits as of December 31, 2018 and 2017, respectively. 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*):

<b>Beginning Balance at January 1, 2017</b>	<b>\$ 1,539</b>
Increase/(Decrease) of unrecognized tax benefits taken in prior years	(126)
Increase/(Decrease) of unrecognized tax benefits related to current year	62
<b>Ending Balance at December 31, 2017</b>	<b>\$ 1,475</b>
Increase/(Decrease) of unrecognized tax benefits taken in prior years	13
Increase/(Decrease) of unrecognized tax benefits related to current year	85
<b>Ending Balance at December 31, 2018</b>	<b>\$ 1,573</b>

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, 2018 and 2017, 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, New Jersey, and Maryland state jurisdictions. The Company is not currently under examination by income tax authorities in federal, state or other jurisdictions. As of December 31, 2018 and 2017, the Company had no uncertain tax positions which affected its financial position as its results of operations or its cash flow, and will continue to evaluate for uncertain tax positions in the future. 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.

## 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 MarZAA. 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. 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**

In December 2018, the Company entered into an amended and restated license agreement with ISU Abxis (the “A&R ISU Abxis Agreement”), which amended and restated in full its previous license and collaboration agreement with ISU Abxis entered into in September 2013, as subsequently amended in October 2014 and December 2016 (the “Original ISU Abxis Agreement”). Under the A&R ISU Abxis Agreement, ISU Abxis will receive commercialization rights in South Korea to DalcA and the Company will receive clinical development and commercialization rights in the rest of world (excluding South Korea) and manufacturing development and manufacturing rights worldwide (including South Korea). The A&R ISU Abxis Agreement eliminates the profit-sharing arrangement in the Original ISU Abxis Agreement and provides for a low single-digit royalty payment to ISU Abxis, on a country-by-country basis, for net product sales of DalcA by the Company or its affiliates in each country other than South Korea. Pursuant to the A&R ISU Abxis Agreement, the Company will also make up to an aggregate of \$19.5 million in milestone payments to ISU Abxis, inclusive of \$2.5 million in regulatory and development milestone payments and up to \$17 million in commercial milestone payments, if the applicable milestones are met.

Under the Original ISU Abxis Agreement, ISU Abxis paid the Company an up-front signing fee of \$1.75 million and was 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.

Contract revenue of \$0.0 million and \$0.3 million for the years ended December 31, 2018 and 2017, respectively, reflects (i) the amortization of the up-front fee over the estimated period of our performance obligations, under the Original ISU Abxis Agreement, which concluded in February 2018, and (ii) milestone payments received under the ISU Abxis Original ISU Abxis Agreement, which were recognized through February 2018, of which the Company received \$0 and \$0.9 million for the years ended December 31, 2018 and 2017, respectively. The adoption of the new revenue standards resulted in a \$0.2 million cumulative adjustment to the Company’s opening balance of accumulated deficit as of January 1, 2018. The deferred revenue balance related to the ISU Abxis collaboration was \$0 and \$0.2 million as of December 31, 2018 and 2017, respectively.

**13. Interest and Other Income**

The following table shows the detail of other income, net for the years ended December 31, 2018 and 2017 (*in thousands*):

	Year Ended December 31,	
	2018	2017
Interest income	\$ 2,229	\$ 215
Dividend income	4	50
Miscellaneous income (expense) (1)	1,650	(1)
Loss on disposal of property and equipment	(116)	(3)
<b>Total other income, net</b>	<b>\$ 3,767</b>	<b>\$ 261</b>

(1) \$1.7 million miscellaneous income is mainly composed of a \$1.5 million milestone payment received under an agreement associated with neuronal nicotinic receptor (“NNR”) assets sold in 2016.

**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 over-allotment 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 over-allotment 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 years ended December 31, 2018 and 2017, 3,680 and 9,670 shares of the Company’s Series A Preferred Stock were converted into 736,000 and 1,934,000 shares of common stock of the Company. As of December 31, 2018, there were no 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 was 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.

**Catalyst Biosciences, Inc.**  
**Notes to Consolidated Financial Statements**

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. As of December 31, 2018, the Company has no warrants outstanding associated with this offering.

The following is a summary of warrant activity for the year ended December 31, 2018 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	
Issued	—	
Exercised	(1,735,419)	\$ 5.50
Forfeited/Cancelled (1)	(6,095)	\$ 5.50
Outstanding — December 31, 2018	10,194	\$ 155.73

(1) In April 2018, 4,250 warrants were forfeited. In November 2018, 1,845 warrants were cancelled by Healthcare Ventures VIII.

*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 \$106.8 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, 2018 and 2017 (in thousands, except share and per share data):

	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Net loss attributable to common stockholders	\$ (30,055)	\$ (25,512)
Weighted-average number of shares used in computing net loss per share, basic and diluted	11,213,884	3,423,901
Net loss per share, basic and diluted	\$ (2.68)	\$ (7.45)

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:

	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Options to purchase common stock	1,361,977	821,741
Convertible preferred stock (1)	—	736,000
Common stock warrants	10,194	1,751,708
Redeemable convertible notes	—	36,883
Total	1,372,171	3,346,332

(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.

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

None.

**Item 9A. CONTROLS AND PROCEDURES**

**(a) Evaluation of disclosure controls and procedures**

Our management maintains disclosure controls and procedures as defined in Rule 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934, as amended (the “Exchange Act”) that are designed to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Exchange Act is processed, recorded, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), as appropriate, to allow for timely decisions regarding required disclosure.

Our management, including the Chief Executive Officer and Chief Financial Officer, carried out an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective to ensure that the information required to be disclosed in the reports filed or submitted by us under the Securities Exchange Act of 1934 was recorded, processed, summarized and reported within the requisite time periods and that such information was accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow for timely decisions regarding required disclosure.

**(b) Management’s Annual 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 Rule 13a-15(f). Because of its inherent limitations, internal control over financial reporting may not prevent or detect all misstatements. Our internal control system was designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. Our assessment was based on the framework in the updated *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our assessment we believe that as of December 31, 2018, our internal control over financial reporting is effective based on those criteria.

EisnerAmper, LLP our independent registered public accounting firm, which audited our consolidated financial statements, has issued an attestation report on our internal control over financial reporting, which is included in this Item 9A below.

**(c) Changes in internal control over financial reporting**

Our management, including our Chief Executive Officer and Chief Financial Officer, evaluated our “internal control over financial reporting” as defined in Exchange Act Rule 13a-15(f) to determine whether any changes in our internal control over financial reporting occurred during the fiscal quarter ended December 31, 2018 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, there were no changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2018 that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of  
Catalyst Biosciences, Inc.

### ***Opinion on Internal Control over Financial Reporting***

We have audited Catalyst Biosciences, Inc.'s (the "Company") internal control over financial reporting as of December 31, 2018, based on criteria established in the *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in the *Internal Control - Integrated Framework* (2013) issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of Catalyst Biosciences, Inc. as of December 31, 2018 and 2017, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years then ended, and the related notes and our report dated March 7, 2019 expressed an unqualified opinion.

### ***Basis for Opinion***

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures, as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

### ***Definition and Limitations of Internal Control over Financial Reporting***

An entity's internal control over financial reporting is a process designed 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. An entity's internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the entity; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the entity are being made only in accordance with authorizations of management and directors of the entity; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the entity's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ EisnerAmper LLP

EISNERAMPER LLP

Iselin, New Jersey

March 7, 2019

**Item 9B. Other Information**

None.

**Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE****Board of Directors**

The members of our Board of Directors as of February 20, 2019, their class, positions and their respective ages on that date are:

<b>Name</b>	<b>Age</b>	<b>Class</b>	<b>Position</b>
Nassim Usman, Ph.D.	59	III	President and Chief Executive Officer
Augustine Lawlor	65	I	Chairman of the Board, Audit Committee Member, Compensation Committee Member, Governance and Nominating Committee Member
Andrea Hunt	59	II	Audit Committee Member, Science and Technology Committee Member
Eddie Williams	63	I	Compensation Committee Member, Governance and Nominating Committee Member
Errol B. De Souza, Ph.D.	65	III	Compensation Committee Chair, Science and Technology Committee Member
Jeff Himawan, Ph.D.	53	II	Governance and Nominating Committee Chair, Compensation Committee and Audit Committee Member, Science and Technology Committee Member
John P. Richard	61	II	Audit Committee Chair, and Governance and Nominating Committee Member
Stephen A. Hill, M.D.	60	I	Science and Technology Committee Chair

**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 board of directors of Mosaic Biosciences, is a past director of Principia Biopharma, 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 two marketed RNA products (Macugen<sup>TM</sup> & Onpattro<sup>TM</sup>).

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 serves on the board of OX2 Therapeutics, Ryan Banks Academy and is an advisor to Cell One Partners. She previously served as a board member of the Alliance for Regenerative Medicine and was 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 Bidel 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 Bidel, 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 Bidel 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. 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. since February 2018, and had previously served as a director of the predecessor company Aviragen 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 suited to serve on the Board.

#### Executive Officers

Our executive officers as of February 8, 2019, their positions and their respective ages on that date are:

Name	Age	Position
Nassim Usman, Ph.D.	59	President and Chief Executive Officer
Fletcher Payne	56	Chief Financial Officer
Howard Levy, M.B.B.Ch., Ph.D., M.M.M	64	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 Behring 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, 2018 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](http://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](http://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. Richard, who serves as Chairman, Ms. Hunt, Dr. Himawan and Mr. Lawlor. 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. Richard is the director who has been determined by the Board to be the audit committee financial expert. 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, as of December 31, 2018 each of Mr. Lawlor, Ms. Hunt, Mr. Williams, Dr. De Souza, Dr. Himawan, Mr. Richard and Dr. Hill 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, 2018.

**Summary Compensation Table**

The following table shows for the years ended December 31, 2018 and 2017 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 (\$)
<b>Nassim Usman, Ph.D.</b>	2018	480,800	240,400	—	1,715,741	—	5,372	2,442,313
President and Chief Executive Officer	2017	464,103	303,417	—	1,062,381	—	5,372	1,835,273
<b>Fletcher Payne</b>	2018	345,301	120,855	—	501,228	—	2,092	969,476
Chief Financial Officer	2017	335,244	152,536	—	289,351	—	2,092	779,223
<b>Howard Levy, M.B.B.Ch., Ph.D., M.M.M</b>	2018	397,838	139,230	—	658,462	—	3,317	1,198,847
Chief Medical Officer	2017	386,250	175,744	—	366,915	—	3,317	932,226

- (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 2018 and 2017 represent payment of life insurance premiums, long-term disability and other insurance-related reimbursements.

**Employment Agreements**

Each of our currently serving Named Executive Officers (each, an “NEO”) is party to an amended and restated employment agreement with us (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. In August 2018, we entered into amended and restated employment agreements with Dr. Usman, Mr. Payne and Dr. Levy. 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 during the applicable change in control protection periods; and (ii) severance without cause or as a result of constructive termination during the applicable post-change in control severance

periods. 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 \$528,900 for the fiscal year ending December 31, 2019, 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 employee benefit plans including, but not limited to, life, disability insurance, medical, dental and vision insurance, and a 401K and Section 125 Flexible Spending Accounts.

The amended and restated 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 outside of the "Change in Control Protection Period" (as defined below), he shall be entitled to receive, subject to certain conditions described in Dr. Usman's amended and restated employment agreement, the following:

- continued base salary for twelve (12) months after the termination (the "Usman Severance Period");
- accelerated vesting of options that would otherwise have vested during the Usman Severance Period; and
- payment by the Company of the same portion of his monthly premium under COBRA as it pays for active employees until the close of the Usman Severance Period.

In addition, if Dr. Usman's employment is terminated without "cause" or as a result of "constructive termination," in each case during the six (6) month period prior to or the eighteen (18) month period following a "change in control" (as defined in the Company's 2018 Omnibus Incentive Plan, as amended from time to time, the "Change in Control Protection Period"), Dr. Usman would be eligible to receive, subject to certain conditions described in Dr. Usman's amended and restated employment agreement, the following:

- severance payments, equal to the sum of (a) 150% of his annual base salary and (b) 150% of his maximum annual performance-based bonus, paid in equal installments for eighteen (18) months after the termination (the "Usman Post-COC Severance Period");
- accelerated vesting of 100% percent of any unvested options; and
- payment by the Company of the same portion of his monthly premium under COBRA as it pays for active employees until the close of the Usman Post-COC Severance Period.

### ***Fletcher Payne***

Under our amended and restated employment agreement with Mr. Fletcher Payne, our Chief Financial Officer, Mr. Payne is entitled to an annual base salary, which is \$379,200 for the fiscal year ending December 31, 2019, 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 employee benefit plans including, but not limited to, life, disability insurance, medical, dental and vision insurance, and a 401K and Section 125 Flexible Spending Accounts.

The amended and restated 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 outside of the Change in Control Protection Period, Mr. Payne would be eligible to receive, subject to certain conditions described in the amended and restated employment agreement, the following:

- continued base salary for nine (9) months after the termination (the "Payne Severance Period");
- accelerated vesting of options that would otherwise have vested during the Payne Severance Period; and
- payment by the Company of the same portion of Mr. Payne's monthly premium under COBRA as it pays for active employees until the close of the Payne Severance Period.

In addition, if Mr. Payne's employment is terminated without "cause" or as a result of "constructive termination," in each case during the Change in Control Protection Period, Mr. Payne would be eligible to receive, subject to certain conditions described in the amended and restated employment agreement, the following:

- severance payments, equal to the sum of (a) 100% of Mr. Payne's annual base salary and (b) 100% of Mr. Payne's maximum annual performance-based bonus, paid in equal installments for twelve (12) months after the termination (the "Payne Post-COC Severance Period");
- accelerated vesting of 100% percent of any unvested options; and
- payment by the Company of the same portion of Mr. Payne's monthly premium under COBRA as it pays for active employees until the close of the Payne Post-COC Severance Period.

### **Howard Levy**

Under our offer letter with Dr. Levy, our Chief Medical Officer, Dr. Levy is entitled to an annual base salary, which is \$419,500 for the fiscal year ending December 31, 2019. Dr. Levy will also have the opportunity to earn an annual performance-based bonus of 35% of his base salary. Dr. Levy is eligible for our employee benefit plans including, but not limited to, life, disability insurance, medical, dental and vision insurance, and a 401K and Section 125 Flexible Spending Accounts

The amended and restated employment 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 outside of the Change in Control Protection Period, Dr. Levy would be eligible to receive, subject to certain conditions described in the amended and restated employment agreement, the following:

- continued base salary for nine (9) months after the termination (the "Levy Severance Period");
- accelerated vesting of options that would otherwise have vested during the Levy Severance Period; and
- payment by the Company of the same portion of Dr. Levy's monthly premium under COBRA as it pays for active employees until the close of the Levy Severance Period.

In addition, if Dr. Levy’s employment is terminated without “cause” or as a result of “constructive termination,” in each case during the Change in Control Protection Period, Dr. Levy would be eligible to receive, subject to certain conditions described in the amended and restated employment agreement, the following:

- severance payments, equal to the sum of (a) 100% of Dr. Levy’s annual base salary and (b) 100% of Dr. Levy’s maximum annual performance-based bonus, paid in equal installments for twelve (12) months after the termination (the “Levy Post-COC Severance Period”);
- accelerated vesting of 100% percent of any unvested options; and
- payment by the Company of the same portion of Dr. Levy’s monthly premium under COBRA as it pays for active employees until the close of the Levy Post-COC Severance Period.

### Outstanding Equity Awards at December 31, 2018

The following table provides information regarding unexercised stock options held by each of the Named Executive Officers as of the end of fiscal year 2018.

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
	3/17/2009	(1)	4,074	—		\$ 109.95	3/17/2019
	10/22/2015	(1)	3,870	891	(2)	\$ 66.00	10/22/2025
	10/22/2015		8,322	1,916	(2)	\$ 66.00	10/22/2025
	7/11/2017		103,037	171,875	(5)	\$ 4.63	7/11/2027
	1/12/2018		21,771	73,229	(6)	\$ 15.13	1/12/2028
	7/30/2018		0	75,000	(7)	\$ 9.68	7/30/2028
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)	800	155	(3)	\$ 90.45	5/8/2025
	10/22/2015		3,870	891	(2)	\$ 66.00	10/22/2025
	10/22/2015		1,553	351	(2)	\$ 66.00	10/22/2025
	7/11/2017		28,066	46,875	(5)	\$ 4.63	7/11/2027
	1/12/2018		5,958	20,042	(6)	\$ 15.13	1/12/2028
7/30/2018		0	25,000	(7)	\$ 9.68	7/30/2028	
Howard Levy M.B.B.Ch., Ph.D., M.M.M.	4/18/2016		4,447	2219	(4)	\$ 22.80	4/18/2026
	7/11/2017		27,743	59,375	(5)	\$ 4.63	7/11/2027
	1/12/2018		7,563	25,437	(6)	\$ 15.13	1/12/2028
	7/30/2018		0	35,000	(5)	\$ 9.68	7/30/2028

- (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 1/48<sup>th</sup> 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 1/48<sup>th</sup> of the number of total shares subject to the option on the 15<sup>th</sup> day of each month, with the final tranche vesting on June 15, 2021.
- (6) The remaining portion of these options to purchase common stock vest at the rate of 1/48<sup>th</sup> of the number of total shares subject to the option on the 12<sup>th</sup> day of each month, with the final tranche vesting on January 12, 2022.
- (7) The remaining portion of these options to purchase common stock vest at the rate of 1/48<sup>th</sup> of the number of total shares subject to the option on the 13<sup>th</sup> day of each month, with the final tranche vesting on July 13, 2022.

### 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), paid quarterly as follows:

Additional annual retainer fees for service as member or chair of	<b>Member</b>	<b>Chair</b>
Board of Directors	\$ 40,000	\$ 30,000
Audit Committee	\$ 7,500	\$ 15,000
Compensation Committee	\$ 5,000	\$ 10,000
Governance and Nominating Committee	\$ 3,750	\$ -
Science and Technology Committee	\$ 3,750	\$ 7,500

Pursuant to a policy approved by our Board of Directors, each director may elect annually to receive some or all of his or her retainer service fees in the form of fully vested shares of Company common stock.

## Director Compensation for Fiscal Year 2018

The following table shows for the year ended December 31, 2018 certain information with respect to the compensation of our non-employee directors serving during 2018. For information regarding compensation paid to Dr. Usman, see the “Summary Compensation Table” on page 109.

Name	Fees Earned or Paid in Cash (\$)	Option Awards (\$)(1)(2)	Stock Grants (\$)(6)	Total (\$)
Augustine Lawlor	59,375	85,924	21,562	166,861
Andrea Hunt <sup>(3)</sup>	51,406	85,924	6,406	143,736
Eddie Williams <sup>(4)</sup>	33,125	203,656	12,187	248,968
Errol B. De Souza	39,688	85,924	13,438	139,050
Jeff Himawan, Ph.D. <sup>(5)</sup>	—	—	—	0
John P. Richard	56,562	85,924	—	142,486
Stephen A. Hill	45,312	85,924	—	131,236

(1) The amounts in this column reflect the aggregate grant date fair value of stock options granted during fiscal 2018 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 2018 as of December 31, 2018:

NAME	Aggregate Number of Option Awards
Augustine Lawlor	16,500
Andrea Hunt	15,000
Eddie Williams	15,000
Errol B. De Souza	18,328
Jeff Himawan, Ph.D.	—
John P. Richard	18,577
Stephen A. Hill	16,500

(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.

(6) The amounts in this column reflect the board of director fees board members elected to receive in fully vested non-restricted common stock awards in lieu of cash compensation.

## Compensation Committee Interlocks and Insider Participation

None of the directors who served on our Compensation Committee during 2018, 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 2018 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 8, 2019, 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 11,963,260 shares of common stock outstanding at February 8, 2019. 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 8, 2019. 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 8, 2019 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.

<b>Name</b>	<b>Number of Shares Owned and Nature of Beneficial Ownership</b>	<b>Percent of Class</b>
<b>5% or Greater Stockholders</b>		
Blackrock Fund Advisors 55 East 52nd Street, New York, NY 10055	846,529 (1)	7.08%
JFL Capital Management 2110 Ranch Road 620 S #341732, Lakeway, TX 78734	839,070 (2)	7.01%
Nantahala Capital Management LLC 19 Old Kings Highway S, Suite 200, Darien, CT 06820	855,243 (3)	7.15%
<b>Directors and Named Executive Officers</b>		
Nassim Usman, Ph.D.	161,972 (4)	*
Fletcher Payne	51,656 (5)	*
Howard Levy, M.B.B.Ch., Ph.D., M.M.M.	59,821 (6)	*
Augustine Lawlor	87,383(7)(8)	*
Andrea Hunt	9,287(9)	*
Eddie Williams	9,589(10)	*
Errol B. De Souza	19,022(11)	*
Jeff Himawan, Ph.D.	81,762(12)	*
John P. Richard	17,543 (13)	*
Stephen A. Hill, M.D.	16,630 (14)	*
<b>All Directors and Executive Officers as a Group (10 persons)</b>	<b>514,661 (15)</b>	<b>3.79%</b>

\* Indicates less than 1% of class.

- (1) The information reported is based on a Schedule 13G filed with the SEC on December 31, 2018.
- (2) The information reported is based on a Schedule 13G filed with the SEC on February 11, 2019.
- (3) The information reported is based on a Schedule 13G filed with the SEC on February 14, 2019.
- (4) Consists of (i) 4,056 shares and one 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) 1,168 shares held in IRA, (iii) 6,167 shares and (iv) 150,580 shares issuable upon the exercise of options within 60 days.
- (5) Consists of (i) 501 shares held by Charles and Nancy Payne 2000 Trust, of which Mr. Payne is a trustee, (ii) 666 shares held in IRA, (iii) 2,564 shares held directly, and (iii) 47,925 shares issuable upon the exercise of options within 60 days.
- (6) Consists of (i) 11,694 shares held directly and (ii) 48,127 shares issuable upon the exercise of options within 60 days.
- (7) Consists of (i) 2,732 shares held directly and (ii) 15,250 shares issuable upon the exercise of options within 60 days.
- (8) Consists of 69,401 shares owned by Healthcare Ventures VIII, L.P. (“HCVVIII”), which was based upon information, as of November 30, 2018, supplied by our transfer agent, American Stock Transfer & Trust Company, LLC. 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 (“HCPVIII LLC”), the general partner of HealthCare Partners VIII, L.P. (“HCPVIII”), which is the general partner of HCVVIII.
- (9) Consists of 8,472 shares issuable upon the exercise of options within 60 days.
- (10) Consists of (i) 1,672 shares and (ii) 7,917 shares issuable upon the exercise of options within 60 days.
- (11) Consists of (i) 1,944 shares, and (ii) 17,078 shares issuable upon the exercise of options within 60 days.
- (12) The information reported is based upon report, as of January 3, 2019, supplied by our transfer agent, American Stock Transfer & Trust Company, LLC. 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 81,762 shares comprising of (i) 78,622 shares and (ii) 3,140 shares that may be purchased upon the exercise of warrants within 60 days. Essex VIII LLC disclaims beneficial ownership to 81,762 shares comprising of (i) 78,622 shares and (ii) 3,140 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 81,762 shares comprising of (i) 78,622 shares and (ii) 3,140 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.
- (13) Consists of (i) 216 shares, and (ii) 17,327 shares issuable upon the exercise of options within 60 days.
- (14) Consists of (i) 1,380 shares, and (ii) 15,250 shares issuable upon the exercise of options within 60 days.
- (15) Includes (i) 35,571 shares, and (ii) 327,926 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. 2018 Equity Incentive Plan (as adopted on June 13, 2018) (the "2018 Plan"), 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, 2018 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 <sup>(1)</sup>	1,340,729	\$ 10.68	1,295,144
Equity compensation plans not approved by security holders <sup>(2)</sup>	21,248	\$ 97.70	—
<b>Total</b>	<b>1,361,977</b>	<b>\$ 12.04</b>	<b>1,295,144</b>

(1) Includes shares issued or issuable upon the exercise of stock option, restricted stock or other stock-based awards under the 2018 Plan, the 2015 Plan, and 2006 Plan.

(2) Includes options to purchase 12,214 shares, at a weighted average exercise price of \$137.26, 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 8, 2019, the maximum aggregate number of shares available for future grants under all the Company-administered equity compensation plans was 1,049,176 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 1,599,213 shares. The weighted average exercise price of these options was \$11.47, and the weighted average remaining term was 8.711 years as of December 31, 2018. On February 8, 2019, the closing sales price of the common stock as reported on Nasdaq was \$8.29 per share.

**Item 13. CERTAIN RELATIONSHIPS, RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE**

Described below are the transactions and series of similar transactions since January 1, 2017 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 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. On December 21, 2018, we amended our collaboration agreement with Mosaic to, among other things, include certain additional products. According to the Mosaic collaboration agreement, as amended, 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, 2018 and 2017 and for other services rendered by EisnerAmper LLP during those periods. All fees described below were approved by the audit committee.

	Fiscal 2018	Fiscal 2017
Audit Fees(1):	\$ 339,600	\$ 282,974
Audit-Related Fees:	—	—
Tax Fees:	—	—
All Other Fees:	—	—
Total Fees:	\$ 339,600	\$ 282,974

(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.

**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

<u>Exhibit Number</u>	<u>Description</u>
2.1(a)	<a href="#">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)</a>
2.1(b)	<a href="#">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)</a>
2.1(c)	<a href="#">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)</a>
3.1	<a href="#">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)</a>
3.2	<a href="#">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)</a>
3.3	<a href="#">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)</a>
3.4	<a href="#">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)</a>
3.5	<a href="#">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)</a>
4.1	<a href="#">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)</a>
4.3	<a href="#">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)</a>
4.4	<a href="#">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)</a>
4.5	<a href="#">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)</a>
4.6	<a href="#">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)</a>
4.7	<a href="#">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)</a>
4.8	<a href="#">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)</a>
4.9	<a href="#">Form of Indenture (incorporated by reference to Exhibit 4.5 to the Company's Form S-3 (Reg. No. 333-228970), as filed with the SEC on December 21, 2018)</a>
10.1**	<a href="#">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)</a>
10.2**	<a href="#">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)</a>

<u>Exhibit Number</u>	<u>Description</u>
10.3**	<a href="#">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)</a>
10.4**	<a href="#">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)</a>
10.5**	<a href="#">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)</a>
10.6**	<a href="#">Catalyst Biosciences, Inc. 2018 Omnibus Incentive Plan (incorporated by reference to Appendix A of the definitive proxy statement for the Annual Meeting filed by the Company on May 11, 2018)</a>
10.7**	<a href="#">Catalyst Biosciences, Inc. 2018 Employee Stock Purchase Plan (incorporated by reference to Appendix B of the definitive proxy statement for the Annual Meeting filed by the Company on May 11, 2018)</a>
10.8**	<a href="#">Form of Stock Option Award Agreement (incorporated by reference to Appendix C of the definitive proxy statement for the Annual Meeting filed by the Company on May 11, 2018)</a>
10.9**	<a href="#">Amended and Restated Employment Agreement, dated as of August 28, 2018, 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 August 31, 2018)</a>
10.10**	<a href="#">Amended and Restated Employment Agreement, dated as of August 30, 2018, by and between Catalyst Biosciences, Inc. and Fletcher Payne (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, as filed with the SEC on August 31, 2018)</a>
10.11**	<a href="#">Amended and Restated Employment Agreement, dated as of August 29, 2018, by and between Catalyst Biosciences, Inc. and Dr. Howard Levy, M.B.B.Ch., Ph.D., M.M.M. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on August 31, 2018)</a>
10.12**	<a href="#">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))</a>
10.13**	<a href="#">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)</a>
10.14**	<a href="#">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)</a>
10.15(a)**	<a href="#">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)</a>
10.15(b)**	<a href="#">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)</a>
10.15(c)**	<a href="#">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)</a>
10.16(a)+	<a href="#">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)</a>
10.16(b)+	<a href="#">Amended and Restated License Agreement, dated December 13, 2018, by and between Catalyst and ISU Abxis</a>
10.17+	<a href="#">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)</a>
10.18+	<a href="#">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)</a>
10.19	<a href="#">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)</a>

<u>Exhibit Number</u>	<u>Description</u>
10.20	<a href="#">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)</a>
10.21(a)	<a href="#">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)</a>
10.21(b)	<a href="#">First Amendment to Office Lease, dated as of August 9, 2018, 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 October 15, 2018.)</a>
21.1	<a href="#">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)</a>
23.1*	<a href="#">Consent of EisnerAmper LLP, Independent Registered Public Accounting Firm</a>
24.1	<a href="#">Power of Attorney (included as part of the signature pages hereto)</a>
31.1*	<a href="#">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</a>
31.2*	<a href="#">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</a>
32.1*	<a href="#">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</a>
32.2*	<a href="#">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</a>
101	The following materials from the Company's Annual Report on Form 10-K for the year ended December 31, 2018, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets as of December 31, 2018 and December 31, 2017; (ii) the Consolidated Statement of Operations for the years ended December 31, 2018, 2017 and 2016; (iii) the Consolidated Statements of Comprehensive Income for the years ended December 31, 2018, 2017 and 2016; (iv) the Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit as of December 31, 2018; (v) the Consolidated Statements of Cash Flows for the twelve months ended December 31, 2018, 2017 and 2016; 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.



Confidential treatment has been sought for portions of this agreement. The copy filed herewithin omits the information subject to the confidential treatment request. Omissions are designated as \*\*\*. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

### AMENDED AND RESTATED LICENSE AGREEMENT

This Amended and Restated License Agreement (this “**Agreement**”) is made as of December 17, 2018 (the “**Effective Date**”) by and between Catalyst Biosciences, Inc., a Delaware corporation having a principal place of business at 611 Gateway Blvd., Suite 710, South San Francisco, CA 94080 (“**Catalyst**”), and ISU Abxis, a Korean corporation having a principal place of business at Pangyo Global R&D Center, C Bldg, 5th Floor, 22 Daewangpangyo-ro, 712 beon-gil, Bundang-gu, Seongnam-si, Gyenggi-do, 13488, Korea (“**ISU**”). ISU and Catalyst may each be referred to as a “**Party**” or collectively be referred to as the “**Parties**”.

**WHEREAS**, Catalyst and ISU entered into that certain License and Collaboration Agreement on September 16, 2013 (the “**Prior Agreement**”), as amended, wherein Catalyst licensed to ISU certain technology relating to human Factor IX (“**FIX**”) for the purpose of conducting Phase 1 clinical trials.

**WHEREAS**, the Parties have worked collaboratively on the initial clinical and manufacturing development of Catalyst’s FIX variant Dalcinacog Alpha (“**DalcA**”, formerly known as CB 2679d/ISU304).

**WHEREAS**, Catalyst and ISU wish to amend and restate the terms of the Prior Agreement to reflect the Parties’ expectations for roles and responsibilities for the development and commercialization of DalcA and to revise the financial obligations of the Parties as set forth herein.

**NOW, THEREFORE**, in consideration of the mutual promises and covenants contained herein, the Parties hereby agree as follows:

### ARTICLE 1 DEFINITIONS

The terms in this Agreement with initial letters capitalized, whether used in the singular or the plural, shall have the meaning set forth below or, if not listed below, the meaning designated elsewhere in this Agreement (and derivative forms of them shall be interpreted accordingly). The terms “include,” “includes,” “including” and derivative forms of them shall be deemed followed by the phrase “without limitation” regardless of whether such phrase appears there (and with no implication being drawn from its inconsistent inclusion or non-inclusion).

“**Affiliate**” means, with respect to a Person, any Person that controls, is controlled by or is under common control with such first Person. For purposes of this definition only, “control” means (a) to possess, directly or indirectly, the power to direct the management or policies of a Person, whether through ownership of voting securities, by contract relating to voting rights or corporate governance or otherwise, or (b) to own, directly or indirectly, fifty percent (50%) or more of the outstanding securities or other ownership interest of such Person. For the purposes of

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**Confidential treatment has been sought for portions of this agreement. The copy filed herewithin omits the information subject to the confidential treatment request. Omissions are designated as \*\*\*. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.**

this Agreement, neither Party shall be considered an Affiliate of the other, and the Affiliates of each Party shall not be considered Affiliates of the other Party or of any of such other Party's Affiliates.

**“Back-Up Compound”** [\* \* \*].

**“Catalyst Know-How”** means [\* \* \*]. Catalyst Patent Rights do not include Catalyst Know-How.

**“Catalyst Technology”** means the Catalyst Know-How and the Catalyst Patent Rights.

**“Clinically Develop” or “Clinical Development”** means all development activities which are directed to the preparation for, conduct of, and analysis of a clinical trial or study of the Product that relate to obtaining, maintaining or expanding Regulatory Approval of a Product, including, without limitation, as applicable, non-clinical testing, toxicology, the examination of particular patient sub-populations within a given indication, and regulatory affairs (including preparation of Regulatory Filings).

**“Commercialize”** means to market, promote, sell, offer for sale and/or distribute.

**“Confidential Information”** means (a) all information disclosed directly or indirectly in writing, orally or by inspection of facilities or tangible objects (including without limitation any technical information, business plan, trade secret, know-how, idea, invention, process, technique, design, schematic, drawing, formula, chemical structure, nucleic acid or amino acid sequence, pre-clinical data, clinical data, other data, plan, strategy, or forecast), that (i) if in written or other tangible form, is marked or labeled as “Confidential” or with a similar legend sufficient to notify the receiving party that such information is Confidential Information, or (ii) if disclosed orally, is identified as “Confidential” by the disclosing party at the time of disclosure, and confirmed in writing as confidential within [\* \* \*] after such oral disclosure and (b) the terms and conditions of this Agreement.

**“Control”** means, with respect to any particular Know-How or Patent, that a Party (a) owns or (b) has a license (other than a license granted to such Party under this Agreement) to such Know-How or Patent and, in each case, has the ability to grant to the other Party access, a license, or a sublicense (as applicable) to the Know-How or Patent on the terms and conditions set forth in this Agreement without violating the terms of any then-existing agreement or other arrangement with any Third Party.

**“DalcA”** has the meaning given in the recitals.

**“Dollar”** or **“\$”** means a US dollar.

**“Enabled Cell Lines”** [\* \* \*].

**“Executive Officer”** means, with respect to Catalyst, its Chief Executive Officer, and with respect to ISU, its Chief Executive Officer.

**Confidential treatment has been sought for portions of this agreement. The copy filed herewithin omits the information subject to the confidential treatment request. Omissions are designated as \*\*\*. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.**

“**Field**” means the treatment or prevention of all human diseases and/or therapeutic indications.

“**First Commercial Sale**” means, with respect to a Product, [\* \* \*].

“**Governmental Authority**” means any multi-national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

“**IND**” means (a) an Investigational New Drug Application as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA, or (b) the equivalent application to the equivalent agency in any other regulatory jurisdiction, the filing of which is necessary to initiate or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.

“**Inventions**” means any and all inventions conceived or reduced to practice by or on behalf of either Party or its Affiliates or sublicensees in the course of activities performed under the terms of this Agreement or contemplated by this Agreement.

“**Information**” means ideas, inventions, discoveries, concepts, formulas, practices, procedures, processes, methods, knowledge, know-how, trade secrets, technology, designs, drawings, computer programs, skill, experience, documents, results, clinical and regulatory strategies, test data, including without limitation pharmacological, toxicological, non-clinical and clinical data, analytical and quality control data, manufacturing data and descriptions, Regulatory Materials, Patent and legal data, market data, financial data or descriptions, assay protocols, specifications, and the like, in written, electronic or other form, now known or hereafter developed, whether or not patentable.

“**ISU Know-How**” means all Know-How Controlled by ISU as of the Effective Date that is [\* \* \*].

“**ISU Patent Rights**” means [\* \* \*]. ISU Patent Rights do not include ISU Know-How.

“**ISU Technology**” means the ISU Know-How and the ISU Patents.

“**Know-How**” means all technical information and know-how, including inventions, discoveries, trade secrets, specifications, instructions, processes, formulae, expertise, materials, methods, protocols and other technology applicable to formulations, compositions or products or to their manufacture, development, registration, use or marketing or processes for their manufacture, formulations containing them or compositions incorporating or comprising them, and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, preclinical and clinical data, instructions, processes, formula, and expertise.

“**Korea**” means the Republic of Korea.

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“**Laws**” means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign.

“**Manufacture**” or “**Manufacturing**” means all manufacturing activities undertaken in support of clinical and commercial supply of Product, including without limitation assembly, sterilization, packaging, labeling, quality control and quality assurance, whether performed directly by a Party or indirectly through an Affiliate or Third Party.

“**Manufacturing Development**” means all development activities which are directed to the Manufacturing of the Product, including, without limitation, [ \* \* \* ].

“**Major Market Country**” means [ \* \* \* ].

“**NDA**” means a New Drug Application, as defined in the US Federal Food, Drug and Cosmetic Act, as amended, and applicable regulations promulgated thereunder by the FDA, and the equivalent application to the equivalent Regulatory Authority in any other regulatory jurisdiction.

“**Net Sales**” means, with respect to any Product, the gross amounts invoiced by Catalyst or its Affiliates, licensees or sublicensees for the sale, transfer or commercial disposition of Product to unaffiliated Third Parties, less the following deductions to the extent reasonable and customary with respect to such sale, transfer or commercial disposition:

- (a) reasonable cash, trade or quantity discounts, charge-back payments, and rebates actually granted to trade customers, managed health care organizations, pharmaceutical benefit managers, group purchasing organizations and national, state, or local government;
- (b) credits, rebates or allowances actually allowed upon prompt payment or on account of claims, damaged goods, rejections or returns of such Product, including in connection with recalls;
- (c) freight, postage, shipping, transportation and insurance charges, in each case actually allowed or paid for delivery of such Product, to the extent included in such invoice; and
- (d) taxes (other than income taxes), duties, tariffs or other governmental charges levied on the sale of such Product, including VAT, exercises taxes and sales taxes, to the extent included in such invoice.

“**Patents**” means, collectively, (a) pending patent applications (and patents issuing therefrom), issued patents, utility models and designs; and (b) reissues, substitutions, confirmations, renewals, extensions, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, divisionals, or any

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Supplementary Protection Certificates or restoration of patent terms of or to any patents, patent applications, utility models or designs, in each case being enforceable within the applicable territory.

“**Person**” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

“**Phase 3 Trial**” means a human clinical trial of a Product on a sufficient number of subjects that is designed to establish that a pharmaceutical product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with such pharmaceutical product in the dosage range to be prescribed, which clinical trial is intended to support Regulatory Approval of such Product, as described in 21 C.F.R. 312.21(c) (as amended or any replacement thereof), or a similar clinical study prescribed by the Regulatory Authorities in the Territory.

“**Pre-Clinical Development**” means all *in vitro* and *in vivo* animal testing, toxicology, or other studies or tests of a Product, including without limitations those studies, trials or tests necessary or useful to support an IND.

“**Product**” means DalcA or any Back-Up Compound.

“**Regulatory Approval**” means all approvals necessary for the commercial sale of a Product in the Field in a given country or regulatory jurisdiction, which may include satisfaction of all applicable regulatory and notification requirements, and shall be deemed to include any stockpiling by any Governmental Authority for civilian or military use, but shall exclude any pricing and reimbursement approvals.

“**Regulatory Authority**” means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction.

“**Territory**” means the entire world except Korea.

“**Third Party**” means any Person not including the Parties or the Parties’ respective Affiliates.

## **ARTICLE 2 LICENSES**

**2.1 License to ISU.** Subject to the terms and conditions of this Agreement, Catalyst hereby grants to ISU an exclusive, sublicensable, fully-paid up, royalty-free license, under the Catalyst Technology, to Commercialize Products in the Field in Korea. ISU shall not, and shall not permit any of its Affiliates to, use or practice any Catalyst Technology outside the scope of the license granted to it under this Section 2.1. For clarity, ISU and its Affiliates and

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sublicensees shall not have the right to Manufacture any Product or to export any Product to any territory outside of Korea.

**2.2 License to Catalyst.** Subject to the terms and conditions of this Agreement, ISU hereby grants to Catalyst an exclusive, sublicenseable (through multiple tiers), royalty-bearing license, under the ISU Technology, to conduct Clinical Development and to Commercialize Products in the Field in the Territory, and to conduct Manufacturing Development and Manufacturing of Products in the Field worldwide, provided that neither Catalyst nor any sublicensee shall have any right to Commercialize any Product in Korea. Catalyst shall not and shall not permit any of its Affiliates or sublicensees to use or practice any ISU Technology outside the scope of the license granted to it under this Section 2.2. For clarity, neither Catalyst nor any Affiliate or sublicensee shall export any Product Manufactured in the Territory to Korea.

**2.3 Retained Rights.** Except as explicitly set forth in this Agreement, neither Party shall be deemed by estoppel or implication to have granted the other Party any other licenses or other rights to any intellectual property.

### **ARTICLE 3 INFORMATION EXCHANGE**

**3.1 Abolition of Committees.** The Joint Steering Committee (“JSC”) and Joint Licensing Committee (“JLC”) from the Prior Agreement are hereby disbanded.

#### **3.2 Information Sharing.**

**(a) Information from Catalyst.** Beginning June 30, 2019, and until Catalyst [ \* \* \* ], Catalyst will provide ISU with a written update regarding Clinical Development of DalcA. Such written updates will be Catalyst Confidential Information. In addition, upon ISU’s reasonable request for the purpose of obtaining Regulatory Approval of a Product in Korea, Catalyst will provide [ \* \* \* ], with copies of any studies or other information in Catalyst’s possession that is reasonably related to obtaining such Regulatory Approval, provided that Catalyst shall provide such information in the language and form that Catalyst possesses it, and ISU shall be responsible for any required translation or reformatting, at ISU’s expense.

**(b) Information from ISU.** Beginning June 30, 2019, [ \* \* \* ], ISU will provide Catalyst a written update regarding its Commercialization of DalcA.

### **ARTICLE 4 DEVELOPMENT AND COMMERCIALIZATION**

**4.1 Development by Catalyst.** Catalyst shall be responsible for Clinical Development and Commercialization of the Product in the Territory and for Manufacturing Development and Manufacturing of the Product worldwide. If Catalyst, in its sole discretion,

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elects to develop one or more Back-Up Compounds, then Catalyst will have sole control over the Pre-Clinical Development of such Back-Up Compound.

**4.2 Development by ISU.** ISU shall use commercially reasonable efforts and shall be responsible for obtaining, maintaining or expanding Regulatory Approval of and Commercialization of Products in Korea. If obtaining Regulatory Approval in Korea would require any Product testing, including clinical trials, that Catalyst has not completed, then ISU shall notify Catalyst of the requirement for such testing and, upon ISU's reasonable request and at ISU's expense, Catalyst will either conduct or arrange for a Third Party to conduct such additional testing or consent to allow ISU to conduct such testing. For clarity, ISU shall not conduct any testing of any Product, directly or indirectly, itself or through any Third Party, without Catalyst's prior written consent. If reasonably requested by ISU, the Parties shall discuss entering into a manufacturing and commercial supply agreement on commercially reasonable terms pursuant to which Catalyst (or its sublicensee) would manufacture and supply to ISU Product for Commercialization in Korea.

## ARTICLE 5 REGULATORY MATTERS

**5.1 Regulatory Activities.** Catalyst shall be responsible for submitting the INDs and NDAs for all indications for the Product in the Territory, and ISU shall be responsible for submitting any INDs and NDAs for all indications for the Product in Korea, provided that ISU shall (a) promptly deliver to Catalyst all material correspondence regarding any Product received from the Ministry of Food and Drug Safety ("MFDS"), (b) consult with Catalyst regarding the responses to any such correspondence or with respect to any anticipated material filings or submissions to MFDS and (c) allow Catalyst to participate in any in-person meetings with MFDS regarding any Product. As between the Parties, Catalyst shall own all right, title and interest in all INDs and other regulatory filings designed to obtain or support Regulatory Approval in the Territory, and ISU shall own all right, title and interest in all INDs and other regulatory filings designed to obtain or support Regulatory Approval in Korea.

**5.2 Notification of Threatened Action.** Each Party shall [\* \* \*] notify the other Party of any information it receives regarding any threatened or pending action, inspection or communication by or from any Third Party, including a Regulatory Authority, which may materially affect the Development, Commercialization or regulatory status of a Product. Catalyst shall have final decision-making authority except for matters specifically related to Korea.

**5.3 Adverse Event Reporting and Safety Data Exchange.** No later than [\* \* \*] after the filing of the first NDA for the Product, Catalyst or Catalyst's sublicensee(s) (if applicable) and ISU shall enter into a commercially reasonable pharmacovigilance agreement (the "**Pharmacovigilance Agreement**"). The Pharmacovigilance Agreement shall include customary guidelines and procedures for the receipt, investigation, recordation, communication, and exchange (as between the Parties) of adverse event reports, pregnancy reports, and any other information concerning the safety of any Product. Such guidelines and procedures shall be in accordance with, and enable the Parties to fulfill, local and national regulatory reporting

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obligations under applicable Laws. Furthermore, such agreed procedure shall be consistent with relevant guidelines of the International Conference on Harmonisation, except where such guidelines may conflict with existing local regulatory reporting or safety reporting requirements, in which case the local reporting requirements shall prevail. The Pharmacovigilance Agreement shall provide for an adverse event database for Products in the Territory to be maintained by Catalyst at its expense. Catalyst shall be responsible for reporting quality complaints, adverse events and safety data related to Products to applicable Regulatory Authorities in the Territory, as well as responding to safety issues and to all requests of Regulatory Authorities relating to Products in the Territory. Each Party hereby agrees to comply with its respective obligations under such Pharmacovigilance Agreement and to cause its Affiliates and sublicensees to comply with such obligations.

**5.4 Remedial Actions.** If ISU has commenced Commercialization of a Product in Korea, each Party shall notify the other Party immediately, and promptly confirm such notice in writing, if it obtains information indicating that any Product may be subject to any recall, corrective action or other regulatory action with respect to a Product taken by virtue of applicable Laws in any part of the world (a “**Remedial Action**”). The Parties shall assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. Each Party shall, and shall ensure that its Affiliates and sublicensees will, maintain adequate records to permit the Parties to trace the distribution and use of the Products. Catalyst or its sublicensee, as applicable, shall have the right to decide whether any Remedial Action with respect to Products in the Field and in the Territory should be commenced and Catalyst or its sublicensee, as applicable, shall have the obligation, at its expense, to control and coordinate all efforts necessary to conduct such Remedial Action for the Field and in the Territory, [\*\*\*],=.

## **ARTICLE 6 MATERIAL TRANSFER**

**6.1 Material Transfer; Further Assurances.** ISU shall complete the activities and transfer the materials mentioned in Exhibit A in good faith within [\*\*\*] of the Effective Date, or as otherwise stated in Exhibit A. The list of detailed materials shall be determined by agreement between Parties based on the Exhibit A. The transfer of all materials on Exhibit A shall be at [\*\*\*] expense. Catalyst shall have the right, at its own expense, to audit ISU’s facilities and records to confirm completion of such activities and transfer, and ISU shall provide reasonable cooperation with respect to such audit. ISU’s obligations to complete the activities and transfer materials under this Section 6.1 are material obligations under this Agreement. Following completion of the activities and transfer of materials set forth on Exhibit A, if reasonably requested by Catalyst, ISU agrees to provide incidental support reasonably requested by Catalyst and to reasonably negotiate in good faith with Catalyst regarding the provision of any additional support required for the Development and Commercialization of Products at [\*\*\*] expense.

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**ARTICLE 7  
COMPENSATION**

**7.1 Regulatory and Development Milestone Payments.**

(a) **DalCA Milestone Payments.** Catalyst shall make each of the following non-refundable, non-creditable milestone payments to ISU upon the achievement of the following milestone events with respect to DalCA. Catalyst shall pay to ISU each such amount within [\*\*\*].

Milestone Event for DalCA	Milestone Payment
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

[\*\*\*]

If more than one milestone occurs within a single year, [\*\*\*].

(b) **Back-Up Compound Milestone Payments.** Catalyst shall make each of the following non-refundable, non-creditable milestone payments to ISU upon the first achievement of the following milestone events with respect to any Back-Up Compounds. [\*\*\*].

Milestone Event for Back-Up Compounds	Milestone Payment
[***]	[***]
[***]	[***]

(c)

(d) During the Royalty Term, on a country-by-country basis, Catalyst shall pay to ISU [\*\*\*].

**7.2 Royalty Reports and Payments.** Within [\*\*\*] following the end of each calendar quarter, commencing with the calendar quarter in which the First Commercial Sale of any Product is made anywhere in the Territory, Catalyst shall provide ISU with a written report containing the following information for the applicable calendar quarter, on a country-by-country and Product-by-Product basis: (i) the amount of gross sales of Product in the Territory, (ii) a calculation of the royalty payment due on such Net Sales, and (iii) the exchange rate for such country. Concurrent with the delivery of the applicable quarterly report, Catalyst shall pay in Dollars all amounts due to ISU pursuant to Section 7.1 with respect to Net Sales by Catalyst or its

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Affiliates for such calendar quarter. Catalyst will be required to provide the above report on a quarterly basis, regardless of the amount and/or level of sales in a particular quarter.

**7.3 Royalty Term.** Royalties under Section 7.1(c) shall be due during the period of time beginning, on a country-by-country basis, from the First Commercial Sale of a Product in such country [\* \* \*] the First Commercial Sale of a Product in such country (the “**Royalty Term**”).

**7.4 Foreign Exchange.** The rate of exchange to be used in computing the amount of Net Sales invoiced in other currencies shall be made at the [\* \* \*].

**7.5 Payment Method; Late Payments.** All payments due to either Party hereunder shall be made in Dollars by wire transfer of immediately available funds into ISU’s account in the Korea designated by such Party. If a Party does not receive payment of any sum due to it on or before the due date, simple interest shall thereafter accrue on the sum due until the [\* \* \*].

**7.6 Records.** Catalyst and its Affiliates and licensees and sublicensees shall maintain complete and accurate records in sufficient detail to permit ISU to confirm the accuracy of the calculation of royalty payments and/or Sublicensing Income payments. ISU shall have the right to audit such records in accordance with Section 7.6.

**7.7 Audits.** For a period of [\* \* \*] from the end of the calendar year in which a payment was due hereunder, upon [\* \* \*] days prior notice, each Party (the “**Audited Party**”) shall (and shall require that its Affiliates) make such records relating to such payment available, during regular business hours and not more often than once [\* \* \*], for examination by an independent certified public accountant selected by the other Party (the “**Auditing Party**”) and reasonably acceptable to the Audited Party, for the purposes of verifying compliance with this Agreement and the accuracy of the financial reports and/or invoices furnished pursuant to this Agreement. The results of any such audit shall be shared by the auditor with both Parties and shall be considered Confidential Information of both Parties. Any amounts shown to be owed by either Party to the other shall be paid [\* \* \*] from the auditor’s report, plus interest (as set forth in Section 7.4) from the original due date. The Auditing Party shall bear the full cost of such audit unless such audit discloses a deficiency in the Audited Party’s payments of greater than [\* \* \*], in which case the Audited Party shall bear the full cost of such audit.

**7.8 Taxes.**

**(a) Taxes on Income.** Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the efforts of the Parties under this Agreement.

**(b) Tax Cooperation.** The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by one Party to the other under this

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Agreement. To the extent either Party is required to deduct and withhold taxes on any payment to the other Party, such Party (the **“Paying Party”**) shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to the other Party (the **“Receiving Party”**) an official tax certificate or other evidence of such withholding sufficient to enable Receiving Party to claim such payment of taxes. The Receiving Party shall provide Paying Party any tax forms that may be reasonably necessary in order for Paying Party not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable Laws, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax.

## **ARTICLE 8 INTELLECTUAL PROPERTY MATTERS**

**8.1 Disclosure.** Each Party shall promptly disclose to the other Party any Inventions that it or its Affiliates or sublicensees or their employees, independent contractors, or agents solely or jointly make, conceive, reduce to practice, or otherwise discover.

### **8.2 Ownership of Inventions.**

**(a) Sole Inventions.** As between the Parties, [\* \* \*].

**(b) Joint Ownership.** Except as expressly provided in this Agreement, it is understood that neither Party will have any obligation to obtain any approval or consent of, nor pay a share of the proceeds to or account to, the other Party to practice, enforce, license, assign or otherwise exploit Inventions or intellectual property owned jointly by the Parties hereunder, and each Party hereby waives any right it may have under the laws of any jurisdiction to require such approval, consent or accounting. Each Party agrees to cooperate with the other Party, as reasonably requested, and to take such actions as may be required to give effect to this Section 8.2(b) in a particular country, including by promptly executing and recording assignments and other documents consistent with such ownership. [\* \* \*].

### **8.3 Prosecution of Patents.**

**(a) Catalyst Prosecuted Patents.** Catalyst shall have the sole right to prepare, file, prosecute and maintain the Patents claiming Inventions in the Territory, [\* \* \*] Catalyst shall provide ISU with a written update regarding the status of Patents claiming Inventions in the Territory.

**(b) ISU Prosecuted Patents.** ISU shall have the sole right to prepare, file, prosecute and maintain the Patents claiming Inventions in Korea, provided that ISU shall provide Catalyst with copies of any material correspondence from the Korean Intellectual Property Office promptly following receipt, and with copies of any material submissions to the Korean Intellectual Property Office [\* \* \*] prior to submission, and with respect to such submissions, will incorporate

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Catalyst's reasonable comments. Upon reasonable request but no more than once per year, ISU shall provide Catalyst with a written update regarding the status of Patents claiming Inventions in Korea.

(c) **Cooperation.** Each Party shall provide the other Party all reasonable assistance and cooperation, at the other Party's request and expense, in the patent prosecution efforts provide above in this Section 8.3, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

#### **8.4 Enforcement of Product Patents.**

(a) **Notification.** If either Party becomes aware of any existing or threatened infringement of any Catalyst Patent Rights or ISU Patent Rights relating to the Products (collectively the "**Product Patents**") in the Territory, which infringing activity involves the using, making, importing, offering for sale or selling Products or a competitive product or otherwise adversely affects or is reasonably expected to adversely affect the Commercialization of any Product in the Territory, it shall promptly notify the other Party in writing to that effect and the Parties shall consult with each other regarding any actions to be taken with respect to such infringement.

(b) **Actions Controlled by [\*\*\*].** [\*\*\*] shall have the first right, but not the obligation, to bring an appropriate suit or take other action against any Third Party engaged in any infringement of the Product Patents in the Territory, [\*\*\*].

(c) **Actions Controlled by [\*\*\*].** [\*\*\*] shall have the first right, but not the obligation to bring an appropriate suit or take other action against any Third Party engaged in any infringement of the Product Patents in Korea, [\*\*\*]. Notwithstanding the foregoing, if [\*\*\*] any infringement of the Product Patents in Korea by a Third Party, [\*\*\*] has not obtained a discontinuance of infringement of the Product Patents, filed suit against any such Third Party infringer of the Product Patents, or provided [\*\*\*] with information and arguments demonstrating to [\*\*\*] reasonable satisfaction that there is insufficient basis for the allegation of such infringement of the Product Patents, then [\*\*\*] shall have the right, but not the obligation, to bring suit against such Third Party infringer of the Product Patents at [\*\*\*] sole expense, and [\*\*\*] shall take all actions reasonably requested in connection therewith, including being joined as a Party to any such action. Any recovery of damages or otherwise in connection with such suit or action shall be allocated first to the reimbursement of any expenses incurred by the Parties in such suit or action (including, for this purpose, a reasonable allocation of expenses of internal counsel), and any remaining amounts shall be retained by the Party that commenced such action, unless otherwise agreed by the Parties.

(d) **Collaboration.** Each Party shall provide to the enforcing Party reasonable assistance in such enforcement, at such enforcing Party's request and expense, including joining such action as a party plaintiff if required by applicable Laws to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts, shall reasonably consider the other Party's comments on any such efforts, provided the

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enforcing Party shall have all decision-making authority with respect to all aspects of such enforcement, including determination of litigation strategy and filing of material papers to the competent court. The non-enforcing Party shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the enforcing Party.

**8.5 Patents Licensed From Third Parties.** Each Party's rights under this Article 8 with respect to the prosecution, maintenance and enforcement of any [\* \* \*] that is licensed by [\* \* \*] from a Third Party shall be subject to the rights of such Third Party to prosecute, maintain and enforce such Patent.

**8.6 Patent Marking.** Catalyst and its Affiliates and sublicensees shall mark each Product marketed and sold by Catalyst or its Affiliates or sublicensees hereunder with appropriate patent numbers or indicia; provided, however, that Catalyst shall only be required to so mark such Product to the extent such markings or such notices would affect recoveries of damages or equitable remedies available under applicable Laws with respect to infringement of Patents in the Territory.

**8.7 Trademarks.** Catalyst shall have the right to brand the Products in the Territory using trademarks and trade names it determines appropriate for the Products, which may vary by country or within a country. ISU shall have the right to brand the Products in Korea using trademarks and trade names it determines appropriate, provided that ISU shall provide Catalyst written notice at least six (6) months prior to using any such trademark or trade name and shall reasonably consider any comments provided by Catalyst with respect thereto.

## **ARTICLE 9 REPRESENTATIONS AND WARRANTIES; COVENANTS**

**9.1 Mutual Representations and Warranties.** Each Party hereby represents and warrants to the other Party as follows:

**(a) Corporate Existence.** As of the Effective Date, it is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it is incorporated.

**(b) Corporate Power, Authority and Binding Agreement.** As of the Effective Date or the date of any required approval by its shareholders, (i) it has the power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder; (ii) it has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid and binding obligation of such Party that is enforceable against it in accordance with its terms.

**(c) No Conflict.** The execution and delivery of this Agreement and the performance of such Party's obligations hereunder do not, in any material respect, conflict with,

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violate, or breach or constitute a default or require any consent that has not been obtained under any contractual obligation or court or administrative order by which such Party is bound.

(d) **Title; Encumbrances.** [\*\*\*] to grant the licenses to the other Party as purported to be granted pursuant to this Agreement;

(e) **No Proceeding.** [\*\*\*].

(f) **Patents.** [\*\*\*].

## 9.2 Mutual Covenants.

(a) **No Debarment.** In the course of the Development of the Product, each Party shall not use any employee or consultant who has been debarred by any Regulatory Authority, or, to such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority. Each Party shall notify the other Party promptly upon becoming aware that any of its employees or consultants has been debarred or is the subject of debarment proceedings by any Regulatory Authority.

(b) **Compliance.** Each Party and its Affiliates shall comply in all material respects with all applicable Laws in the Development and Commercialization of Products and performance of its obligations under this Agreement, including the statutes, regulations and written directives of the FDA, the EMA and any Regulatory Authority having jurisdiction in the Territory, the FD&C Act, the Prescription Drug Marketing Act, the Federal Health Care Programs Anti-Kickback Law, 42 USAC. 1320a-7b(b), the statutes, regulations and written directives of Medicare, Medicaid and all other health care programs, as defined in 42 USAC. § 1320a-7b(f), and the Foreign Corrupt Practices Act of 1977, each as may be amended from time to time.

9.3 **Disclaimer.** Each Party understands that the Compound and Products are the subject of ongoing clinical research and development and that the other Party cannot assure the safety or efficacy of any Compound or Product. In addition, neither Party makes any warranties except as set forth in this Article 10 with respect to the Catalyst Technology or ISU Technology, as applicable. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD-PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY, AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

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## ARTICLE 10 INDEMNIFICATION

**10.1 Indemnification by Catalyst.** Catalyst shall indemnify and hold harmless ISU, and its directors, officers, employees, agents, Affiliates and contractors (collectively, the “**ISU Indemnitees**”), from and against all losses, liabilities, damages and expenses, including reasonable attorneys’ fees and costs (collectively, “**Liabilities**”), resulting from any claims, demands, actions or other proceedings by any Third Party (“**Claims**”) to the extent resulting from (a) the breach of any representation, warranty or covenant by Catalyst under this Agreement or (b) the negligence or willful misconduct of Catalyst or its agents, Affiliates and contractors. The foregoing indemnity obligation shall not apply to the extent that (i) the ISU Indemnitees fail to comply with the indemnification procedures set forth in Section 10.3 and Catalyst’s defense of the relevant Claims is prejudiced by such failure, or (ii) any Claim arises from, is based on, or results from any activity set forth in Section 10.2(a), or 10.2(b) for which ISU is obligated to indemnify the Catalyst Indemnitees under Section 10.2.

**10.2 Indemnification by ISU.** ISU shall indemnify and hold harmless Catalyst, and its directors, officers, employees, agents, Affiliates and contractors (collectively, the “**Catalyst Indemnitees**”), from and against all Liabilities resulting from any Claims to the extent resulting from (a) the breach of any representation, warranty or covenant by ISU under this Agreement, or (b) the negligence or willful misconduct of ISU or its agents, Affiliates and contractors. The foregoing indemnity obligation shall not apply to the extent that (i) the Catalyst Indemnitees fail to comply with the indemnification procedures set forth in Section 10.3 and ISU’s defense of the relevant Claims is prejudiced by such failure, or (ii) any Claim arises from, is based on, or results from any activity set forth in Section 10.1(a) or 10.1(b) for which Catalyst is obligated to indemnify the ISU Indemnitees under Section 10.1.

**10.3 Indemnification Procedures.** The Party claiming indemnity under this Article 10 (the “**Indemnified Party**”) shall give written notice to the Party from whom indemnity is being sought (the “**Indemnifying Party**”) promptly after learning of such Claim. The Indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice, and the Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party’s expense, in connection with the defense of the Claim for which indemnity is being sought. Each Party shall not settle or compromise any Claim without the prior written consent of the other Party, which consent shall not be unreasonably withheld, delayed or conditioned. If the Parties cannot agree as to the application of the foregoing Sections 10.1 and 10.2, each may conduct separate defenses of the Claim, and each Party reserves the right to claim indemnity from the other in accordance with this Article 10 upon the resolution of the underlying Claim.

**10.4 Limitation of Liability.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH

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DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 10.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 10.1 OR 10.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 11.

**10.5 Insurance.** Each Party shall, at all times during the Term of this Agreement, obtain and maintain at its own expense the following types of insurance, with limits of liability not less than those specified below:

(a) Commercial general liability insurance against claims for bodily injury and property damage which shall include contractual coverage, with limits of not less than [\* \* \*] per occurrence and in the aggregate.

(b) Clinical studies and product liability insurance with bodily injury death and property damage limits of not less than [\* \* \*] per occurrence and in the aggregate.

(c) Workers compensation and employers' liability with limits to comply with the statutory requirements of the state(s) in which the Agreement is to be performed. The policy shall include employers' liability for not less than [\* \* \*] per accident.

All policies shall be issued by insurance companies with an A.M. Best's rating of Class A-V (or its equivalent) or higher status. Each Party shall deliver certificates of insurance evidencing coverage to the other Party promptly after the execution of this Agreement and annually thereafter. All policies provided for herein shall expressly provide that such policies shall not be cancelled, terminated or altered without at least [\* \* \*] prior written notice to the insured Party, and each insuring Party shall immediately notify the insured party in the event that a policy provided for herein is cancelled, terminated or altered.

## **ARTICLE 11 CONFIDENTIALITY**

**11.1 Confidentiality.** During the Term and for a period of [\* \* \*] thereafter, each Party shall maintain all Confidential Information of the other Party in trust and confidence and shall not, without the written consent of the other Party, disclose any Confidential Information of the other Party to any Third Party or use any Confidential Information of the other Party for any purpose other than as provided in this Agreement. The confidentiality obligations of this Section 11.1 shall not apply to Confidential Information to the extent that the receiving Party can establish by competent evidence that such Confidential Information: (a) is publicly known prior or subsequent to disclosure without breach of confidentiality obligations by such Party or its employees, consultants or agents; (b) was in such Party's possession at the time of disclosure without any restrictions on further disclosure; (c) is received by such receiving Party, without any restrictions on further disclosure, from a Third Party who has the lawful right to disclose it, or (d) is independently developed by employees or agents of the receiving Party who had no access to the disclosing Party's Confidential Information. Notwithstanding the foregoing, the Parties agree

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that all pre-clinical and clinical data regarding DalcA, all correspondence with Regulatory Authorities anywhere in the world regarding DalcA, and all information related to the manufacturing and testing of DalcA shall be Confidential Information of Catalyst and the terms and conditions of this Agreement shall be Confidential Information of both Parties.

**11.2 Authorized Disclosure.** Nothing herein shall preclude a Party from disclosing the Confidential Information of the other Party to the extent:

(a) such disclosure is reasonably necessary (i) for the filing or prosecuting of Patents as contemplated by this Agreement; (ii) to comply with the requirement of Regulatory Authorities with respect to obtaining and maintaining Regulatory Approval (or any pricing and reimbursement approvals) of a Product; or (iii) for prosecuting or defending litigations as contemplated by this Agreement;

(b) such disclosure is reasonably necessary to its employees, agents, consultants, contractors, licensees or sublicensees on a need-to-know basis for the sole purpose of performing its obligations or exercising its rights under this Agreement; provided that in each case, the disclosees are bound by written obligations of confidentiality and non-use consistent with those contained in this Agreement;

(c) such disclosure is reasonably necessary to any bona fide potential or actual investor, acquiror, merger partner, sublicensee or other financial or commercial partner for the sole purpose of evaluating an actual or potential investment, acquisition, sublicense or other business relationship; provided that in connection with such disclosure, such Party shall use all reasonable efforts to inform each disclosee of the confidential nature of such Confidential Information and cause each disclosee to treat such Confidential Information as confidential;

(d) such disclosure is reasonably necessary to comply with applicable Laws, including regulations promulgated by applicable security exchanges, a valid order of a court of competent jurisdiction, administrative subpoena or order.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 11.2(a) or 11.2(d), such Party shall promptly notify the other Party of such required disclosure and shall use reasonable efforts to obtain, or to assist the other Party in obtaining, a protective order preventing or limiting the required disclosure.

**11.3 Return of Confidential Information.** Promptly after the termination or expiration of this Agreement for any reason, each Party shall return to the other Party all tangible manifestations including, but not limited to, all written materials of such other Party's Confidential Information at that time in the possession of the receiving Party.

**11.4 Publicity.**

(a) [\* \* \*]. If ISU desires to make any other public announcement concerning the material terms or other matters related to this Agreement, ISU shall give [\* \* \*] advance notice

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of the proposed text of such announcement to Catalyst for its prior review and approval (except as otherwise provided herein), such approval not to be unreasonably withheld. If Catalyst desires to make a public announcement concerning the material terms or other matters related to this Agreement, Catalyst shall give at least [\* \* \*] prior written notice of the proposed text of such announcement to ISU for its prior review (except as otherwise provided herein). Notwithstanding the foregoing, ISU shall not be required to seek the permission of Catalyst to repeat any information regarding the terms of this Agreement or DalcA that has already been publicly disclosed, provided such information remains accurate as of such time.

**(b)** In addition, the Parties acknowledge that either or both Parties may be obligated to disclose the material terms of this Agreement and to file under applicable law and regulation a copy of this Agreement with the United States Securities and Exchange Commission or similar stock exchange authorities or other governmental authorities. Each Party shall be entitled to make such disclosure and required filing; *provided, however*, that it requests confidential treatment of the commercial terms and sensitive technical terms hereof to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing, each Party shall provide the other Party with a copy of this Agreement marked to show provisions for which such Party intends to seek confidential treatment and shall reasonably consider and incorporate the other Party's comments thereon, if timely provided, to the extent consistent with the legal requirements, with respect to the filing Party, governing disclosure of material agreements and material information that must be publicly filed.

**11.5 Technical Publication.** ISU may not publish peer reviewed manuscripts or give other forms of public disclosure, such as abstracts and media presentations of results of studies carried out under this Agreement, without Catalyst's prior written consent.

**11.6 Equitable Relief.** Each Party acknowledges that its breach of Article 11 of this Agreement may cause irreparable injury to the other Party for which monetary damages may not be an adequate remedy. Therefore, each Party shall be entitled to seek injunctive and other appropriate equitable relief to prevent or curtail any actual or threatened breach of the obligations relating to Confidential Information set forth in this Article 11 by the other Party. The rights and remedies provided to each Party in this Article 11 are cumulative and in addition to any other rights and remedies available to such Party at law or in equity.

## **ARTICLE 12 TERM AND TERMINATION**

**12.1 Term.** This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 12, shall remain in effect on a Product-by-Product and country-by-country basis until the expiration of the Royalty Term of such Product in such country (the "**Term**"). On expiration in the particular country and for the particular Product, the licenses granted in Sections 2.1 and 2.2 for the Product shall automatically convert to be perpetual, irrevocable and non-exclusive in such country.

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## 12.2 Termination for Breach.

(a) Each Party shall have the right to terminate this Agreement in its entirety immediately upon written notice to the other Party if the other Party materially breaches its obligations under this Agreement and, after receiving written notice identifying such material breach in reasonable detail, fails to cure such material breach within [\* \* \*] from the date of such notice (or [\* \* \*] from the date of such notice in the event such material breach is solely based on the breaching Party's failure to pay any amounts due hereunder).

(b) If the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party in accordance with Section 12.2(a), and such alleged breaching Party provides the other Party notice of such dispute within the applicable cure period, then the non-breaching Party shall not have the right to terminate this Agreement under Section 12.2(a) unless and until an arbitrator, in accordance with Article 13, has determined that the alleged breaching Party has materially breached the Agreement and such breaching Party fails to cure such breach within the applicable cure period (measured as commencing after the arbitrator's decision). It is understood and agreed that during the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

12.3 **Termination for Bankruptcy.** To the extent permitted under applicable Laws, if at any time during the Term of this Agreement, an Event of Bankruptcy (as defined below) relating to either Party (the "**Bankrupt Party**") occurs, the other Party (the "**Other Party**") shall have, in addition to all other legal and equitable rights and remedies available hereunder, the option to terminate this Agreement upon [\* \* \*] written notice to the Bankrupt Party. It is agreed and understood that if the Other Party does not elect to terminate this Agreement upon the occurrence of an Event of Bankruptcy, except as may otherwise be agreed with the trustee or receiver appointed to manage the affairs of the Bankrupt Party, the Other Party shall continue to make all payments required of it under this Agreement as if the Event of Bankruptcy had not occurred, and the Bankrupt Party shall not have the right to terminate any license granted herein. The term "**Event of Bankruptcy**" means: (a) filing, in any court or agency pursuant to any statute or regulation of any state or country, (i) a petition in bankruptcy or insolvency, (ii) for reorganization or (iii) for the appointment of (or for an arrangement for the appointment of) a receiver or trustee of the Bankrupt Party or of its assets; (b) with respect to the Bankrupt Party, being served with an involuntary petition filed in any insolvency proceeding, which such petition is not dismissed within [\* \* \*] after the filing thereof; (c) proposing or being a Party to any dissolution or liquidation when insolvent; or (d) making an assignment for the benefit of creditors. Without limitation, the Bankrupt Party's rights under this Agreement shall include those rights afforded by 11 USAC. § 365(n) of the United States Bankruptcy Code (the "**Bankruptcy Code**") and any successor thereto. If the bankruptcy trustee of a Bankrupt Party as a debtor or debtor-in-possession rejects this Agreement under 11 USAC. § 365(o) of the Bankruptcy Code, the Other Party may elect to retain its rights licensed from the Bankrupt Party hereunder (and any other supplementary agreements hereto) for the duration of this Agreement and avail itself of all rights and remedies to the full

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extent contemplated by this Agreement and 11 USAC. § 365(n) of the Bankruptcy Code, and any other relevant Laws.

**12.4 Termination by Mutual Consent.** The Parties may terminate this Agreement upon the mutual agreement of both Parties.

**12.5 Effect of Termination.**

(a) In the event of termination by ISU for Catalyst’s material breach pursuant to Section 12.2 or Catalyst’s Event of Bankruptcy pursuant to Section 12.3, the license granted to ISU in Section 2.1 will continue.

(b) In the event of termination by Catalyst for ISU’s material breach pursuant to Section 12.2 or ISU’s Event of Bankruptcy pursuant to Section 12.3, or by mutual agreement of the Parties pursuant to Section 12.4:

(i) The license granted to ISU in Section 2.1 will terminate;

(ii) The license to Catalyst in Section 2.2 shall become perpetual, irrevocable and royalty free. Thereafter, Catalyst shall have no further royalty payment obligations under Section 7.2(b).

**12.6 Effect of Expiration.** Upon the expiration of this agreement, the licenses granted pursuant to Sections 2.1 and 2.2 will become perpetual, irrevocable and royalty free.

**12.7 Survival.** Termination or expiration of this Agreement shall not affect any rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration. Notwithstanding anything to the contrary, the following provisions shall survive any expiration or termination of this Agreement: Sections 5.2, 5.3, and 5.4 and Articles 7 (but with respect to 7.1, 7.2 and 7.3, only with respect to events that occur prior to termination), 8, 10, 11, 12, 13, and 14.

**12.8 Rights in Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement by ISU are, and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to “intellectual property” as defined under Section 101 of the U.S. Bankruptcy Code.

**ARTICLE 13  
DISPUTE RESOLUTION**

**13.1 Disputes.** The Parties recognize that disputes as to certain matters may from time to time arise that relate to either Party’s rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 13 to

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resolve any controversy or claim arising out of, relating to or in connection with any provision of this Agreement, if and when a dispute arises under this Agreement.

**13.2 Internal Resolution.** With respect to all disputes arising between the Parties under this Agreement, including any alleged breach under this Agreement or any issue relating to the interpretation or application of this Agreement, if the Parties are unable to resolve such dispute within [\* \* \*] after such dispute is first identified by either Party in writing to the other, the Parties shall refer such dispute to the Executive Officers of the Parties for attempted resolution by good faith negotiations within [\* \* \*] after such notice is received, including at least one (1) in-person meeting of the Executive Officers within [\* \* \*] after such notice is received.

**13.3 Arbitration.** If the Executive Officers of the Parties are not able to resolve such dispute referred to them under Section 13.2 within such [\* \* \*] period, then subject to Section 13.4, such dispute shall be settled by binding arbitration in accordance with the then current rules of commercial arbitration of the American Arbitration Association (“AAA”). A single arbitrator with experience in the development and commercialization of drugs and diagnostics shall be appointed by mutual agreement of the Parties, but failing such agreement, selected in accordance with the AAA rules. The place of arbitration shall be [\* \* \*]. The arbitrator’s fees and expenses shall be shared equally by the Parties. Each Party shall bear and pay its own expenses incurred in connection with any dispute resolution under this Section 13.3. The proceedings, including any outcome, shall be confidential. Notwithstanding the foregoing, either Party shall have the right, without waiving any right or remedy available to such Party under this Agreement or otherwise, to seek and obtain from any court of competent jurisdiction any interim or provisional relief that is necessary or desirable to protect the rights or property of such Party, pending the selection of the arbitrator hereunder or pending the arbitrator’s decision of the dispute subject to arbitration.

**13.4 Patent and Trademark Disputes.** Notwithstanding Section 13.3, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patent covering the manufacture, use, importation, offer for sale or sale of any Product or of any trademark rights relating to any Product shall be submitted to a court of competent jurisdiction in the country in which such Patent or trademark rights were granted or arose.

**13.5 Injunctive Relief.** Notwithstanding anything to the contrary in this Article 13, either party may seek equitable relief, including an injunction, in any court of competent jurisdiction, related to any violation or potential violation of Article 11 hereof.

## **ARTICLE 14 MISCELLANEOUS**

**14.1 Entire Agreement; Termination of Prior Agreement; Amendment.** This Agreement, together with the exhibits attached hereto and which are hereby incorporated herein, represents the entire agreement and understanding between the Parties with respect to its subject matter and supersedes and terminates any prior and/or contemporaneous discussions, representations or agreements, whether written or oral, of the Parties regarding the subject matter hereto, and supersedes, as of the Effective Date, all prior and contemporaneous agreements and

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understandings between the Parties with respect to the subject matter hereof (including the Prior Agreement). There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth in this Agreement. For the avoidance of doubt, the Parties agree that neither has any obligations under the Prior Agreement, which is hereby terminated in its entirety and superseded by the terms and conditions hereof. After the Effective Date, neither Party shall make any claim or demand whatsoever against the other Party or any of its officers, directors, shareholders, agents, employees, subsidiaries and Affiliates (each a **“Released Party”** and together the **“Released Parties”**) with respect to the Prior Agreement, and each Party hereby irrevocably and forever releases all such Released Parties from any and all liabilities, demands, claims (including third Party claims), costs, losses, damages and expenses (including, without limitation, interest, penalties and attorney fees), known or unknown, contingent or otherwise, which such releasing Party may otherwise have against or recover from such Released Parties under the Prior Agreement, except as resulted from fraud, gross negligence or intentional misconduct by a Released Party. Amendments or changes to this Agreement shall be valid and binding only if in writing and signed by duly authorized representatives of the Parties.

**14.2 Force Majeure.** Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the control of the Parties, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party. If a force majeure persists for more than [\*\*\*], then the Parties shall discuss in good faith the modification of the Parties’ obligations under this Agreement in order to mitigate the delays caused by such force majeure.

**14.3 Notices.** Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 15.3, and shall be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by confirmed facsimile or a reputable courier service, or (b) [\*\*\*] after mailing, if mailed by first class certified or registered airmail, postage prepaid, return receipt requested.

If to Catalyst: Catalyst Biosciences, Inc.  
611 Gateway Blvd., Suite 710

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South San Francisco, CA 94080  
Attn: Nassim Usman, Ph.D., President & Chief Executive Officer

With a copy to (which shall not constitute notice):

Morrison & Foerster LLP  
1650 Tysons Blvd., Suite 400  
McLean, Virginia 22102 USA  
Attn: Stephen Thau

If to ISU:

ISU Abxis.  
Pangyo Global R&D Center, C-5th Bldg.  
22 Daewangpangyo-ro, 712 Beon-gil  
Bundang-gu, Seungnam-si,  
13488, Republic of Korea  
Attn. : Dr.Bumjun Lee  
(and his successor)

**14.4 No Strict Construction; Headings.** This Agreement has been prepared jointly by the Parties and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. Except where the context otherwise requires, the use of any gender shall be applicable to all genders, and the word “or” is used in the inclusive sense (and/or). The term “including” as used herein means including, without limiting the generality of any description preceding such term.

**14.5 Assignment.** Neither Party may assign this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld, except that either Party may assign this Agreement without the prior consent of the other Party: (a) to a Third Party successor to all or substantially all of its stock or assets relating to the Product (an “Acquiror”), whether in connection with a merger, consolidation or sale of assets or other transaction; or (b) to its Affiliate. Any permitted assignment shall be binding on the successors of the assigning Party. Any successor or assignee of rights and/or obligations permitted hereunder shall, in writing to the other Party, expressly assume performance of such rights and/or obligations. [\* \* \*]. Any attempted or purported assignment in violation of this Section 14.5 shall be null and void.

**14.6 Performance by Affiliates.** Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party’s obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party’s Affiliate of any of such Party’s obligations under this Agreement shall be

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deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

**14.7 Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**14.8 Severability.** If any provision of this Agreement is found by a court of competent jurisdiction to be unenforceable, then such provision shall be construed, to the extent feasible, so as to render the provision enforceable, and if no feasible interpretation would save such provision, it shall be severed from the remainder of this Agreement. The remainder of this Agreement shall remain in full force and effect, unless the severed provision is essential and material to the rights or benefits received by either Party. In such event, the Parties shall negotiate, in good faith, and substitute a valid and enforceable provision or agreement that most nearly implements the Parties' intent in entering into this Agreement.

**14.9 No Waiver.** No provision of this Agreement can be waived except by the express written consent of the Party waiving compliance. Except as specifically provided for herein, the waiver from time to time by either Party of any of its rights or its failure to exercise any remedy shall not operate or be construed as a continuing waiver of same or of any other of such Party's rights or remedies provided in this Agreement.

**14.10 Independent Contractors.** For all purposes under this Agreement, ISU and Catalyst are independent contractors with respect to each other, and shall not be deemed to be an employee, agent, partner or legal representative of the other Party. This Agreement does not grant any Party or its employees, consultants or agents any authority (express or implied) to do any of the following without the prior express written consent of the other Party: create or assume any obligation; enter into any agreement; make any representation or warranty; serve or accept legal process on behalf of the other Party; settle any claim by or against the other Party; or bind or otherwise render the other liable in any way.

**14.11 Governing Law.** This Agreement shall be governed by the laws of the state of California, without regard to its choice of law provisions that would require the application of the laws of a different jurisdiction.

**14.12 Counterparts.** This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original but all of which together shall constitute the same legal instrument.

*[Signature page follows]*

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IN WITNESS WHEREOF, the Parties have executed this Agreement by their duly authorized officers as of the Effective Date.

**ISU ABXIS**

**CATALYST BIOSCIENCES**

By:/s/ Mr. Seok Joo Lee

By: /s/ Nassim Usman

Name: Mr. Seok Joo Lee

Name: Nassim Usman, Ph.D.

Title: CEO and President

Title: President & Chief Executive Officer

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**EXHIBIT A**  
**MATERIAL TRANSFER OBLIGATIONS**

**Pre-Clinical and Clinical Samples, Data and Information:**

[\* \* \*]

**Technical Operations:**

[\* \* \*]

**Regulatory**

[\* \* \*]

**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. 333-206523, 333-206526, 333-212345, 333-219301, and 333-225902), and Form S-3 (Nos. 333-210248, 333-222644, and 333-228970) of our reports dated March 7, 2019, on our audits of the consolidated financial statements as of December 31, 2018 and 2017, and for each of the years then ended, and the effectiveness of Catalyst Biosciences, Inc.'s internal control over financial reporting as of December 31, 2018, which reports are included in this Annual Report on Form 10-K to be filed on or about March 7, 2019.

/s/ EisnerAmper LLP

EISNERAMPER LLP  
Iselin, New Jersey  
March 7, 2019

**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 7, 2019

/s/ Nassim Usman, Ph.D.

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

**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 7, 2019

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/s/ Fletcher Payne  
Fletcher Payne  
Chief Financial Officer

**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, 2018 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 7, 2019

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

**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, 2018 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 7, 2019

/s/ Fletcher Payne

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**Fletcher Payne  
Chief Financial Officer**