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, 2019

OR

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

For the transition period from _____ to _____

Commission file number: 000-51173

Catalyst Biosciences, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**56-2020050**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
611 Gateway Blvd. Suite 710 South San Francisco, California	**94080**
(Address of Principal Executive Offices)	**(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	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	**CBIO**	**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 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 February 7, 2020 was 12,076,777. The aggregate market value of the voting stock held by non-affiliates of the registrant as of June 30, 2019, was $86,980,239.

CATALYST BIOSCIENCES, INC.
Annual Report on Form 10-K
TABLE OF CONTENTS

PART I

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 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.

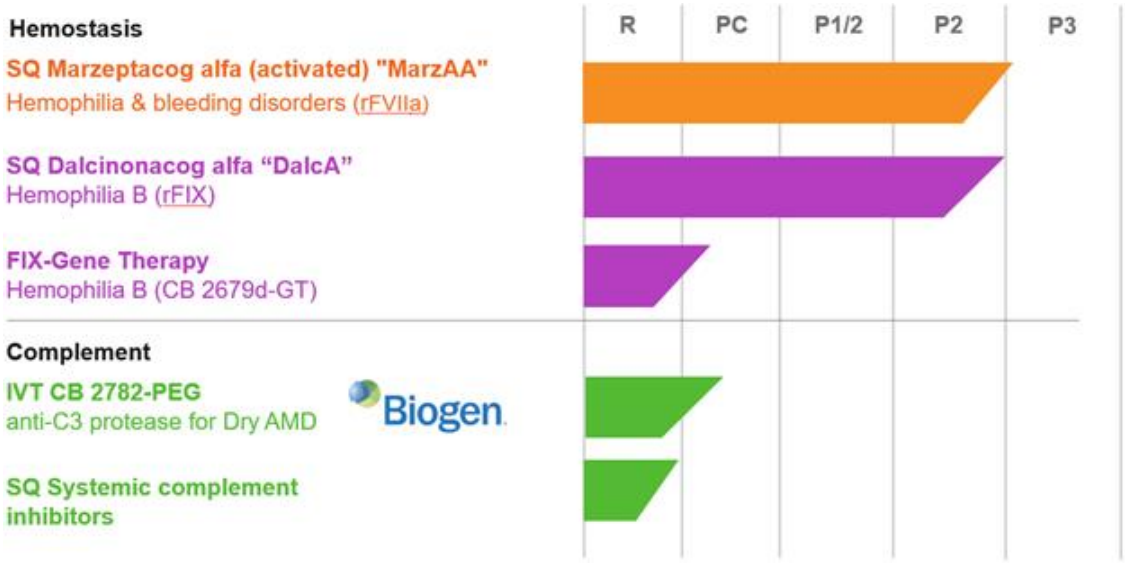
Unless the context requires otherwise, in this Annual Report on Form 10-K the terms “Catalyst,” the “Company,” “we,” “us” and “our” refer to Catalyst Biosciences, Inc., together with our subsidiary, Catalyst Bio, Inc., which we refer to as “Catalyst Bio.” See “Item 1— Business— Business Organization.”

ITEM 1. BUSINESS.

Overview

We are a fully integrated research and clinical development biopharmaceutical company with expertise in protease engineering, discovery and translational research, clinical development and manufacturing. We have a versatile protease engineering platform that feeds our research and development pipeline. Currently, we are focused on advancing and extending our Hemostasis and Complement product candidates. One of our key competitive advantages is that our systemically dosed product candidates, due to the improvements we have made using our protease engineering platform, can be delivered subcutaneously ("SQ") which is less invasive, more convenient and more efficacious than intravenous ("IV") drugs currently on the market. Our SQ product candidates demonstrate prolonged duration of activity enabling them to provide continuous therapeutic levels.

The following table summarizes our current development programs.



We are currently focusing on the clinical development of MarzAA for Hemophilia A and B and DalcA for Hemophilia B. MarzAA is 'Phase 3 ready' and DalcA is currently in Phase 2b. Both product candidates have received orphan drug designation in the U.S. and in the E.U. MarzAA for routine prophylaxis to prevent bleeding episodes in individuals with Hemophilia A and B with inhibitors and DalcA for routine prophylaxis to prevent bleeding episodes for Hemophilia B patients. We believe MarzAA may also provide significant on-demand and prophylaxis benefits for other therapeutic areas with high unmet medical needs, such as Factor VII Deficiency, Glanzmann Thrombasthenia, Acquired Hemophilia, and SQ treatment of bleeds in Hemophilia A patients.

We control worldwide development, manufacturing and commercialization rights of both MarzAA and DalcA, except for the commercialization rights of DalcA in South Korea. We estimate the global market opportunity for MarzAA and DalcA to be approximately $3.7 billion: $2.2 billion for the Factor VIIa market and $1.5 billion for the Factor IX market.

We have an early stage Factor IX gene therapy construct - CB 2679d-GT - for Hemophilia B. This gene therapy product candidate has demonstrated a 2-3-fold higher specific activity and a 4-5-fold reduction in bleeding time in a mouse preclinical Hemophilia B model compared with the Factor IX Padua variant currently being developed by others. Recently, we have shown that combination of a novel AAV gene therapy delivery vector expressing our CB 2679d-GT construct provides significantly enhanced expression and Factor IX activity in mouse hemophilia B model.

Using our protease engineering platform, we have also developed a novel anti-C3 protease for dry Age-related Macular Degeneration ("AMD") - CB 2782-PEG. Dry AMD is estimated to have a $5 billion market opportunity with no approved drugs on the market. We entered into an exclusive worldwide license and collaboration agreement with Biogen International GmbH (Biogen) on December 18, 2019, for the development and commercialization of this product candidate. We received a $15.0 million upfront payment from Biogen in January 2020 and are eligible to receive up to $340 million in milestone payments, along with tiered royalties for worldwide net sales of this product candidate up to low double-digits. As a result of a collaboration, Mosaic Biosciences, Inc. is entitled to receive a double-digit percentage of funds we receive from Biogen.

Hemostasis

Background on Hemophilia

Hemophilia is a rare and serious bleeding disorder that results from a genetic or an acquired deficiency of a factor required for normal blood coagulation. There are two major types of hemophilia: Hemophilia A and Hemophilia B, caused by abnormalities in coagulation Factor VIII or Factor IX, respectively. Deficiencies in these factors reduce the ability of the affected individuals to form clots and stop bleeding. The disease is X chromosome-linked, meaning that most people who inherit the disorder and suffer from bleeding are male; however, female carriers of mutations in Factor VIII or Factor IX can also have reduced coagulation factor levels and resultant bleeding. Hemophilia A occurs in approximately 1 in 5,000 male births, and Hemophilia B in approximately 1 in 20,000 male births. The estimated number of patients with hemophilia worldwide is 1.1 million, of whom 418,000 are estimated to have severe hemophilia. The prevalence of severe Hemophilia A and Hemophilia B in the United States is approximately 20,000 patients. Patients with hemophilia suffer from spontaneous and traumatic bleeding episodes that can become limb- or life-threatening. In cases of severe hemophilia, spontaneous bleeding into muscles or joints is frequent and often results in disabling irreversible joint damage. Currently there is no cure for hemophilia.

Standard of Care for Hemophilia Management and Opportunities for a New Paradigm with SQ Therapy

Current hemophilia treatment involves on-demand management of acute bleeding episodes or prophylactic treatment through factor replacement or bypass therapy. Replacement therapy involves frequent IV administration of the missing factors to prevent or stop bleeding. IV infusion is invasive, painful, time consuming and particularly challenging to administer to children. Often times, patients must seek assistance of a health professional for the IV infusion.

Another significant challenge in managing patients with hemophilia is the risk for development of inhibitors, which are neutralizing anti-drug-antibodies ("nAbs") that reduce the efficacy of the factor replacement. This occurs in approximately 30% of Hemophilia A and 5-10% of Hemophilia B patients. Inhibitor patients must be treated with bypass agents to achieve coagulation in the absence of effective factor levels.

Currently, two types of IV bypass treatment exist: recombinant activated coagulation factor VII (rFVIIa: NovoSeven RT) and activated prothrombin complex concentrates (*e.g.*, FEIBA). rFVIIa is the current leading bypass agent for on-demand treatment in inhibitor complicated hemophilia. rFVIIa has a strong safety profile and has proven effective in multiple rare bleeding disorders, including Hemophilia A or B with inhibitors, Severe Factor VII Deficiency, Glanzmann Thrombasthenia, and Acquired Hemophilia A. FEIBA is also administered for acute bleeding but its effect is reduced by the need for frequent dosing and the risk of anaphylaxis and renal side effects in Hemophilia B with inhibitor patients.

We believe SQ dosing is the future in hemophilia and other rare hematology indications. Our clinical studies have shown that MarzAA is nine-fold more potent than NovoSeven RT and that DalcA is 22-fold more potent than BeneFIX. The enhanced potency of MarzAA and DalcA allows for SQ dosing using a small volume, which we believe will provide for more effective, durable and convenient treatments of spontaneous bleeds with MarzAA and prophylactic protection with MarzAA and DalcA, especially for children and adults with difficult IV access. Recently, Hemlibra®, a bispecific antibody mimicking FVIIIa, was approved for SQ prophylaxis in Hemophilia A with or without inhibitors but it is ineffective in treatment of breakthrough bleeding.

MarzAA Clinical Development

Our most advanced product candidate - MarzAA, a potent, subcutaneously administered, next-generation Factor VIIa variant, is ‘Phase 3 ready’.

The development program began with a Phase 1 clinical trial evaluating the pharmacokinetics and pharmacodynamics of MarzAA administered IV in patients with severe Hemophilia A and B with and without inhibitors. In this study, we demonstrated that single IV administration of doses of MarzAA ranging from 0.5 µg/kg/day to 30 µg/kg/day was safe and well tolerated. Moreover, there was a dose dependent increase in MarzAA antigen and activity levels with normalization of coagulation parameters at the higher dose levels.

We completed our Phase 2 open-label SQ trial and met all our primary and secondary end points in 2019. The Phase 2 trial was designed to evaluate the efficacy of MarzAA in reducing total bleeding episodes in hemophilia patients with inhibitors. The primary endpoint was to assess the effect of MarzAA on the annualized bleed rate (ABR) at a subject’s final dose level, with each patient’s prior 6-month ABR serving as his own control. The secondary endpoints included safety, tolerability and lack of anti-drug-antibody (“ADA”) and neutralizing antibody formation.

We reported in July 2019 that daily SQ administration of MarzAA for 50 days significantly reduced the 6-month pre-study mean ABR from 19.8 to 1.6 at the subjects’ final individual dose levels ($p<0.01$) at the International Society for Thrombosis & Hemostasis (“ISTH”) 2019 Congress in July 2019. Additionally, during the 6-month pre-treatment period patients were bleeding on average 12.3% of days also referred to as Proportion of Days with Bleeding (“PDB”). MarzAA treatment was able to successfully reduce this number to 0.8% ($p<0.01$) during the active treatment period. The median ABR and PDB were both reduced to zero during treatment, with seven of nine subjects experiencing no bleeds, either traumatic or spontaneous, at their final dose levels. Only 2 subjects required dose escalation due to spontaneous bleeding from 30 µg/kg/day to 60 µg/kg/day per protocol. SQ treatment with MarzAA was safe and well-tolerated. Six mild to moderate localized skin reactions were observed in 2 subjects, that resolved spontaneously without sequelae. Neither ADAs nor nAbs to MarzAA were detected after administration of a total of 517 SQ doses. Moreover, our pharmacokinetics data has shown that SQ dosing prolonged the half-life of MarzAA from 3.7 hours after IV administration to approximately 17 hours after SQ administration.

Interplay of On-demand Treatment of Bleed and Prophylaxis for Hemophilia Management

Our preclinical data has shown that SQ injections of MarzAA given one minute after injury to mirror on-demand therapy significantly reduced bleeding in a mouse model of Hemophilia A. In this setting, reduction of bleeding after SQ administration of MarzAA was as efficient as NovoSeven RT administered IV. Moreover, bleeding was reduced in a dose-dependent manner when MarzAA was given 15 minutes prior to the injury. These data suggest that MarzAA has the potential to be used on-demand for treatment of acute bleeding episodes and supports further clinical testing for on-demand treatment of bleeds in individuals with hemophilia or Factor VII deficiency.

Patients on prophylaxis with Hemlibra or other Factor replacement therapy may experience breakthrough bleeds— bleeding despite preventive treatment—or require additional treatments for certain procedures or surgery. Our preclinical data showed that MarzAA is expected to have a similar safety profile as NovoSeven when used in combination with Hemlibra. Specifically, as tested *in vitro* by the thrombin-generation assay with Hemophilia A plasma, both MarzAA and NovoSeven were equally effective at triggering blood coagulation at their respective clinically relevant concentrations without overshooting safe levels when combined with Hemlibra. Current therapies used with Hemlibra include FEIBA (a pro-coagulation complex) and NovoSeven. However, the concurrent administration of FEIBA with Hemlibra has been associated with thrombotic events (when a blood clot forms inside a blood vessel), requiring a boxed warning in the package insert. While NovoSeven is safe in patients on Hemlibra prophylaxis, it is administered through an IV infusion to treat a bleed. Ideally, add-on therapy for patients on SQ Hemlibra would be given subcutaneously. We believe MarzAA provides a potential SQ solution to this problem and that MarzAA could be a SQ rescue therapy for hemophilia patients experiencing breakthrough bleeds while on prophylaxis with other agents such as Hemlibra.

We are currently conducting a SQ Phase 1 study to evaluate the pharmacokinetics and pharmacodynamics in patients with Hemophilia A or B with or without inhibitors at ascending dose levels. The purpose of the trial is to determine if the timing of the peak levels achieved is sufficient to treat a breakthrough bleed with SQ dosing and determine if increasing dose levels increase blood levels in a dose proportional manner. This trial will enable final dose selection for a MarzAA Phase 3 study. We reported interim data from this trial at the 13th Annual Congress of the European Association of Haemophilia and Allied Disorders (EAHAD) on February 5, 2020 that showed SQ dosing of MarzAA reaches target levels that are consistent with the treatment of a bleed.

DalcA Clinical Development

Our next most advanced product candidate is DalcA, a next-generation SQ Factor IX drug for the prophylactic treatment of individuals with Hemophilia B. DalcA is completing a Phase 2b study. We completed our Phase 1/2 SQ dosing trial that evaluated the safety and efficacy of DalcA in patients with severe Hemophilia B in a collaboration with ISU Abxis. The objective was to demonstrate the feasibility of increasing Factor IX activity levels from approximately 1% (severe hemophilia) to greater than 12% (mild hemophilia corresponding to a reduced risk of spontaneous joint bleeds) with daily SQ injections. DalcA maintained protective Factor IX activity levels of 12-30%. Mild to moderate injection site reactions were reported and all resolved spontaneously without sequelae. Two subjects, who were cousins with the same rare Factor IX mutation, developed nAbs, one transiently. The nAbs were specific to DalcA (did not bind to wild-type Factor IX) and therefore did not interfere with the patients' ability to resume use of their prior Factor IX therapy. Thus, the nAbs to DalcA are not referred to as inhibitors.

We completed a comprehensive investigation of the cause of the nAbs in 2018 and concluded that the immunogenic potential of DalcA was low and similar to that of commercial Factor IX products. Furthermore, the drug product quality of DalcA was shown to be comparable to commercial Factor IX products. Based on the results of the investigation, and discussions with clinicians and regulatory experts, we initiated an open-label Phase 2b study to evaluate the ability of DalcA to maintain steady state protective Factor IX levels above 12% in six individuals with severe hemophilia B. Each subject received a single intravenous dose, followed by daily SQ doses of DalcA for 28 days. Pharmacokinetics, pharmacodynamics, safety and tolerability of daily SQ dosing and anti-drug antibody formation are being monitored. We reported interim data from this trial at The European Association for Haemophilia and Allied Disorders (EAHAD) on February 7, 2020. Data from the trial showed that 28 days of daily SQ dosing of DalcA achieved protective target Factor IX levels of >12%, with steady state Factor IX levels of up to 27% after 14 days with no bleeds, demonstrating effective prophylaxis and the potential for lower or less frequent dosing. One subject withdrew on day 7. No anti-drug antibodies were detected and no serious adverse events were reported. Three subjects reported injection site reactions ("ISRs"), the majority of which were mild in severity and resolved without sequelae. We have completed enrollment for the Phase 2b study and expect to report final data in Q2 2020.

Factor IX Gene Therapy

Our Factor IX gene therapy construct CB 2679d-GT has demonstrated a 2-fold to 3-fold higher activity resulting in improved clotting time in a preclinical Hemophilia B mouse model compared with the Padua variant of Factor IX. Fidanacogene elaparvovec (Pfizer/Spark), AMT-061 (uniQure) and FLT180A (Freeline) use the Padua variant as the transgene in their AAV-based gene therapy clinical programs. Fidanacogene elaparvovec, AMT-061 and FLT180A have demonstrated encouraging Factor IX levels in their respective Phase 1/2 and Phase 2/3 studies with median Factor IX activity levels of approximately 30-45%. By its increased activity, CB 2679d-GT has the potential to reach higher Factor IX activity levels at lower vector doses which could improve tolerability of the vector as well as efficacy of the transgene, and ultimately lower manufacturing costs. We have licensed AAV technology from The Board of Trustees of The Leland Stanford Junior University ("Stanford") and are currently optimizing the vector under a sponsored research agreement with Stanford. Data presented at EAHAD show that the combination of our proprietary potency enhanced CB 2679d-GT Factor IX construct with a novel chimeric AAV capsid may reduce the vector dose required in gene therapy while maintaining high Factor IX levels. We expect the completion of our next generation vector and nonhuman primate efficacy study in Q2 2020.

Factor Xa

We have 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 efforts on the MarzAA and DalcA clinical programs.

Complement

The complement system shares many similarities with the hemostatic system. They both function as cascades of enzymes. Whereas the hemostatic system is central to stopping bleeding, the complement system plays a central role in both innate and adaptive immune responses. The resultant process helps to attract certain immune system cells at the site of infection or inflammation, to eliminate pathogens, and to mediate various specific responses to foreign proteins through effects on the immune system. When the complement system is over-reactive, it can cause severe diseases. Thus, drugs that target the complement cascade could potentially be beneficial in a variety of indications, including but not limited to dry AMD, atypical hemolytic uremic syndrome (aHUS), paroxysmal nocturnal hemoglobinuria (PNH), complement 3 glomerulopathy (C3G) as well as neurological disorders, such as myasthenia gravis. Common to these diseases are that they are relatively rare and severely debilitating or life-threatening, for which large unmet medical needs still exist. Many key targets, such as the complement proteins C3 and C5, within the complement cascade circulate in high concentrations such that it can be difficult or impractical to block their action using antibody-based or small molecule approaches. We believe that targeting complement proteins using engineered enzymes is an efficient way to overcome some of the challenges of inhibiting the complement cascade. In contrast to an antibody or small molecule where one therapeutic compound neutralizes one target, a single protease has the potential to neutralize thousands of target complement molecules. Preclinical support for using this design strategy to target the complement pathway was presented at the 2019 Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO) in the spring of 2019 highlighting our preclinical anti-C3 candidate being developed for the treatment of geographic atrophy (GA) associated dry AMD. We continue to pursue the development of novel proteases that target the complement cascade and are leveraging our proprietary protease engineering platform in this therapeutic space.

IVT CB 2782-PEG

Geographic atrophy is an advanced stage of dry AMD that results in the irreversible loss of retinal cells and can lead to blindness. Dry AMD affects approximately one million people in the United States and approximately over five million people worldwide. Complement factor 3 (C3) is the central regulator of the complement cascade. Apellis Pharmaceuticals' APL-2 (C3 binding cyclic peptide) clinically validated C3 as a target for geographic atrophy in AMD after demonstrating statistically significant reduction in geographic atrophy associated dry AMD in a randomized Phase 2 study with monthly APL-2 intravitreal injections.

We have developed CB 2782-PEG, which is a potent, long acting anti-C3 protease that selectively degrades C3 into inactive fragments. Our preclinical data predict best-in-class human intravitreal dosing three or four times a year. As described below in the "Collaboration" section, we have entered into a license and collaboration with Biogen for the development and commercialization of CB 2782-PEG.

SQ Systemic complement inhibitors

We have initiated discovery research to identify novel complement pathway regulating proteases.

Our Strategy

We are building a portfolio of engineered proteases to enable the development of valuable therapies for individuals with rare diseases who need new or better treatment options. Our key objective is to get our novel treatments to patients rapidly and we are constantly exploring ways to quickly advance our programs which may include research and/or development collaborations. Key focus areas for us in the near and longer term include:

- Build a Hemostasis Franchise:
    - Initiate and complete a MarzAA phase 3 study for the treatment of acute bleeds.
    - Expand clinical development of MarzAA in additional indications.
    - Advance clinical development of DalcA.
    - Advance development of CB 2679d-GT and select a development candidate
- Build a Complement Franchise:
    - Build a systemic complement regulation program with our proprietary protease engineering platform.

Collaborations

MarzAA

In 2009, we licensed MarzAA to Wyeth Pharmaceuticals, Inc. (Wyeth). Wyeth was subsequently acquired by Pfizer, Inc. (“Pfizer”) who terminated the license and collaboration agreement after completing an IV Phase 1 trial. Pursuant to the collaboration termination agreement, in exchange for the rights to certain Pfizer technology, we agreed to make 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 Phase 2 study.

DalcA

We collaborated with ISU Abxis (“ISU”), in the early development of DalcA. Under the collaboration agreement, ISU conducted the Phase I clinical trial of DalcA and was responsible for all manufacturing activities for the Phase 1 clinical trial. Pursuant to the agreement, as amended in December 2018, ISU is entitled to a low single-digit royalty payment, 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. ISU is also entitled up to $19.5 million in milestone payments, of which $2.5 million are regulatory and development milestone payments and up to $17 million in commercial milestone payments.

Under the original agreement with ISU, we received and recognized $2.65 million from ISU through 2018.

Anti-C3

On December 18, 2019, we agreed to collaborate with Biogen to develop and commercialize CB 2782-PEG and our other anti-C3 proteases for potential treatment of dry AMD and other disorders. We will perform pre-clinical and manufacturing activities, and Biogen will be solely responsible for funding the pre-clinical and manufacturing activities and performing IND-enabling activities, worldwide clinical development, and commercialization. We received a $15.0 million upfront payment from Biogen in January 2020 and are eligible to receive up to $340 million in milestone payments, along with tiered royalties for worldwide net sales of this product candidate up to low double-digits.

We also collaborated with Mosaic Biosciences, Inc. (“Mosaic”) in the development of our complement product candidates, including CB 2782-PEG. Under the collaboration agreement, as amended in December 2019, Mosaic will perform all future services for a fee. Mosaic is entitled to a double-digit percentage of funds we receive from Biogen. Mosaic is also entitled to sublicense fees and/or research and development, commercial milestones and royalties on one non-anti-C3 complement product.

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 currently on market or being developed by competitors in indications overlapping with those of our programs.

- ***Factor VIIa Competition:***
  - Approved products
    - Novo Nordisk’s NovoSeven RT is an intravenous recombinant Factor VIIa indicated for treatment of bleeding episodes in individuals with Hemophilia A or B with an inhibitor to Factor VIII or Factor IX. NovoSeven was approved in 1999 and was approved in a room temperature formulation “NovoSeven RT” in 2008. The treatment has since been approved for use in individuals with Factor VII deficiency and Glanzmann thrombasthenia. It is also approved for bleeding episodes and peri-operative management in adults with Acquired Hemophilia.

      Takeda’s FEIBA is a plasma-based composition of coagulation factors indicated for intravenous on-demand and prophylactic use in the treatment of individuals with Hemophilia A or B with inhibitors. FEIBA has been on the market for more than 30 years.

      Roche’s Hemlibra (emicizumab-kxwh), a bispecific Factor IXa-Factor X monoclonal antibody is indicated for routine SQ prophylaxis in adults and children with Hemophilia A with a Factor VIII inhibitor. Emicizumab received approval from the FDA in 2017. Emicizumab cannot treat episodic bleeding.

In-development product candidates

- rEVO Biologics (an LFB company) is developing LR769 , an IV recombinant form of human Factor VIIa, and has completed a Phase 3 clinical trial in episodic bleeding for patients with congenital Hemophilia A or B with inhibitors. Two additional Phase 3 trials investigating the use of LR769 in pediatric and surgical patients with Hemophilia A or B with inhibitors may be ongoing in partnership with HEMA Biologics.

- Novo Nordisk and Pfizer are also developing SQ agents that neutralize Tissue Pathway Factor Inhibitor in mid-stage clinical trials. Novo Nordisk's Concizumab (received FDA Breakthrough Designation for the treatment of Hemophilia B with Inhibitors) is in Phase 3 studies for individuals with Hemophilia A or B with and without inhibitors (separate studies) and the studies are expected to complete in 2023. Pfizer expects to complete a Phase 3 study with its anti-TFPI (PF-06741086) in 2023.

- Genzyme (a Sanofi company) is developing Fitusiran, acquired from Alnylam, an investigational SQ RNA interference ("RNAi") therapeutic targeting antithrombin for the treatment of adults and adolescents with Hemophilia A or B with or without inhibitors and expects to complete its Phase 3 clinical trial in 2021. The pediatric study in the same population is in Phase 2/3 with an estimated study completion in 2024.

- OPKO Health's Factor VIIa-CTP for Hemophilia A or B has completed a SQ Phase 1 trial.

- Novo Nordisk's Mim8, a next-generation FVIII mimetic bi-specific antibody, has completed a SQ Phase 2 study in hemophilia A patients with or without inhibitors.

- ***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. 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). Idelvion, a Factor IX-albumin fusion product marketed by CSL Behring was approved by the FDA in 2016. Idelvion is approved for weekly dosing for adolescents and adults and bi-weekly at a higher dose for those same patients if well controlled on the original regimen. It is approved for weekly in patients <12 years of age. Novo Nordisk's glycopegylated-Factor IX product Rebinyn® was approved by the FDA in 2017 but is not indicated for routine prophylaxis in the U.S. Rebinyn is approved for on-demand treatment and control of bleeding episodes as well as Perioperative management of bleeding.

- ***Factor IX Gene Therapy Competition:*** While there are no currently approved Factor IX gene therapy treatments for Hemophilia B, several companies, are developing Factor IX gene therapy treatments in clinical studies:

  - Spark (now Pfizer) started its Phase 3 study of SPK-9001 with Fidanacogene elaparvovec (AAV-Spark100-FIX co-Padua) and expects to complete the study in 2021.

  - uniQure expects to complete a Phase 3 trial investigating a serotype 5 adeno-associated viral vector containing the Padua variant of a codon-optimized human Factor IX Gene (AAV5-hFIXco-Padua, AMT-061) in 2020.

  - Freeline (in association with St. Jude) expects to complete its Phase 2/3 study of FLT180a (a replication-incompetent adeno- associated viral vector) in 2024.

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 are developing cyclic peptide, aptamer or antibody-based anti-complement product candidates for the treatment of dry AMD that are currently in clinical studies:

- Apellis is conducting two Phase 3 studies to compare the efficacy and safety of intravitreal APL-2 therapy with sham injections in patients aged 60 years and older with GA secondary to AMD, which is scheduled to be completed in 2021.

- Ophthotech (now Iveric bio) is developing two therapies to treat GA secondary to dry AMD. Iveric Bio completed its Phase 2b clinical of Zimura® (avacincaptad pegolmet) with positive data in patients with dry AMD.

Our commercial opportunity in different indications could be reduced or eliminated if our competitors develop and market products that are safer, more effective, more convenient to use, or less expensive 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.

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 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, 2019, our patent portfolio included approximately 177 patents; including 15 issued U.S. patents and 162 foreign granted and accepted patents, and 7 U.S. patent applications, plus an additional 35 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.

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. There is a 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.

We are aware of a patent family that includes issued patents in the United States, Australia, and Japan, and pending applications in Europe and Canada. The patents and pending applications may include claims that may read on a contemplated Factor Xa ("FXa") clinical candidate. There is prior art that we believe discloses subject matter on which a challenge to the patentability of such claims can be based. In the event that development of the FXa candidate is pursued we would, if necessary, consider appropriate action to challenge such claims.

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 granted South Korean patent 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:

- 72 patents, including 3 issued U.S. patents, and 5 patent applications, including 3 pending U.S. patent applications, covering modified Factor VII polypeptides, including our lead product candidate, MarzAA, and methods of production of modified Factor VII polypeptides. The U.S. patents, with patent term adjustment, expire in 2029 and 2031. The foreign patents expire in 2029.

- 21 patents, including 3 issued U.S. patents, and 8 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 2030-2031 and 2038, and the foreign patents and patent applications, if granted, expire, or are expected to expire, respectively, in 2031.

- 19 patents, including 2 issued U.S. patents, covering improved Factor Xa variants and methods of production of improved Factor Xa variants. The issued patents, including patent term adjustment, expire in 2033.

- 62 patents, including 5 issued U.S. patents, and 29 patent applications filed or in progress, 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, respectively, in 2025-2027 and 2038-2039.

- 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 USPTO 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 or Biologic License Application). The approval phase is the period between the submission and approval of the marketing application. Extensions can be reduced by any time that the applicant did act not with due diligence as determined by the FDA. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent applicable to each regulatory review period may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar provisions are available in the European Union and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug.

In the future, to the extent our product candidates including MarzAA, DalcA, Anti-C3 and systemic complement 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.

Manufacturing

Our team has in-depth knowledge on biologics development, manufacturing and CMC regulatory requirements. We do not have any manufacturing facilities and we currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for clinical or commercial uses. We own or have rights to all intellectual property developed in such manufacturing development activities that are specifically related to our product candidates and have a royalty-free and perpetual license to use the intellectual property to the extent reasonably necessary to make our product candidates, including commercial manufacturing.

Drug Substance manufacturing

We have a long-term development and manufacturing services agreement with AGC Biologics, Inc. ("AGC"). AGC has global manufacturing sites and we use their facilities in the U.S. and Europe for drug substance manufacturing of MarzAA and DalcA. We have successfully manufactured MarzAA to support our Phase 2 clinical trial and received FDA agreement that we have demonstrated comparability between our current manufacturing and that previously produced by Pfizer. In the third quarter of 2019, we also successfully completed a GMP batch of MarzAA at a larger scale that will support our future pivotal studies and commercialization requirements. We started clinical scale manufacturing of DalcA in February 2019.

Drug Product manufacturing

We have a long-term clinical supply services agreement with Catalent Indiana, LLC ("Catalent"). Catalent has facilities in the U.S. and Europe and conducts drug product development and manufacturing for MarzAA and DalcA. At the end of 2019 we have successfully completed development work for a variety of vial sizes which will support flexible dosing and will initiate large scale engineering batches in Q1 2020.

We also work with Symbiosis Pharmaceutical Services Limited on drug product manufacturing for MarzAA on a fee-for-services basis. Symbiosis has a facility in the United Kingdom.

Commercialization

We have yet to establish a sales, marketing, or product distribution infrastructure for our product candidates, which are still in clinical development. We expect to retain commercial rights for our product candidates in the United States except for our anti-C3 dry AMD program, for which we entered into a license and collaboration agreement with Biogen to develop and commercialize CB 2782-PEG and other products or compounds that target complement Factor 3 globally. We have also granted ISU rights to commercialize DalcA in South Korea. 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.

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 single arm 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 often 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. 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 and DalcA has received orphan designation for routine prophylaxis to prevent bleeding episodes for Hemophilia B patients.

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, Orphan Drug Designation, and Breakthrough Therapy Programs

Fast Track

There are several FDA programs intended to help facilitate the development of new drugs and biologics 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.

Priority Review

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.

Accelerated Approval

A product that is being studied for safety and effectiveness in treating serious or life-threatening illnesses and provides meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that it 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 pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product.

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. 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.

MarzAA has been granted orphan drug designation in the U.S. and the E.U. for routine prophylaxis to prevent bleeding episodes in individuals with Hemophilia A and B with inhibitors. DalcA has been granted orphan drug designation in the U.S. and the E.U. for routine prophylaxis to prevent bleeding episodes for Hemophilia B patients. We may seek orphan drug designation for MarzAA and DalcA for a different indication, or other product candidates, but the FDA may disagree with our analysis of the prevalence of the particular disease or condition or other criteria for designation and refuse to grant orphan status. We cannot guarantee that we will obtain orphan drug designation or approval for any product candidate, or that we will be able to secure orphan drug exclusivity if we do obtain approval.

Break Through Designation

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 they 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.

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 USPTO, 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 (“ACA” 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 ACA 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 ACA, 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 which 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, privately 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, 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. The National Institute for Health and Care Excellence (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.

Employees

As of December 31, 2019, we had 34 full-time employees. Of the full-time employees, 21 employees are engaged in manufacturing and clinical development activities and 13 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 merged with Targacept, Inc. Our corporate headquarters are in South San Francisco, California. We conduct our research and development activities and general and administrative functions primarily from our South San Francisco, California location.

Available Information

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports, are available for free at www.catalystbiosciences.com as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. They are also available for free on the SEC's website at www.sec.gov. The information in or accessible through the SEC and our website are not incorporated into, and are not considered part of, this filing.

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 $55.2 million and $30.1 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of $258.5 million.

We are still in the early stages of development of our product candidates, and have no products approved for commercial sale. To date, we have financed our operations primarily through issuances of shares of common stock, from private placements of convertible preferred stock, and from payments under collaboration agreements.

We have devoted most of our financial resources to research and development, including our preclinical and clinical development activities. We expect to continue to incur significant expenses and operating losses over the next several years as we continue clinical development of MarzAA and DalcA and continue research and development of other product candidates. 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;
- further develop the manufacturing process for our product candidates;
- continue research and development of anti-complement 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, develop 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 we may enter;

- 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 license agreement with ISU, the Company will also make up to an aggregate of $19.5 million in milestone payments to ISU, 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.

In connection with our collaboration with Mosaic Biosciences, Inc. regarding our anti-complement program, we have agreed to pay Mosaic a double-digit percentage of funds we receive from Biogen or other sublicensees, or certain milestone payments and royalties if we develop and commercialize products from the collaboration ourselves.

Further, in connection with the development and manufacturing agreement that we have with AGC, we have firm work orders with AGC to manufacture MarzAA and DalcA to support our clinical trials totaling $12.4 million and the payment obligations remaining at December 31, 2019 was $4.6 million. Furthermore, in connection with the clinical supply services agreement we have with Catalent, we have firm work orders with Catalent to manufacture DalcA to support its clinical trial totaling $0.5 million and the payment obligations remaining at December 31, 2019 was $0.4 million. 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 our common stock 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 our common stock 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 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, or other product candidates, 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 January 2018, we filed a shelf registration statement with the SEC, which registration statement was declared effective on February 6, 2018 and which allowed us to offer up to $150 million of securities from time to time in one or more offerings (the "January 2018 Registration Statement"). In February 2018, we sold an aggregate of 3,382,352 registered shares of common stock at a price of $34.00 per share, for net proceeds, after deducting underwriting discounts and offering expenses, 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 which allowed us to offer up to $200 million of securities from time to time in one or more offerings (the "December 2018 Registration Statement"). In February 2020, we sold an aggregate of 5,307,692 registered shares of common stock at $6.50 per share, for net proceeds, after deducting underwriting discounts and offering expenses, of approximately $32.0 million. Pursuant to the December 2018 Registration Statement, we may sell up to approximately $165 million in additional securities in one or more offerings.

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

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

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, establishing collaborations and conducting Phase 2 clinical trials on small numbers of patients. We have not yet demonstrated an ability to successfully conduct a Phase 3 clinical trial, obtain marketing approvals, manufacture a product at commercial scale repeatedly, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about the Company's future product development timelines, clinical trial plans, expenses, 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. MarzAA has completed a Phase 2 open-label SQ trial in eleven patients and we are currently completing a Phase 2b open-label trial of DalcA in six patients. We reported interim data from this trial at EAHAD on February 7, 2020. Data from the trial showed that 28 days of daily SQ dosing of DalcA achieved protective target Factor IX levels of >12%, with steady state Factor IX levels of up to 27% after 14 days with no bleeds, demonstrating effective prophylaxis and the potential for lower or less frequent dosing. One subject withdrew on day 7. No anti-drug antibodies were detected and no serious adverse events were reported. Three subjects reported injection site reactions ("ISRs"), the majority of which were mild in severity and resolved without sequelae. We have completed enrollment for the Phase 2b study and expect to report final data in Q2 2020.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. If 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. Each product candidate requires 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 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. The regulatory path for MarzAA and DalcA is uncertain. 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 has completed a Phase 2 clinical trial and DalcA is completing a Phase 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 or EMA 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, EMA or other foreign regulatory agencies to support marketing approval. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical studies and clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities;
- launching commercial sales of the products, if and when approved, whether alone or in collaboration with others;
- acceptance of the products, if and when approved, by patients, the medical community and third-party payors;

- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement;
- protecting our rights in our intellectual property portfolio; and
- maintaining a continued acceptable safety profile of the products following approval.

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

Clinical drug development involves a lengthy and expensive process with an uncertain outcome. Results from our successful Phase 1 or Phase 2 trials may not be confirmed in later trials, and if serious adverse or unacceptable side effects are identified during the development of our product candidates, we may need to abandon or limit our development of some of our product candidates.

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

In addition, the outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials. Our Phase 2 trial of MarzAA was conducted in eleven patients, and DalcA has been dosed repeatedly in a subcutaneous prophylaxis trial in only six 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 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 enrollment 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

Our collaboration with Biogen may not result in successful product development or payments to us.

We have entered into a collaboration and license agreement with Biogen to develop and commercialize CB 2782-PEG and our other anti-C3 proteases for potential treatment of dry AMD and other disorders. We will perform pre-clinical and manufacturing activities, and Biogen will be solely responsible for funding the pre-clinical and manufacturing activities and performing IND-enabling activities, worldwide clinical development, and commercialization. Future revenues from this collaboration depend upon the achievement of milestones and payment of royalties based on product sales after successful product development and regulatory approval. Biogen can terminate this agreement on 60 days' prior written notice. If Biogen terminates the agreement, our reputation in the business and scientific community may suffer and we will not receive payments from them after termination. If milestones are not achieved or Biogen is unable to successfully develop and commercialize products from which milestones and royalties are payable, we will not earn the revenues contemplated by the collaboration.

We have limited or no control over the resources that Biogen may devote to the development and commercialization of products under our agreement. Biogen may not perform its obligations as expected or may breach or terminate the agreement with us or otherwise fail to conduct research, development or commercialization activities successfully or in a timely manner. Further, Biogen may elect not to develop pharmaceutical products arising out of our collaborative arrangement or may not devote sufficient resources to the development, regulatory approval, manufacture, marketing or sale of these products. If any of these events occurs, we may not receive collaboration revenue or otherwise realize anticipated benefits from such collaborations, our product development efforts may be delayed and our business, operating results and financial condition could be adversely affected.

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, to contribute to the development of our product candidates, and we are currently working with Biogen and 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 other complement mediated diseases 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 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.

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 executive management and scientific personnel. 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 us. to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans that, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Risks related to our intellectual property

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

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. Third parties may challenge the validity, enforceability or scope of our patents, which 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 USPTO, 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. 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. There is a 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.

We are aware of a patent family that includes issued patents in the United States, Australia, and Japan, and pending applications in Europe and Canada. The patents and pending applications may include claims that may read on a contemplated FXa clinical candidate. There is prior art that we believe discloses subject matter on which a challenge to the patentability of such claims can be based. In the event that development of the FXa candidate is pursued we would, if necessary, consider appropriate action to challenge such claims.

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, which 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.

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 has completed a Phase 2 clinical trial, and DalcA is completing a Phase 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 Current Good Manufacturing Practice ("cGMPs") regulations 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 ACA, which requires manufacturers of approved 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.

Our results of operations may be adversely affected by current and potential future healthcare legislative and regulatory actions.

Legislative and regulatory actions affecting government prescription drug procurement and reimbursement programs occur relatively frequently. In the United States, the ACA was enacted in 2010 to expand healthcare coverage. Since then, numerous efforts have been made to repeal, amend or administratively limit the ACA in whole or in part. For example, the Tax Cuts and Jobs Act, signed into law by President Trump in 2017, repealed the individual health insurance mandate, which is considered a key component of the ACA. In December 2018, a Texas federal district court struck down the ACA on the grounds that the individual health insurance mandate is unconstitutional, although this ruling has been stayed pending appeal. The ongoing challenges to the ACA and new legislative proposals have resulted in uncertainty regarding the ACA's future viability and destabilization of the health insurance market. The resulting impact on our business is uncertain and could be material.

Efforts to control prescription drug prices could also have a material adverse effect on our business. For example, in 2018, President Trump and the Secretary of the U.S. Department of Health and Human Services ("HHS") released the "American Patients First Blueprint" and have begun implementing certain portions. The initiative includes proposals to increase generic drug and biosimilar competition, enable the Medicare program to negotiate drug prices more directly and improve transparency regarding drug prices and ways to lower consumers' out-of-pocket costs. The Trump administration also proposed to establish an "international pricing index" that would be used as a benchmark to determine the costs and potentially limit the reimbursement of drugs under Medicare Part B. Among other pharmaceutical manufacturer industry-related proposals, Congress has proposed bills to change the Medicare Part D benefit to impose an inflation-based rebate in Medicare Part D and to alter the benefit structure to increase manufacturer contributions in the catastrophic phase. The volume of drug pricing-related bills has dramatically increased under the current Congress, and the resulting impact on our business is uncertain and could be material.

In addition, many states have proposed or enacted legislation that seeks to indirectly or directly regulate pharmaceutical drug pricing, such as by requiring biopharmaceutical manufacturers to publicly report proprietary pricing information or to place a maximum price ceiling on pharmaceutical products purchased by state agencies. For example, in 2017, California's governor signed a prescription drug price transparency state bill into law, requiring prescription drug manufacturers to provide advance notice and explanation for price increases of certain drugs that exceed a specified threshold. Both Congress and state legislatures are considering various bills that would reform drug purchasing and price negotiations, allow greater use of utilization management tools to limit Medicare Part D coverage, facilitate the import of lower-priced drugs from outside the United States and encourage the use of generic drugs. Such initiatives and legislation may cause added pricing pressures on our products.

Changes to the Medicaid program at the federal or state level could also have a material adverse effect on our business. Proposals that could impact coverage and reimbursement of our products, including giving states more flexibility to manage drugs covered under the Medicaid program and permitting the re-importation of prescription medications from Canada or other countries, could have a material adverse effect by limiting our products' use and coverage. Furthermore, state Medicaid programs could request additional supplemental rebates on our products as a result of an increase in the federal base Medicaid rebate. To the extent that private insurers or managed care programs follow Medicaid coverage and payment developments, they could use the enactment of these increased rebates to exert pricing pressure on our products, and the adverse effects may be magnified by their adoption of lower payment schedules.

Other proposed regulatory actions affecting manufacturers could have a material adverse effect on our business. It is difficult to predict the impact, if any, of any such proposed legislative and regulatory actions or resulting state actions on the use and reimbursement of our products in the United States, but our results of operations may be adversely affected.

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; and 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. BeneFIX, a recombinant Factor IX indicated for treatment of individuals with Hemophilia B, was approved in 1997 and is marketed by Pfizer. 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). Idelvion, a Factor IX-albumin fusion product marketed by CSL Behring was approved by the FDA in 2016. Idelvion is approved for weekly dosing for adolescents and adults and bi-weekly at a higher dose for those same patients if well controlled on the original regimen. It is approved for weekly in patients <12 years of age. Novo Nordisk's glycopegylated-Factor IX product Rebinyn was approved by the FDA in 2017 but is not indicated for routine prophylaxis in the U.S. Rebinyn is approved for on-demand treatment and control of bleeding episodes as well as Perioperative management of bleeding.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 $200 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 1,577,541 shares of common stock at a weighted average exercise price of $10.85 as of December 31, 2019. 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.

Our business could be negatively affected as a result of actions of activist stockholders, and such activism could impact the trading value of our securities.

Two of our stockholders have requested that we add one or more individuals to our board of directors. Although we have entered into a cooperation agreement with one such stockholder and appointed two new members to our board of directors, one or more other stockholders could engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on our board of directors and management. Such an activist campaign could conflict with our strategic direction or seek changes in the composition of our board of directors and could have an adverse effect on our operating results and financial condition. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs, and require significant time and attention by our board of directors and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our board of directors or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business or instability which

may result in the loss of potential business opportunities, make it more difficult to pursue our strategy, or limit our ability to attract and retain qualified personnel, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our business strategy and create additional value for our stockholders. We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our board of directors and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

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

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that in the opinion of our management, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, financial condition or cash flows.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Catalyst Biosciences, Inc. is listed on the Nasdaq Capital Market under the symbol "CBIO."

Holders of Common Stock

As of February 7, 2020, 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 reference from the discussion responsive thereto under the caption "Equity Compensation Plan Information" in Item 12. Security Ownership Of Certain Beneficial Owners And Management.

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.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers.

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 fully integrated research and clinical development biopharmaceutical company with expertise in protease engineering, discovery and translational research, clinical development and manufacturing. We have a versatile protease engineering platform that feeds our research and development pipeline. Currently, we are focused on advancing and extending our Hemostasis and Complement product candidates. One of our key competitive advantages is that our systemically dosed product candidates, due to the improvements we have made using our protease engineering platform, can be delivered subcutaneously ("SQ") which is less invasive, more convenient and more efficacious than intravenous ("IV") drugs currently on the market. Our SQ product candidates demonstrate prolonged duration of activity enabling them to provide continuous therapeutic levels. The following table summarizes our current development programs.

Recent Development Program Updates

MarzAA Our most advanced product candidate is MarzAA, a potent, subcutaneously administered, next-generation Factor VIIa variant that is 'Phase 3 ready'. We completed our Phase 2 open-label SQ trial and met all our primary and secondary end points in 2019. The Phase 2 trial was designed to evaluate the efficacy of MarzAA in reducing total bleeding episodes. The primary endpoint was to assess the effect of MarzAA on the annualized bleed rate (ABR) at a subject's final dose level, with each patient's prior 6-month ABR serving as his own control. The secondary endpoints included safety, tolerability and lack of anti-drug-antibody (ADA) and neutralizing antibody formation.

Our preclinical data suggest that MarzAA has the potential to be used on-demand for treatment of acute bleeding episodes and support further clinical testing for on-demand treatment of bleeds in individuals with hemophilia or Factor VII deficiency.

Our preclinical data also indicate that MarzAA is expected to have a similar safety profile when used in combination with Hemlibra as that of NovoSeven. Specifically, as tested *in vitro* by the thrombin-generation assay with Hemophilia A plasma, both MarzAA and NovoSeven were equally effective at triggering blood coagulation at their respective clinically relevant concentrations without overshooting safe levels when combined with Hemlibra. Current therapies used with Hemlibra include FEIBA (a pro-coagulation complex) and NovoSeven. However, the concurrent administration of FEIBA with Hemlibra has been associated with thrombotic events (when a blood clot forms inside a blood vessel), requiring a boxed warning in the package insert. While NovoSeven is safe in patients on Hemlibra prophylaxis, it is administered through an IV infusion to treat a bleed. Ideally, add-on therapy for patients on SQ Hemlibra would be given subcutaneously. We believe MarzAA provides a potential SQ solution to this problem and that MarzAA could be a SQ rescue therapy for hemophilia patients experiencing breakthrough bleeds while on prophylaxis with other agents such as Hemlibra.

We are currently conducting a SQ Phase 1 study to evaluate the pharmacokinetics and pharmacodynamics in patients with Hemophilia A or B with or without inhibitors at ascending dose levels. The purpose of the trial is to determine if the timing of the peak levels achieved is sufficient to treat a breakthrough bleed with SQ dosing and determine if increasing dose levels increase blood levels in a dose proportional manner. This trial will enable final dose selection for a MarzAA Phase 3 study. We reported interim data from this trial at the 13th Annual Congress of the European Association of Haemophilia and Allied Disorders (EAHAD) on February 5, 2020 that showed SQ dosing of MarzAA reaches target levels that are consistent with the treatment of a bleed.

DalcA

Our next most advanced product candidate is DalcA, a next-generation SQ Factor IX drug for the prophylactic treatment of individuals with Hemophilia B, which is completing a Phase 2b study. We completed our Phase 1/2 SQ dosing trial that evaluated the safety and efficacy of DalcA in patients with severe Hemophilia B in a collaboration with ISU Abxis. The objective was to demonstrate the feasibility of increasing Factor IX activity trough levels from approximately 1% (severe hemophilia) to greater than 12% (mild hemophilia corresponding to a reduced risk of spontaneous joint bleeds) with daily SQ injections. DalcA maintained protective Factor IX activity levels of 12-30%. Mild to moderate injection site reactions were reported and all resolved without sequelae. Two subjects, who were cousins and had the same rare Factor IX mutation, developed nAbs, one transiently. The nAbs were specific to DalcA (did not bind to wild-type Factor IX) and therefore did not interfere with the patients' ability to resume use of their prior Factor IX therapy. Thus, the nAbs to DalcA are not referred to as inhibitors.

We completed a comprehensive investigation of the cause of the nAbs in 2018 and concluded that the immunogenic potential of DalcA was low and similar to that of commercial Factor IX products. Furthermore, the drug product quality of DalcA was shown to be comparable to commercial Factor IX products. Based on the results of the investigation, and discussions with clinicians and regulatory experts, we initiated a Phase 2b trial to assess safety and efficacy of DalcA in a 2b study that includes 28 days of daily SQ dosing in six subjects. We reported interim data from this trial at EAHAD on February 7, 2020. Data from the trial showed that 28 days of daily SQ dosing of DalcA achieved protective target Factor IX levels of >12%, with steady state Factor IX levels of up to 27% after 14 days with no bleeds, demonstrating effective prophylaxis and the potential for lower or less frequent dosing. One subject withdrew on day 7. No anti-drug antibodies were detected and no serious adverse events were reported. Three subjects reported injection site reactions (ISRs), the majority of which were mild in severity and resolved without sequelae. We have completed enrollment for the Phase 2b study and expect to report final data in Q2 2020.

Recent Collaborations

On December 18, 2019, we entered into a license and collaboration agreement with Biogen to develop and commercialize CB 2782-PEG and our other anti-C3 proteases for potential treatment of dry AMD and other disorders. We will perform pre-clinical and manufacturing activities, and Biogen will be solely responsible for funding the pre-clinical and manufacturing activities and performing IND-enabling activities, worldwide clinical development, and commercialization. We received a $15.0 million upfront payment from Biogen in January 2020 for the transfer of an exclusive license and the related know-how, and we are eligible to receive up to $340 million in milestone payments, along with tiered royalties for worldwide net sales of this product candidate up to low double-digits. As of December 31, 2019, the Company has recorded the $15.0 million payment in deferred revenue.

We also collaborated with Mosaic in the development of our complement product candidates including CB 2782-PEG. Under the collaboration agreement, as amended in December 2019, Mosaic will perform all future services for a fee. Mosaic is entitled to a double-digit percentage of funds we receive from Biogen. Mosaic is also entitled to sublicense fees and/or research and development and commercial milestones and royalties on one non-C3 complement product. 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. 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.

Recent Manufacturing Updates

Drug Substance manufacturing

We have a long-term development and manufacturing services agreement with AGC Biologics, Inc. ("AGC"). AGC has global manufacturing sites and we use their facilities in the U.S. and Europe for drug substance manufacturing of MarzAA and DalcA. We have successfully manufactured MarzAA to support our Phase 2 clinical trial and received FDA agreement that we have demonstrated comparability between our current manufacturing and that previously produced by Pfizer. In the third quarter of 2019, we also successfully completed a GMP batch of MarzAA at a larger scale that will support our future pivotal studies and commercialization requirements. We started clinical scale manufacturing of DalcA in February 2019.

Drug Product manufacturing

We have a long-term clinical supply services agreement with Catalent Indiana, LLC ("Catalent"). Catalent has facilities in the U.S. and Europe and conducts drug product development and manufacturing for MarzAA and DalcA. At the end of 2019 we successfully completed development work for a variety of vial sizes which will support flexible dosing and will initiate large scale engineering batches in Q1 2020.

Recent Financing Developments

In February 2020, we sold an aggregate of 5,307,692 registered shares of common stock at $6.50 per share, for net proceeds, after deducting underwriting discounts and offering expenses, of approximately $32.0 million.

We have no products approved for commercial sale and have not generated any revenue from product sales. From inception to December 31, 2019, 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.

We have never been profitable and have incurred significant operating losses in each year since inception. Our net losses were $13.6 million and $10.8 million for the three months ended December 31, 2019 and 2018, respectively, and $55.2 million and $30.1 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of $258.5 million. As of December 31, 2019, our cash, cash equivalents and short-term investments balance were $76.9 million. Substantially all our operating losses were incurred in our research and development programs and in our general and administrative 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. Our operating losses may fluctuate significantly from quarter to quarter and year to year due to timing of preclinical, manufacturing, clinical development programs and regulatory guidance spending.

Financial Operations Overview

Contract Revenue Contact revenue consists of revenue received from third party collaborators pursuant to agreements with them. Revenue generated in 2018 was from our collaboration with ISU. The collaboration revenue from ISU ended in 2018 per the terms of the arrangement.

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, 2019 and 2018 *(in thousands)*:

	Year Ended December 31,	
	2019	2018
Personnel costs	$ 8,284	$ 4,366
Preclinical research (1)	8,484	4,549
Clinical manufacturing (1)	26,137	12,184
Facility and overhead (1)	954	375
Total research and development expenses	$ 43,859	$ 21,474

(1) Prior year numbers have been reclassified to conform with the current year presentation.

The largest component of our total operating expenses has historically been our investment in research and development activities, including the clinical and manufacturing development of our product candidates. We are currently focusing substantially most of our resources and development efforts on MarzAA and DalcA. 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 advance the clinical and manufacturing development of MarzAA and DalcA and build out our Systemic complement inhibitors pipeline. While ISU has previously been responsible for clinical and development expenses for DalcA under our agreement with them, their funding obligations ended in 2018, and we have assumed responsibility for these expenses.

At December 31, 2019, we have firm work orders with AGC to manufacture MarzAA and DalcA to support its clinical trials totaling $12.4 million, of which $4.6 million was still outstanding. We also have firm work orders with Catalent as of December 31, 2019, to manufacture DalcA to support its clinical trial totaling $0.5 million, of which was $0.4 million was still outstanding.

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, net consist primarily of interest income on our investment portfolio.

Results of Operations

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

	Year Ended December 31,			
	2019	2018	Change ($)	Change (%)
Contract revenue	$ —	$ 6	$ (6)	(100)%
Operating expenses:				
Research and development	43,859	21,474	22,385	104%
General and administrative	13,418	12,354	1,064	9%
Total operating expenses	57,277	33,828	23,449	69%
Loss from operations	(57,277)	(33,822)	(23,455)	69%
Interest and other income, net	2,099	3,767	(1,668)	(44)%
Net loss	$ (55,178)	$ (30,055)	$ (25,123)	84%

Contract revenue

Contract revenue was $0.0 million and $0.01 million during the years ended December 31, 2019 and 2018, respectively, a decrease of $0.01 million, or 100%. The decrease was due to revenue from our ISU collaboration that ended in 2018 per terms of the arrangement. We expect contract revenue to increase in 2020 as a result of the $15.0 million upfront payment and the on-going reimbursable collaboration activities under the Biogen collaboration agreement.

Research and Development Expenses

Research and development expenses were $43.9 million and $21.5 million during the years ended December 31, 2019 and 2018, respectively, an increase of $22.4 million, or 104%. The increase was due primarily to an increase of $14.0 million in manufacturing activities, an increase of $3.9 million in personnel related expenses, including stock-based compensation, as a result of increased headcount, and an increase of $3.9 million in complement and other preclinical research.

Based on our current programs and related commitments, we expect our research and development expenses for the year ending December 31, 2020 to increase materially compared with 2019, due primarily to costs associated with furthering clinical trials and manufacturing for MarzAA and DalcA.

General and Administrative Expenses

General and administrative expenses were $13.4 million and $12.4 million during the years ended December 31, 2019 and 2018, respectively, an increase of $1.0 million, or 9%. The increase was due primarily to an increase of $0.9 million in personnel-related costs, including stock-based compensation, as a result of increased headcount, and an increase of $0.3 million in D&O insurance premium; partially offset by a $0.1 million decrease in professional fees due to fewer corporate transactions in 2019.

Interest and Other Income, Net

Interest and other income, net, was $2.1 million and $3.8 million during the years ended December 31, 2019 and 2018, respectively, a decrease of $1.7 million, or 44%. The decrease was due primarily to a $1.5 million milestone payment received from the sale of an NNR asset in 2018, and the absence of similar transactions in 2019.

Recent Accounting Pronouncements

Refer to Note 3 to our consolidated financial statements included within Item 8 of this Annual Report on Form 10-K for a description of recent accounting pronouncements adopted and not yet adopted for the year ended December 31, 2019.

Liquidity and Capital Resources

As of December 31, 2019, we had $76.9 million of cash, cash equivalents and short-term investments. During the year ended December 31, 2019, we had a $55.2 million net loss and $43.6 million cash used in operating activities. We have an accumulated deficit of $258.5 million as of December 31, 2019. 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. We have effective registration statements on Form S-3 that enable us to sell up to $200.0 million in securities. The sale of additional equity or convertible debt could result in additional dilution to our stockholders. The incurrence of indebtedness would result in debt service obligations and could result in operating and financing covenants that would restrict our operations. Licensing transactions, collaborations or strategic partnerships may result in us relinquishing valuable rights. We can provide no assurance that financing will be available in the amounts we need or on terms acceptable to us, if at all. If we are not able to secure adequate additional funding we may be forced to delay, make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially harm our business.

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

	Year Ended December 31,	
	2019	2018
Cash used in operating activities	$ (43,613)	$ (28,553)
Cash provided by (used in) investing activities	27,392	(71,321)
Cash provided by financing activities	327	111,332
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (15,894)	$ 11,458

Cash Flows from Operating Activities

Cash used in operating activities for the year ended December 31, 2019 was $43.6 million, primarily due to a net loss of $55.2 million, partially offset by non-cash charges of $3.4 million and cash used in operating activities reflected a net change in our net operating assets and liabilities of $8.2 million: primarily due to a $15.0 million increase in deferred revenue related to the upfront payment from Biogen, a $5.6 million increase in accrued compensation and other accrued liabilities, and a $3.0 million increase in accounts payable, partially offset by a $15.0 million increase in accounts receivable related to the upfront payment from Biogen, and a $0.5 million increase in prepaid and other assets.

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

Cash Flows from Investing Activities

Cash provided by investing activities for the year ended December 31, 2019 was $27.4 million, primarily due to $157.4 million in proceeds from maturities of investments, partially offset by $130.0 million in purchases of investments.

Cash used in investing activities for the year ended December 31, 2018 was $71.3 million, primarily due 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 flows from Financing Activities

Cash provided by financing activities for the year ended December 31, 2019 was $0.3 million due to proceeds from the issuance of common stock from stock grants and option exercises.

Cash provided by financing activities for the year ended December 31, 2018 was $111.3 million, primarily due 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.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Critical Accounting Polices and Estimates

The preparation of the consolidated 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 3 "Summary of Significant Accounting Policies" of the Notes to the 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

License and Collaboration Arrangements

Effective January 1, 2018, we adopted Accounting Standards Codification ("ASC") 606 using the modified retrospective method and applied the standard only to contracts that were still active or in place at that date.

We may enter into collaboration arrangements that fall under the scope Collaborative Arrangements (Topic 808) ("ASC 808"). We analyze collaboration arrangements to assess whether they are within the scope of ASC 808 to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. The accounting for some of the activities under collaboration arrangements may be analogized to ASC 606 for distinct units of accounting that are reflective of a vendor-customer relationship.

Under ASC 606, in determining the appropriate amount of revenue to be recognized as we fulfill our 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.

If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues attributed to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, we use our judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time.

At the inception of each arrangement that contains development milestones, we evaluate whether the development milestones included are considered probable of being reached and estimate 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. Milestone payments that are not within our control or the licensee, such as regulatory approvals, are not generally considered probable of being achieved until those approvals are received.

At the end of each reporting period, we re-evaluate the probability of achievement of any development milestones, and if necessary, adjust its estimate of the transaction price. Any such adjustments would be recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment. For research and development services, we elected the practical expedient to recognize revenue as the research and development services are invoiced.

The transaction price is allocated to each performance obligation on a relative stand-alone selling price (“SSP”) basis. We recognize revenue as or when the performance obligations under the contract are satisfied. As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the timing of recognition and the SSP for each performance obligation identified in the contract.

The SSP 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 the SSP for research and development services, 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 stock-based compensation expense only for those stock-based awards that are expected to vest, over their requisite service period, based on the vesting provisions of the individual grants. See Note 10 to our consolidated financial statements included in this Annual Report on Form 10-K for more information.

Leases

On January 1, 2019, we adopted the new lease accounting standard ASC 842 using the optional transition method under which comparative financial information is not restated and continues to apply the provisions of the previous lease accounting standard in its financial disclosures for the comparative periods. We also elected relevant optional practical expedients including 1) did not reassess whether expired or existing contracts are or contain a lease, 2) did not reassess the lease classifications or reassess the initial direct costs associated with expired or existing leases, and 3) did not separate lease and non-lease components of its operating leases in which it is the lessee.

Under the new lease accounting standard, at the inception of an arrangement, we determine whether the arrangement is or contains a lease based on the unique facts and circumstances present. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, we utilize our incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received.

We have elected to combine lease and non-lease components as a single component. The lease expense is recognized over the expected term on a straight-line basis. Operating leases are recognized on the balance sheet as right-of-use assets, operating lease liabilities, current and operating lease liabilities, non-current. As a result, we no longer recognize deferred rent on the balance sheet.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

CATALYST BIOSCIENCES, INC.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Catalyst Biosciences, Inc. (the “Company") as of December 31, 2019 and 2018, 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, 2019 and 2018 and the consolidated results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

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, 2019, 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 February 20, 2020 expressed an unqualified opinion.

Change in Accounting Principle

As discussed in Note 3 to the financial statements, the Company has changed its method of accounting for leases in the 2019 consolidated financial statements due to the adoption of ASU No. 2016-02, Leases (Topic 842).

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
February 20, 2020

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

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 15,369	$ 31,213
Short-term investments	61,496	88,914
Restricted cash	—	50
Accounts receivable	15,000	—
Prepaid and other current assets	4,201	3,814
Total current assets	96,066	123,991
Other assets, noncurrent	257	543
Right-of-use assets	1,927	—
Property and equipment, net of $0.4 million and $0.3 million of accumulated depreciation in 2019 and 2018, respectively	304	386
Total assets	$ 98,554	$ 124,920
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,279	$ 1,248
Accrued compensation	2,106	1,495
Deferred revenue	15,000	—
Other accrued liabilities	7,031	2,043
Operating lease liability	483	—
Deferred rent, current portion	—	15
Total current liabilities	28,899	4,801
Operating lease liability, noncurrent	1,319	—
Deferred rent, noncurrent portion	—	174
Total liabilities	30,218	4,975
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized; zero shares issued and outstanding	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized; 12,040,835 and 11,954,528 shares issued and outstanding at December 31, 2019 and 2018, respectively	12	12
Additional paid-in capital	326,810	323,279
Accumulated other comprehensive income (loss)	34	(4)
Accumulated deficit	(258,520)	(203,342)
Total stockholders' equity	68,336	119,945
Total liabilities and stockholders' equity	$ 98,554	$ 124,920

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

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

	Year Ended December 31,	
	2019	2018
Contract revenue	$ —	$ 6
Operating expenses:		
Research and development	43,859	21,474
General and administrative	13,418	12,354
Total operating expenses	57,277	33,828
Loss from operations	(57,277)	(33,822)
Interest and other income, net	2,099	3,767
Net loss	$ (55,178)	$ (30,055)
Net loss per share attributable to common stockholders, basic and diluted	$ (4.60)	$ (2.68)
Shares used to compute net loss per share attributable to common stockholders, basic and diluted	12,004,489	11,213,884

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

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

	Year Ended December 31,	
	2019	2018
Net loss	$ (55,178)	$ (30,055)
Other comprehensive income (loss):		
Unrealized gain (loss) on available-for-sale debt securities	38	(4)
Total comprehensive loss	$ (55,140)	$ (30,059)

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	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
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	—	—	6,790	—	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 option exercises	—	—	12,716	—	107	—	—	107
Conversion of redeemable convertible notes to common stock	—	—	21	—	3	—	—	3
Unrealized loss on available-for-sale debt 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
Stock-based compensation expense	—	—	24,235	—	3,204	—	—	3,204
Issuance of common stock from stock grants and option exercises	—	—	62,072	—	327	—	—	327
Unrealized gain on available-for-sale debt securities	—	—	—	—	—	38	—	38
Net loss	—	—	—	—	—	—	(55,178)	(55,178)
Balance at December 31, 2019	—	$ —	12,040,835	$ 12	$ 326,810	$ 34	$ (258,520)	$ 68,336

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

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

	Year Ended December 31,	
	2019	**2018**
Operating Activities		
Net loss	$ (55,178)	$ (30,055)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,204	2,606
Depreciation and amortization	146	149
Loss on disposal of property and equipment	—	116
Changes in operating assets and liabilities:		
Accounts receivable	(15,000)	—
Prepaid and other assets	(490)	(2,895)
Accounts payable	3,031	500
Accrued compensation and other accrued liabilities	5,599	850
Operating lease liability and right-of-use asset	75	—
Deferred revenue	15,000	(6)
Deferred rent	—	182
Net cash flows used in operating activities	(43,613)	(28,553)
Investing Activities		
Proceeds from maturities of short-term investments	157,433	127,967
Purchase of short-term investments	(129,977)	(198,912)
Purchases of property and equipment	(64)	(376)
Net cash flows provided by (used in) investing activities	27,392	(71,321)
Financing Activities		
Payments for the redemption of redeemable convertible notes	—	(5,082)
Issuance of common stock for secondary public offering, net of issuance costs	—	106,762
Issuance of common stock from stock grants and option exercises	327	107
Proceeds from exercise of warrants	—	9,545
Net cash flows provided by financing activities	327	111,332
Net (decrease) increase in cash, cash equivalents and restricted cash	(15,894)	11,458
Cash, cash equivalents and restricted cash at beginning of the period	31,263	19,805
Cash, cash equivalents and restricted cash at end of the period(a)	$ 15,369	$ 31,263
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Adoption of ASC 606	$ —	$ 207
Conversion of redeemable convertible notes to common stock	$ —	$ 3
Right-of-use asset and operating lease liability recorded upon the adoption of ASC 842	$ 2,052	$ —
(a) The following table provides a reconciliation of cash and restricted cash to amounts reported within the consolidated balance sheets:		
Cash and cash equivalents	$ 15,369	$ 31,213
Restricted cash	—	50
Total cash and restricted cash	$ 15,369	$ 31,263

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 biopharmaceutical company focused on developing novel treatments for hemophilia and other rare bleeding disorders using its engineered subcutaneous (SQ) coagulation factors that promote blood clotting. The Company is located in South San Francisco, California and operates in one segment.

2. Liquidity

The Company had a net loss of $55.2 million for the year ended December 31, 2019 and an accumulated deficit of $258.5 million as of December 31, 2019. The Company expects to continue to incur losses for the next several years. As of December 31, 2019, the Company had $76.9 million of cash, cash equivalents and short-term investments. Its primary uses of cash are to fund operating expenses, including research and development expenditures and general and administrative expenditures. Based on the current status of its research and development plans, the Company believes that its existing cash, cash equivalents and short-term investments as of December 31, 2019 will be sufficient to fund its cash requirements for at least the next 12 months from the date of the filing of this report. If, at any time, the Company’s prospects for financing its research and development programs decline, the Company may decide to reduce research and development expenses by delaying, discontinuing or reducing its funding of one or more of its research or development programs. Alternatively, the Company might raise funds through strategic collaborations, public or private financings or other arrangements. Such funding, if needed, may not be available on favorable terms, or at all.

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, if applicable, 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

Leases

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), to enhance the transparency and comparability of financial reporting related to leasing arrangements. The Company adopted the standard effective January 1, 2019 using the optional transition method and applied the standard only to leases that existed at that date. Under the optional transition method, the Company does not need to restate the comparative periods in transition and will continue to present financial information and disclosures for periods before January 1, 2019 in accordance with ASC Topic 840. The Company also elected relevant optional practical expedients including that the Company did not (1) reassess whether expired or existing contracts are or contain a lease, (2) reassess the lease classifications or reassess the initial direct costs associated with expired or existing leases, and (3) separate lease and non-lease components of its operating leases in which it is the lessee. The adoption of the new lease accounting standard had an impact of approximately $2.1 million on the Company's assets and liabilities on January 1, 2019 and had no impact on cash provided by or used in operating, investing or financing activities on the Company's consolidated statements of cash flows. The adoption of the new lease accounting standard did not impact previously reported financial results.

Financial Instruments

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 consolidated financial statements, as the Company only has debt securities in its investment portfolio.

Revenue from Contracts with Customers

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASC 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 related standards: 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 ASU No. 2014-09 effective January 1, 2018, using the modified retrospective method through a cumulative adjustment to equity. The Company identified one active collaboration arrangement with multiple deliverables at that time, see Note 12. Under the superseded guidance, deliverables and consideration under the collaboration agreement 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 ASU No. 2014-09, 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 from the collaboration arrangement of $0.2 million was adjusted to record in an early accounting period upon the adoption of ASU No. 2014-09 as an increase to the Company's opening balance of accumulated deficit.

Classification of certain cash receipts and cash payments in the statement of cash flows

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.

New Accounting Pronouncements – Issued But Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, Measurement of Credit Losses on Financial Instruments, or ASU 2016-13. The main objective of ASU 2016-13 is to provide financial statement users with more decision-useful information about an entity's expected credit losses on financial instruments and other commitments to extend credit at each reporting date. To achieve this objective, the amendments in this update replace the incurred loss impairment methodology currently used today with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to develop credit loss estimates. Subsequent to issuing ASU 2016-13, the FASB issued ASU 2018-19, Codification Improvements to Topic 326, Financial Instruments – Credit Losses, for the purpose of clarifying certain aspects of ASU 2016-13. In May 2019, the FASB issued ASU 2019-05, Financial Instruments – Credit Losses (Topic 326): Targeted Transition Relief, to provide entities with more flexibility in applying the fair value option on adoption of the credit impairment standard. ASU 2018-19 and ASU 2019-05 have the same effective date and transition requirements as ASU 2016-13. ASU 2016-13 will be effective for all entities except public companies that are not smaller reporting companies for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, using a modified retrospective approach. Early adoption is permitted. The Company plans to adopt ASU 2016-13 and related updates as of January 1, 2023. The Company will assess the impact of adoption of this standard on its consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, Collaborative Arrangements (Topic 808) ("ASC 808"): Clarifying the Interaction Between Topic 808 and Topic 606. The amended guidance precludes presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. The new guidance is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted. The Company plans to adopt ASU 2018-18 as of January 1, 2020. The Company does not expect the adoption of ASU 2018-18 to have a material impact on its consolidated financial statements.

Cash and Cash Equivalents

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

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 consolidated 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

The Company invests its excess cash in investment grade, short to intermediate-term, fixed income securities and recognizes purchased securities on the settlement date. All investments have been classified as "available-for-sale" and are carried at estimated fair value 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 on available-for-sale debt securities 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 debt securities are included in interest and other income, net. The cost of securities sold is based on the specific-identification method. Interest on short-term investments is included in interest and other income, net.

Revenue Recognition

License and Collaboration Arrangements

Effective January 1, 2018, the Company adopted Accounting Standards Codification ("ASC") 606 using the modified retrospective method and applied the standard only to contracts that were still active or in place at that date.

The Company may enter into collaboration arrangements that fall under the scope Collaborative Arrangements (Topic 808). The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808 to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. The accounting for some of the activities under collaboration arrangements may be analogized to ASC 606 for distinct units of account that are reflective of a vendor-customer relationship.

Under ASC 606, 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.

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues attributed to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time.

At the inception of each arrangement that contain development milestones, the Company evaluates whether the development milestones included 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. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not generally considered probable of being achieved until those approvals are received.

At the end of each reporting period, the Company re-evaluates the probability of achievement of any development milestones, and if necessary, adjusts its estimate of the transaction price. Any such adjustments would be recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment. For research and development services, the Company elected the practical expedient to recognize revenue as the research and development services are invoiced.

The transaction price is allocated to each performance obligation on a relative stand-alone selling price ("SSP") basis. The Company recognizes revenue as or when the performance obligations under the contract are satisfied. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the timing of recognition and the SSP for each performance obligation identified in the contract.

The SSP 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 the SSP for research and development services, the Company uses a cost-plus margin approach. As of December 31, 2019, the Company recorded $15.0 million of deferred revenue from a license and collaboration agreement that was executed on December 18, 2019. See Note 12.

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, 2019 and 2018, the Company recorded a reduction to research and development expenses of $0.0 million and $0.05 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 high quality of investment and investment duration. 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 as of December 31, 2019 of $15.0 million was due from one party, see Note 12. The amount was subsequently received in full.

Contract Balances

Amounts payable to the Company are recorded as accounts receivable when the Company's right to consideration is unconditional. Customer payments are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until the Company performs its obligations under the arrangements. The Company regularly reviews the outstanding accounts receivable, including consideration of factors such as the age of the receivable balance. As of December 31, there was no allowance for doubtful accounts deemed necessary.

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, non-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, non-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, Improvements to Employee Share-Based Payment Accounting, 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.

Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes its incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received.

The Company has elected to combine lease and non-lease components as a single component. The lease expense is recognized over the expected term on a straight-line basis. Operating leases are recognized on the balance sheet as right-of-use assets, operating lease liabilities, current and operating lease liabilities, non-current.

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.

Reclassification

Certain amounts for the year ended December 31, 2018 have been reclassified, to be consistent with the current year's presentation.

4. Fair Value Measurements

For a description of the fair value hierarchy and fair value methodology, see "*Note 3 – Summary of Significant Accounting Policies*". As of December 31, 2019 and 2018, 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. U.S. 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.

The following tables present the fair value hierarchy for assets and liabilities measured at fair value on a recurring basis as of December 31, 2019 and 2018 *(in thousands)*:

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds(1)	$ 15,369	$ —	$ —	$ 15,369
U.S. government agency securities(2)	51,490	—	—	51,490
Federal agency securities(2)	—	10,006	—	10,006
Total financial assets	$ 66,859	$ 10,006	$ —	$ 76,865

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

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

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

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

(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 sheet and are classified as available-for-sale debt 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)*:

December 31, 2019	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds (cash equivalents)	$ 15,369	$ —	$ —	$ 15,369
U.S. government agency securities	51,467	23	—	51,490
Federal agency securities	9,995	11	—	10,006
Total financial assets	$ 76,831	$ 34	$ —	$ 76,865
Classified as:				
Cash and cash equivalents				$ 15,369
Short-term investments				61,496
				$ 76,865

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

As of December 31, 2019, the remaining contractual maturities of available-for-sale debt securities was less than one year. There have been no material realized gains or losses on available-for-sale debt securities for the periods presented. The carrying amounts of cash, other assets, accounts receivable, accounts payable and other payables approximate their fair values due to the short-term maturity of these instruments.

6. Other Accrued Liabilities

Other accrued liabilities consisted of the following *(in thousands)*:

	Year Ended December 31,	
	2019	2018
Manufacturing	$ 4,320	$ 1,012
Professional and consulting services	2,026	597
Clinical	435	234
Other	250	200
Total other accrued liabilities	$ 7,031	$ 2,043

7. Commitments and Contingencies

Manufacturing Agreements

On May 20, 2016, the Company signed a development and manufacturing services agreement with AGC Biologics, Inc. (“AGC”), formerly known as CMC ICOS Biologics, Inc., pursuant to which AGC will conduct manufacturing development of agreed upon product candidates. The Company had firm work orders with AGC to manufacture MarzAA and DalcA to support its clinical trials totaling $12.4 million at December 31, 2019 and the payment obligations remaining was $4.6 million.

On October 9, 2019, the Company and Catalent Indiana, LLC (“Catalent”) signed a clinical supply services agreement, effective October 4, 2019, pursuant to which Catalent will conduct drug product development of agreed upon product candidates. The Company currently has firm work orders with Catalent to manufacture DalcA to support its clinical trial totaling $0.5 million and the payment obligations remaining at December 31, 2019 was $0.4 million.

Collaborative Agreements

The Company has committed to make potential future sublicense, milestone, and royalty payments to collaborative partners as part of licensing and development programs. The Company is unable to determine precisely when and if its payment obligations under the agreements will become due as these obligations are based on uncertain events, the achievement of which is subject to a significant number of risks and uncertainties. Because it is uncertain if and when these milestones will be achieved, such contingencies are not recorded until become probable. See Note 8.

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 Age-related Macular Degeneration (AMD) and other retinal diseases. Dr. Usman, the Company's Chief Executive Officer and a member of the Company's board of directors, and Mr. Lawlor, a member of the Company's board of directors, are also members of the board of directors of Mosaic. 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 co-funded certain research. Expenses related to the co-funded research were $1.1 million and $1.3 million for the years ended December 31, 2019 and 2018, respectively.

On December 18, 2019, the Company entered into the second amendment to the Mosaic collaboration agreement, which added future fees for services upon completion of the co-funded research. Also, Mosaic will perform all future services for a fee. Mosaic is entitled to a low double-digit percentage of funds the Company receives from any C3 collaboration. Mosaic is also entitled to sublicense fees and/or research and development and commercial milestones and royalties on one non-C3 complement product. In connection with the Biogen collaboration, the Company received a $15.0 million upfront license fee on January 10, 2020, see Note 12, and Mosaic is entitled to a $3 million payment from the Company.

9. Leases

The Company leases office space for its corporate headquarters, located in South San Francisco, CA. The lease term is through April 30, 2023 and there are no stated renewal options. Operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term. In calculating the present value of the lease payments, the Company has elected to utilize its incremental borrowing rate based on the original lease term and not the remaining lease term. The lease includes non-lease components (*e.g.*, common area maintenance) that are paid separately from rent based on actual costs incurred and therefore were not included in the right-of-use asset and lease liability but are reflected as an expense in the period incurred.

For the year ended December 31, 2019, the Company's operating lease expense was $0.6 million. The present value assumptions used in calculating the present value of the lease payments were as follows:

Weighted-average remaining lease term	3.33 years
Weighted-average discount rate	6.0%

The maturity of the Company's operating lease liabilities as of December 31, 2019 were as follows *(in thousands):*

Undiscounted lease payments	**Operating Leases**
2020	$ 578
2021	596
2022	613
2023	209
Total undiscounted lease payments	$ 1,996
Less: imputed interest	(194)
Total operating lease liability	1,802
Less: current portion of operating lease liability	483
Operating lease liability, noncurrent	$ 1,319

Supplemental cash flow information for the year ended December 31, 2019 related to operating leases was as follows *(in thousands)*:

Cash paid for leases that were included in operating cash outflows	$	562

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, 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	1,361,977	$	12.04	8.71	$	2,294
Options granted	450,900	$	7.85			
Options exercised	(41,219)	$	4.57		$	159
Options forfeited	(182,722)	$	8.36			
Options expired	(11,395)	$	96.49			
Outstanding — December 31, 2019	1,577,541	$	10.85	8.15	$	1,350
Exercisable — December 31, 2019	740,356	$	13.30			
Shares available to be granted — December 31, 2019	1,014,126					

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 5.98 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 fair value of employee stock options was estimated using the following weighted-average assumptions for the year ended December 31, 2019 and 2018:

	Year Ended December 31,	
	2019	2018
Employee Stock Options:		
Expected term (in years)	5.98	6.04
Risk-free interest rate	2.35%	2.67%
Dividend yield	—	—
Volatility	90.81%	92.61%
Weighted-average fair value of stock options granted	$ 5.85	$ 9.97

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

	Year Ended December 31,	
	2019	2018
Research and development	$ 1,052	$ 606
General and administrative (1)	2,152	2,000
Total stock-based compensation	$ 3,204	$ 2,606

(1) Included $0.03 and $0.1 million related to modifications of certain Board member stock options in the years ended December 31, 2019 and 2018, respectively. These modifications extended the post-termination exercise period of certain options.

Also included in general and administrative stock-based compensation for the year ended December 31, 2019 and 2018 is expense related to 24,235 and 6,790 shares of common stock issued to certain board members in lieu of their cash compensation, respectively.

As of December 31, 2019, 1,014,126 shares of common stock were available for future grant and 1,577,541 options to purchase shares of common stock were outstanding. As of December 31, 2019, the Company had unrecognized employee stock-based compensation expense of $5.3 million, related to unvested stock option awards, which is expected to be recognized over an estimated weighted-average period of 2.41 years.

2018 Employee Stock Purchase Plan

In June 2018, the Company's stockholders approved the 2018 Employee Stock Purchase Plan (the "ESPP"). The 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 9th and August 9th 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.

The Company's ESPP is subject to an Evergreen provision which shares may be added to the pool as needed. As of December 31, 2019, a total of 239,545 shares of common stock may be granted in accordance with the terms of the ESPP. As of December 31, 2019, 20,853 shares of common stock have been issued to employees participating in the ESPP and 218,692 shares are available for issuance under the ESPP. Compensation expense, using Black-Scholes, for the ESPP was $0.1 million and $0.03 million as of December 31, 2019 and 2018, respectively, and is included in stock-based compensation expense.

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, 2019 and 2018 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, 2019 and 2018 are as follows:

	Year Ended December 31,	
	2019	2018
Tax at statutory federal rate	-21.00%	-21.00%
State Tax (benefit)—net of federal benefit	-0.06%	-0.03%
Permanent differences	0.43%	0.68%
Tax credits	-11.20%	-0.76%
Derecognition due to Sec. 382 and 383 limitations	0.00%	-20.16%
Change in valuation allowance	31.20%	39.33%
Other	0.63%	1.94%
Effective tax rate	0.00%	0.00%

Significant components of the Company's deferred tax assets as of December 31, 2019 and 2018 consist of the following *(in thousands)*:

	Year Ended December 31,	
	2019	2018
Deferred tax assets:		
Accruals and reserves	$ 936	$ 751
Net operating loss carry forwards	34,392	23,559
Tax credit carry forwards	9,945	3,772
Fixed and intangible assets	10	3
Valuation allowance	(45,283)	(28,085)
Net deferred tax assets:	**$ —**	**$ —**

Based on the available objective evidence at December 31, 2019, 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, 2019 and 2018.

As of December 31, 2019, after consideration of certain limitations (see below), the Company had approximately $163.8 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. The federal net operating loss carryforward includes $80.1 million that have an indefinite life.

As of December 31, 2019, the Company also had tax credit carry forwards available to offset future tax liabilities of approximately $6.2 million for federal and $4.7 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 percent 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.

The Company had approximately $1.9 million and $1.6 million of unrecognized tax benefits as of December 31, 2019 and 2018, 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)*:

Beginning Balance at January 1, 2018	**$**	**1,475**
Increase/(Decrease) of unrecognized tax benefits taken in prior years		13
Increase/(Decrease) of unrecognized tax benefits related to current year		85
Ending Balance at December 31, 2018	**$**	**1,573**
Increase/(Decrease) of unrecognized tax benefits taken in prior years		45
Increase/(Decrease) of unrecognized tax benefits related to current year		253
Ending Balance at December 31, 2019	**$**	**1,871**

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, 2019 and 2018, the Company had not recognized any tax-related penalties or interest in its consolidated financial statements.

The Company files income tax returns in the United States federal, California, and New Jersey state jurisdictions. The Company is not currently under examination by income tax authorities in federal, state or other jurisdictions. As of December 31, 2019 and 2018, 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

In 2009, the Company licensed MarzAA to Wyeth Pharmaceuticals, Inc. (Wyeth). Wyeth was subsequently acquired by Pfizer who terminated the license and collaboration agreement after completing an IV Phase 1 trial. Pursuant to the collaboration termination agreement entered on December 8, 2016, in exchange for the rights to certain Pfizer technology, 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 $1.0 million milestone payment based on the dosing of the first patient in the ongoing Phase 2 study; the amount was recorded as a research and development expense for the year ended December 31, 2018. No additional payments were made to Pfizer for the year ended December 31, 2019.

ISU Abxis

The Company collaborated with ISU Abxis (ISU), in the early development of DalcA. Under the collaboration agreement, ISU conducted the Phase I clinical trial of DalcA and was responsible for all manufacturing activities for the Phase 1 clinical trial. In December 2018, the Company entered into an amended and restated license agreement with ISU (the “A&R ISU Abxis Agreement”), which amended and restated its previous license and collaboration agreement with ISU previously 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 will receive commercialization rights in South Korea to the Company’s engineered Factor IX dalcinonacog alfa - 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, 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 pay up to an aggregate of $19.5 million in milestone payments to ISU, inclusive of $2.5 million in regulatory and development milestone payments and up to $17.0 million in commercial milestone payments, if the applicable milestones are met. As of December 31, 2019, the milestones have not been met.

Biogen

On December 18, 2019, the Company and Biogen International GmbH (“Biogen”) entered into a License and Collaboration Agreement (the “Biogen Agreement”), under which the Company granted Biogen a worldwide, royalty-bearing, exclusive, sublicenseable license (“Exclusive License”) to develop and commercialize CB 2782-PEG and other anti-C3 proteases for potential treatment of dry AMD and other retinal disorders. Pursuant to the Biogen Agreement, the Company will perform certain pre-clinical and manufacturing activities (“Research Services”), and Biogen will be solely responsible for funding the pre-clinical and manufacturing activities and performing IND-enabling activities, worldwide clinical development, and commercialization. The Company will provide the Research Services over a term of thirty months with Biogen having the option to extend the term for two additional twelve-month periods.

Under the terms of the Biogen Agreement, the Company received an up-front payment for the transfer of the Exclusive License (inclusive of certain know-how) of $15.0 million in January 2020. The Company is eligible to receive development milestones and sales milestones of up to $340.0 million. In addition, the Company is eligible to receive royalties in the range of single-digit to low double-digit percentage rates of annual net sales on a product-by-product and country-by-country basis. The Company will also receive reimbursements for costs associated with the performance of the Research Services.

The Company determined that the performance obligations under the Biogen Agreement were the Exclusive License and the Research Services. For the Exclusive License, the Company used the residual approach in determining the standalone selling price SSP, which includes the upfront payments, milestones and royalties. For the Research Services, the Company used the historical pricing approach for determining the SSP, which includes the reimbursement of personnel and out-of-pocket costs.

The Biogen Agreement will continue on a product-by-product and country-by-country basis until the tenth anniversary of the first commercial sale of the first product in a country, unless being early terminated by either party as specified under the agreement.

As of December 31, 2019, the Company recorded $15.0 million in accounts receivable and deferred revenue for the Exclusive License. The deferred revenue has been recognized in revenue in 2020 upon the transfer of the Exclusive License and the related know-how.

13. Interest and Other Income, Net

The following table shows the detail of interest and other income, net for the years ended December 31, 2019 and 2018 *(in thousands):*

	Year Ended December 31,	
	2019	2018
Interest income	$ 2,145	$ 2,229
Dividend income	—	4
Miscellaneous (expense) income(1)	(39)	1,650
Loss on disposal of property and equipment	—	(116)
Other	(7)	—
Total interest and other income, net	$ 2,099	$ 3,767

(1) $1.7 million miscellaneous income for the year ended December 31, 2018 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

In connection with the closing of an underwritten public offering on April 12, 2017, the Company issued Series A Preferred Stock. During the year ended December 31, 2018, 3,680 shares of the Series A Preferred Stock were converted into 736,000 shares of common stock of the Company. As of December 31, 2018, there were no shares of Series A Preferred stock issued and outstanding.

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.

In connection with the closing of the underwritten public offering on April 12, 2017, the Company also 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, 2019, the Company had no warrants outstanding associated with this offering.

The following is a summary of warrant activity for the year ended December 31, 2019 and 2018:

	Number of Shares Underlying Warrants	Weighted Average Exercise Price
Outstanding — December 31, 2017	1,751,708	$ 6.46
Issued	—	
Exercised	(1,735,419)	$ 5.50
Forfeited/Cancelled (1)	(6,095)	$ 5.50
Outstanding — December 31, 2018	10,194	$ 155.73
Issued	—	
Exercised	—	
Forfeited/Cancelled	(2,337)	$ 499.50
Outstanding — December 31, 2019	7,857	$ 53.61

(1) In November 2018, 1,845 warrants were cancelled by Healthcare Ventures VIII, a related party.

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, 2019 and 2018 *(in thousands, except share and per share data)*:

	Year Ended December 31,	
	2019	2018
Net loss	$ (55,178)	$ (30,055)
Weighted-average number of shares used in computing net loss per share, basic and diluted	12,004,489	11,213,884
Net loss per share, basic and diluted	$ (4.60)	$ (2.68)

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

	Year Ended December 31,	
	2019	2018
Options to purchase common stock	1,577,541	1,361,977
Common stock warrants	7,857	10,194
Total	1,585,398	1,372,171

16. Subsequent Event

In February 2020, the Company sold an aggregate of 5,307,692 registered shares of common stock at $6.50 per share, for net proceeds, after deducting underwriting discounts and offering expenses, of approximately $32.0 million.

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 (our principal executive officer and principal financial officer), as appropriate, to allow for timely decisions regarding required disclosure.

Our management, including the Chief Executive 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 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 Exchange Act 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, 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, 2019. 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, 2019, 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, 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, 2019 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, 2019 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
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, 2019, 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, 2019, 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, 2019 and 2018, and the related consolidated statements of operations, comprehensive loss, and stockholders' equity, and cash flows for each of the years then ended, and the related notes and our report dated February 20, 2020 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
February 20, 2020

Item 9B. Other Information

On February 19, 2020, our board of directors appointed Nassim Usman, Ph.D., our President and Chief Executive Officer, to serve as our Principal Financial Officer and Veronica Cai, our Controller, to serve as our Principal Accounting Officer.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Board of Directors

The members of our Board of Directors as of February 7, 2020, their class, positions and their respective ages on that date are:

Name	Age	Class	Position
Nassim Usman, Ph.D.	60	III	President and Chief Executive Officer
Errol B. De Souza, Ph.D.	66	III	Compensation Committee Chair
Jeff Himawan, Ph.D.	54	II	Governance and Nominating Committee Chair
Andrea Hunt	60	II	Compensation Committee Member and Governance and Nominating Committee Member
Augustine Lawlor	66	I	Chairman of the Board, Audit Committee Member, Compensation Committee Member and Governance and Nominating Committee Member
Geoffrey Ling, M.D. Ph.D.	63	I	Board of Directors
John P. Richard	62	II	Governance and Nominating Committee Member and Audit Committee Chair
Sharon Tetlow	60	III	Board of Directors
Eddie Williams	64	I	Audit Committee Member

Nassim Usman, Ph.D. served as Chief Executive Officer and a member of the board of directors of Catalyst Bio from February 2006 until the completion of the merger in August 2015. Since the merger, Dr. Usman has served as our President and Chief Executive Officer and as a Class III director. Dr. Usman is currently a Venture Partner at Morgenthaler Ventures. 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™& Onpattro™).

Dr. Usman's role as our President and Chief Executive Officer 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.

Errol B. De Souza, Ph.D. served as a member of the board of directors of Targacept from 2004 until the completion of the merger in 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 the Executive Chairman and a member of the board of directors of Bionomics Ltd, a biopharmaceutical company. Dr. De Souza has substantial experience as an executive in the biopharmaceutical industry. From March 2010 until January 2016, he served as President and Chief Executive Officer of Biodel Inc., a specialty pharmaceutical company, and from January 2017 until December 2019, he served as President, CEO and a member of the board of directors of Neuropore Therapies, Inc., a biotechnology company. Previously, Dr. De Souza also served as President and Chief Executive Officer of Archemix Corporation, a biopharmaceutical company, and as President and Chief Executive Officer of Synaptic Pharmaceutical Corp. until its sale to H. LundbeckA/S. Over Dr. De Souza's career, he has served in a number of high-ranking research and

development roles, including Senior Vice President and U.S. head of Research and Development for Aventis (now Sanofi-Aventis), Co-Founder, Executive Vice President of Research and Development and Director at Neurocrine Biosciences, Inc., and head of CNS Disease Research at DuPont Merck. Dr. De Souza received his B.A. (Honors) in Physiology and his Ph.D. in Neuroendocrinology from the University of Toronto and was postdoctoral fellow in Neuroscience at The Johns Hopkins University School of Medicine.

These experiences, together with his service as a director for other biopharmaceutical companies, 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, a biopharmaceutical company, and Horizon Pharma, a biopharmaceutical company. Dr. Himawan received his B.S. from Massachusetts Institute of Technology and his Ph.D. from Harvard University.

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.

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 her M.B.A. from the University of Michigan at Ann Arbor and her B.S. in Hospital Dietetics and B.A. in Foods & Nutrition from the University of Illinois at Urbana-Champaign.

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.

Augustine Lawlor has served as a member of our Board since February 2006 and as Chairman of the Board since February 2018. Since August 2015, Mr. Lawlor has served on our Board as a Class I director. Since January 2016, Mr. Lawlor has served as Chief Operating Officer of Leap Therapeutics, Inc., an 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 biotechnology company acquired by Millennium Pharmaceuticals Inc. in 1999. Prior to joining LeukoSite, Mr. Lawlor was Chief Financial Officer and Vice President of Corporate Development for Alpha-Beta Technologies, Inc., a company that specializes in electronics design, development, manufacturing and system obsolescence issues. He has held similar positions at both BioSurface Technologies Corporation, a company that provides products for biofilm investigations, and Armstrong Pharmaceuticals, a division of Amphastar Pharmaceuticals, Inc., a specialty pharmaceutical company. 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 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.

Geoffrey Ling, M.D., Ph.D. has served as a member of our Board since January 15, 2020 as a Class I director. Dr. Ling has been Professor of Neurology and Attending Neuro Critical Care Physician at Johns Hopkins Medical Institutions since 2000 and the Emeritus Professor of Neurology, Uniformed Services University of the Health Science since 2017. He has also been Vice-Chair of Research in the Department of Clinical Neurosciences at Inova Fairfax Medical Center, Fairfax, Virginia since 2017. In September 2016, he co-founded Predigen, Inc., a molecular diagnostics company, and since January 2016, he has served as the Chief Executive Officer of On Demand Pharmaceuticals, Inc., a company that he founded in 2016. Dr. Ling served as the Director of the Defense Advanced Research Projects Agency (DARPA) Biological Technologies Office from 2004 to 2015. Dr. Ling received a B.S. in Biology and History from Washington University, a Ph.D. in Pharmacology from Cornell University – Graduate School of Medical Sciences and an M.D. from Georgetown University School of Medicine.

Dr. Ling's experience in the healthcare industry as an executive in the pharmaceutical industry, drug development and research work for both medical and academic institutions qualify him to serve on the Board.

John P. Richard has served as a member of our Board since November 2002, and he served as Chairman of the Board from January 2014 until August 2015. Since August 2015, 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., a clinical-stage biopharmaceutical company, and previously served as an Operating Partner and Venture Partner at Phase4 Partners, a life science investment firm. 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 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. Mr. Richard received his B.S. in Industrial Engineering from Stanford University and his M.B.A. from Harvard University.

In addition, 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.

Sharon Tetlow has served as a member of our Board since January 15, 2020 as a Class III director. She has served as Managing Partner of Potrero Hill Advisors since January 2016. Potrero Hill Advisors provides strategic and operational financial support to life science companies through its team of chief financial officers and controllers. Ms. Tetlow was previously the Managing Director of Danforth Advisors, a firm that provides service offerings for life science companies, from April 2013 to January 2016. She served as Chief Financial Officer of Pathwork Diagnostics, Inc., a biotechnology company, from 2011 to 2013. From 2005 to 2009, she served as Chief Financial Officer of Cell Genesys, Inc., a biotechnology company acquired by BioSante, another life sciences company. In connection with her role as managing partner of Potrero Hill Advisors, Ms. Tetlow and her team have led the finance function at numerous biotechnology companies. Ms. Tetlow received her B.A. in Psychology from University of Delaware and her M.B.A. from Stanford University.

Ms. Tetlow's significant experience in corporate finance and strategic planning in the biotechnology and pharmaceutical industries, including her experience as chief financial officer of various publicly traded companies, qualify her to serve on the Board.

Eddie Williams has served on our Board as a Class I director since January 2018. From 2006 to January 2017, Mr. Williams served as Senior Vice President of biopharmaceuticals at Novo Nordisk Inc., a global healthcare company, 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. From 2003 to 2006, Mr. Williams was Vice President of sales in the Respiratory and Dermatology Business Unit at Novartis Pharmaceuticals Corp., a global healthcare company, where he ran all sales aspects of the respiratory and dermatology businesses. Prior to Novartis Pharmaceuticals Corp., Mr. Williams held numerous sales and marketing positions of increasing responsibility at Pharmacia & Upjohn Company, a global pharmaceutical company that was acquired by Pfizer in 2002. Mr. Williams has also 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 received his B.S. in biology and chemistry from Marshall University.

Mr. Williams brings valuable experience and insight into the hemophilia market and the pharmaceutical business.

Executive Officers

Our executive officers as of February 7, 2020, their positions and their respective ages on that date are:

Name	Age	Position
Nassim Usman, Ph.D.	60	President and Chief Executive Officer
Howard Levy, M.B.B.Ch., Ph.D., M.M.M	65	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.”

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 the global biotechnology company 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, a global healthcare company, 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, a pharmaceutical 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 received his M.B. B.Ch and Ph.D. degrees from the University of the Witwatersrand in Johannesburg, South Africa and his M.M.M. from Carnegie Mellon University’s H. John Heinz III College.

Delinquent Section 16(a) Reports

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, other than a late Form 3 and a late Form 4 for Ms. Cai, our Controller, that became due upon the resignation of our former Chief Financial Officer, there were no delinquent Section 16(a) reports, 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, 2019.

Code of Business Conduct and Ethics

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

Changes in Governance and Nominating Committee Procedures

There have been no material changes to the procedures by which stockholders may recommend individuals for consideration by the Governance and Nominating Committee as potential nominees for director since such procedures were last described in our Annual Report on Form 10-K, filed with the SEC on March 8, 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, Mr. Lawlor and Mr. Williams. 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 February 7, 2020 each of Mr. Lawlor, Ms. Hunt, Mr. Williams, Dr. De Souza, Dr. Himawan, Mr. Richard, Ms. Tetlow and Dr. Ling 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 Dr. Levy was our next highest compensated executive officer serving as of December 31, 2019. Mr. Payne voluntarily resigned from his position as our Chief Financial Officer, effective as of August 30, 2019.

Summary Compensation Table

The following table shows for the years ended December 31, 2019 and 2018 compensation awarded to or paid to our Named Executive Officers.

Name and principal position	Year	Salary ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)(2)	All Other Compensation ($)(3)	Total ($)
Nassim Usman, Ph.D.	2019	524,832	455,364	211,560	7,109	1,198,865
President and Chief Executive Officer	2018	480,800	1,715,742	240,400	5,372	2,442,314
Fletcher Payne(4)	2019	252,800	216,361	—	2,047	471,208
Former Chief Financial Officer	2018	345,301	501,228	120,855	2,092	969,476
Howard Levy, M.B.B.Ch., Ph.D., M.M.M						
Chief Medical Officer	2019	419,500	199,279	110,000	4,239	733,018
	2018	397,838	658,462	139,230	3,317	1,198,847

(1) 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.

(2) These amounts reflect bonuses earned by Drs. Usman and Levy and Mr. Payne based upon our achievement of certain product development and business objectives.

(3) The amounts in this column for Drs. Usman and Levy and Mr. Payne for 2018 and 2019 represent payment of life insurance premiums.

(4) Mr. Payne resigned as our Chief Financial Officer effective August 30, 2019.

Employment Agreements

Each of our currently serving Named Executive Officers 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 and Dr. Levy agreed not to disclose our confidential information. In August 2018, we entered into amended and restated employment agreements with Dr. Usman 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 Named Executive Officer's base salary and target bonus opportunity from time to time to ensure compensation adequately reflects the Named Executive Officer'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 $550,000 for the fiscal year ending December 31, 2020, 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 401(k) 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.

Howard Levy

Under our offer letter with Dr. Levy, our Chief Medical Officer, Dr. Levy is entitled to an annual base salary, which is $432,085 for the fiscal year ending December 31, 2020. Dr. Levy will also have the opportunity to earn an annual performance-based bonus of 40% 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 401(k) 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, 2019

The following table provides information regarding unexercised stock options held by each of the Named Executive Officers as of the end of fiscal year 2019.

Name	Grant Date	FN	Number of Securities Underlying Unexercised Option Exercisable(#)	Number of Securities Underlying Unexercised Option Unexercisable(#)	FN	Option Exercise Price($)	Option Expiration Date
Nassim Usman, Ph.D.	8/20/2015	(1)	1,500	0	(3)	172.80	1/3/2023
	10/22/2015	(1)	4,761	0	(2)	66.00	10/22/2025
	10/22/2015	(1)	10,238	0	(2)	66.00	10/22/2025
	7/11/2017		161,658	103,125	(5)	4.63	7/11/2027
	1/12/2018		35,625	59,375	(6)	15.13	1/12/2028
	7/30/2018		28,125	46,875	(7)	9.68	7/30/2028
	1/24/2019		18,333	61,667	(8)	7.97	1/24/2029
Fletcher Payne	1/22/2015	(1)	488	0		114.00	1/22/2025
	1/22/2015	(1)	162	0		114.00	1/22/2025
	5/8/2015	(1)	955	0		90.45	5/8/2025
	10/22/2015		4,662	0		66.00	10/22/2025
	10/22/2015		1,870	0		66.00	10/22/2025
	7/11/2017		39,063	0		4.63	7/11/2027
	1/12/2018		10,292	0		15.13	1/12/2028
	7/30/2018		7,292	0		9.68	7/30/2028
	1/24/2019		5,542	0		7.97	1/24/2029
Howard Levy M.B.B.Ch, Ph.D., M.M.M.	4/18/2016		6,113	553	(4)	22.80	4/18/2026
	7/11/2017		45,593	35,625	(5)	4.63	7/11/2027
	1/12/2018		15,812	17,188	(6)	15.13	1/12/2028
	7/30/2018		13,125	21,875	(7)	9.68	7/30/2028
	1/24/2019		8,021	26,979	(8)	7.97	1/24/2029

(1) These stock options were granted by the board of directors 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 vested at the rate of 1/48th of the total number of 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 vested at the rate of 1/48th of the total number of shares subject to the option on the 1st of each month, with the final tranche vesting on August 20, 2019.

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

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

(8) The remaining portion of these options to purchase common stock vest at the rate of 1/48th of the total number of shares subject to the option on the 24th day of each month, with the final tranche vesting on January 24, 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	Member	Chair
Board of Directors	$ 40,000	$ 70,000
Audit Committee	$ 7,500	$ 15,000
Compensation Committee	$ 5,000	$ 10,000
Governance and Nominating 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 2019

The following table shows for the year ended December 31, 2019 certain information with respect to the compensation of our non-employee directors serving during 2019. For information regarding compensation paid to Dr. Usman, see the "Summary Compensation Table" on page 96.

Name	Fees Earned or Paid in Cash ($) (4)	Option Awards ($)(1)(2)	Stock Grants ($)(3)	Total ($)
Augustine Lawlor	—	29,609	86,232	115,841
Andrea Hunt	22,813	29,609	28,708	81,130
Eddie Williams	—	29,609	48,106	77,715
Errol B. De Souza	—	29,609	51,853	81,462
Jeff Himawan, Ph.D.(4)	—	—	—	—
John P. Richard	57,812	29,609	—	87,421
Stephen A. Hill(5)	35,625	—	—	35,625

(1) The amounts in this column reflect the aggregate grant date fair value of stock options granted during the fiscal year ended December 31, 2019 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 2019 as of December 31, 2019:

NAME	Aggregate Number of Option Awards
Augustine Lawlor	21,500
Andrea Hunt	20,000
Eddie Williams	20,000
Errol B. De Souza	23,079
Jeff Himawan, Ph.D.	—
John P. Richard	23,577
Stephen A. Hill	—

(3) 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.

(4) Dr. Himawan has declined to receive any compensation for his service as a director.

(5) Dr. Hill resigned from the board of directors effective July 1, 2019.

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

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of February 7, 2020, 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 12,076,777 shares of common stock outstanding at February 7, 2020. 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 7, 2020. 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 7, 2020 are included for that person or group, but not the stock options of any other person or group.

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

Name	Number of Shares Owned and Nature of Beneficial Ownership		Percent of Class
5% or Greater Stockholders			
22NW Fund, LP			
1455 NW Leary Way, Suite 400, Seattle, WA 98107	735,841	(1)	6.1
Entities and Individuals Affiliated with Julian Singer			
	821,378	(2)	6.8
Entities Affiliated with Integrated Core Strategies (US) LLC			
c/o Millennium Management LLC, 666 Fifth Avenue, 8th Floor, New York Ny 10103	717,365	(3)	5.9
JFL Capital Management, LLC			
2110 Ranch Road 620 S, #341732, Lakeway, TX 78734	839,070	(4)	7.0
Mangrove Partners Master Fund, Ltd.			
	599,519	(5)	5.0
Nantahala Capital Management, LLC			
19 Old Kings Highway S, Suite 200, Darien, CT 06820	855,243	(6)	7.1
Directors and Named Executive Officers			
Nassim Usman, Ph.D.	314,048	(7)	2.5
Howard Levy, M.B.B.Ch., Ph.D., M.M.M.	119,422	(8)	*
Augustine Lawlor	105,259	(9)(10)	*
Andrea Hunt	21,932	(11)	*
Eddie Williams	25,089	(12)	*
Errol B. De Souza	31,467	(13)	*
Jeff Himawan, Ph.D.	81,538	(14)	*
John P. Richard	23,543	(15)	*
All Directors and Executive Officers as a Group (10 persons)	**722,298**	(16)	**5.9%**

* Indicates less than 1% of class.

(1) The information reported is based on a Schedule 13D filed with the SEC on July 24, 2019. The shares are held directly by 22NW Fund, LP (the "22NW Fund"). The following affiliates of the 22NW Fund may be deemed to have shared voting and dispositive power of these shares: (i) 22NW, LP (the "22NW Fund Investment Manager"), as investment manager to the 22NW Fund, (ii) 22NW Fund GP, LLC (the "22NW Fund GP"), as general partner to the 22NW Fund, (iii) 22NW GP, Inc., (the "22NW Fund Investment Manager GP"), as general partner to the 22NW Fund Investment Manager, and (iv) Aron R. English, as manager to the 22NW Fund GP.

(2) The information reported is based on a Schedule 13D/A filed with the SEC on January 17, 2020. Consists of (i) 150,000 shares held directly by CCUR Holdings, Inc. (“CCUR”), (ii) 398,838 shares held directly by JDS1, LLC (“JDS1”), (iii) 327,942 shares held directly by David S. Oros, and (iv) 50,500 shares of common stock subject to call options held directly by Mr. Oros which are exercisable within 60 days of January 13, 2020. Wayne Barr, Jr. is the Chief Executive Officer, President and Executive Chairman of CCUR and may be deemed to have shared voting control and investment discretion over the shares held by CCUR. Julian Singer, as a managing member of JDS1, has sole voting control and investment discretion over the shares held by JDSI. The principal business address of each of CCUR and Mr. Barr, Jr. is 4375 River Green Parkway, Suite 210 Duluth, Georgia 30096. The principal business address of each of JDS1 and Mr. Singer is 2200 Fletcher Avenue, Suite 501 Fort Lee, New Jersey 07024. The principal business address of Mr. Oros is 702 W. Lake Avenue, Baltimore, Maryland 21210.

(3) The information reported is based on a Schedule 13G/A filed with the SEC on January 17, 2020. Consists of (i) 707,365 shares held directly by Integrated Core Strategies (US) LLC ("Integrated Core Strategies"), and (ii) 10,000 shares held directly by Integrated Assets II LLC ("Integrated Assets II"). Millennium International Management LP, a Delaware limited partnership ("Millennium International Management"), is the investment manager to Integrated Assets II and may be deemed to have shared voting control and investment discretion over the shares owned by Integrated Assets II. Millennium Management LLC ("Millennium Management") is the general partner of the managing member of Integrated Core Strategies and may be deemed to have shared voting control and investment discretion over the shares owned by Integrated Core Strategies. Millennium Management is also the general partner of the 100% owner of Integrated Assets II and may also be deemed to have shared voting control and investment discretion over the shares owned by Integrated Assets II. Millennium Group Management LLC ("Millennium Group Management") is the managing member of Millennium Management and may also be deemed to have shared voting control and investment discretion over the shares owned by Integrated Core Strategies. Millennium Group Management is also the general partner of Millennium International Management and may also be deemed to have shared voting control and investment discretion over the shares owned by Integrated Assets II. The managing member of Millennium Group Management is a trust of which Israel A. Englander currently serves as the sole voting trustee. Therefore, Mr. Englander may also be deemed to have shared voting control and investment discretion over the shares owned by Integrated Core Strategies and Integrated Assets II.

(4) The information reported is based on a Schedule 13G/A filed with the SEC on February 11, 2019.

(5) The information reported is based on a Schedule 13G filed with the SEC on May 14, 2019. The shares are held directly by The Mangrove Partners Master Fund, Ltd. (the “Master Fund”). Mangrove Partners, as the investment manager of the Master Fund and Nathaniel August, the principal of Mangrove Partners, may be deemed to have shared voting and dispositive power of these shares. The principal business address of the Master Fund and Mangrove Partners is c/o Maples Corporate Services, Ltd., PO Box 309, Ugland House, South Church Street, George Town, Grand Cayman, Cayman Islands KY1-1104. The principal business office of Mr. August is 645 Madison Avenue, 14th Floor, New York, New York 10022.

(6) The information reported is based on a Schedule 13G filed with the SEC on February 14, 2019. The shares are held directly by Nantahala Capital Management, LLC (“Nantahala”). Wilmot B. Harkey and Daniel Mack, as managing members of Nanthala, may be deemed to have shared voting and dispositive power of these shares.

(7) Consists of (i) 8,456 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 an IRA, (iii) 6,580 shares and (iv) 297,844 shares issuable upon the exercise of options within 60 days of February 7, 2020.

(8) Consists of (i) 16,094 shares held by the Howard and Gillian Levy Revocable Trust dated November 21, 1994 and (ii) 103,328 shares of common stock subject to stock options which are vested and exercisable within 60 days of February 7, 2020.

(9) Consists of (i) 15,608 shares held directly and (ii) 20,250 shares of common stock subject to stock options which are vested and exercisable within 60 days of February 7, 2020.

(10) 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 ("HCPVIIILLC"), the general partner of HealthCare Partners VIII, L.P. ("HCPVIII"), which is the general partner of HCVVIII.

(11) Consists of (i) 5,126 shares and (ii) 16,806 shares of common stock subject to stock options which are vested and exercisable within 60 days of February 7, 2020.

(12) Consists of (i) 8,839 shares and (ii) 16,250 shares of common stock subject to stock options which are vested and exercisable within 60 days of February 7, 2020.

(13) Consists of (i) 9,638 shares, and (ii) 21,829 shares of common stock subject to stock options which are vested and exercisable within 60 days of February 7, 2020.

(14) 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 81,538 shares comprising of (i) 78,622 shares and (ii) 2,916shares that may be purchased upon the exercise of warrants within 60 days. Essex VIII LLC disclaims beneficial ownership to 81,538 shares comprising of (i) 78,622 shares and (ii) 2,916 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 81,538 shares comprising of (i) 78,622 shares and (ii) 2,916 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.

(15) Consists of (i) 1,216 shares, and (ii) 22,327 shares of common stock which are subject to stock options vested and exercisable within 60 days of February 7, 2020.

(16) Includes 498,634 shares of common stock subject to stock options which are vested and exercisable within 60 days of February 7, 2020.

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 2018 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, 2019 with respect to the Company's equity compensation plans and standalone options.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options Warrants and Rights (A)	Weighted-Average Exercise Price of Outstanding Options (B)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (A)) (C)
Equity compensation plans approved by security holders(1)	1,564,913	$ 10.29	1,014,126
Equity compensation plans not approved by security holders(2)	12,628	$ 74.91	—
Total	1,577,541	$ 10.85	1,014,126

(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 3,594 shares, at a weighted average exercise price of $170.23, which were granted under the 2004 Plan. No further grants may be made under the 2004 Plan. Includes an aggregate of 763 shares issuable upon the exercise of standalone options with a weighted average exercise price of $114.00, issued to Dr. Hansoo Keyoung , 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 December 31, 2019, the maximum aggregate number of shares available for future grants under all the Company-administered equity compensation plans was 1,014,126 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 1,577,541 shares. The weighted average exercise price of these options was $10.85, and the weighted average remaining term was 8.147 years as of December 31, 2019. On December 31, 2019, the closing sales price of the common stock as reported on Nasdaq was $6.81 per share.

Item 13. CERTAIN RELATIONSHIPS, RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Described below are the transactions and series of similar transactions since January 1, 2018 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. On December 18, 2019, the Company entered into the second amendment to the collaboration agreement, which added fees for future services upon completion of the co-funded research. Mosaic is entitled to sublicense fees and/or research and development and commercial milestones and royalties on C3 and one non-C3 complement product. In connection with the Biogen collaboration for dry AMD and other retinal products, the Company received a $15.0 million upfront fee in January 2020, and Mosaic is entitled to receive a double-digit percentage of the amount the Company received from Biogen. 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, 2019 and 2018 and for other services rendered by EisnerAmper LLP during those periods. All fees described below were approved by the Audit Committee.

	Fiscal 2019	Fiscal 2018
Audit Fees(1):	$ 369,671	$ 339,600
Audit-Related Fees:	—	—
Tax Fees:	—	—
All Other Fees:	—	—
Total Fees:	$ 369,671	$ 339,600

(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-3 and S-8.

Audit Committee Pre-Approval Policy

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

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

1. Consolidated Financial Statements

   See Index to Consolidated Financial Statements at Item 8 herein.

2. Consolidated Financial Statement Schedules

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

3. See LIST OF EXHIBITS

(b) See LIST OF EXHIBITS

Item 16. FORM 10-K SUMMARY

None.

LIST OF EXHIBITS

Exhibit No.	Exhibit title	Incorporated by reference				Filed or Furnished herewith
		Form	File No.	Exhibit No.	Filing Date	
2.1(a)	Agreement and Plan of Merger dated as of March 5, 2015, by and among Targacept, Catalyst Biosciences, Inc. and Talos Merger Sub, Inc.	8-K	000-51173	2.1	Mar. 6, 2015	
2.1(b)	Amendment No. 1 to Agreement and Plan of Merger by and among Targacept, Talos Merger Sub, Inc., and Catalyst dated May 6, 2015.	8-K	000-51173	10.1	May 12, 2015	
2.1(c)	Amendment No. 2 to Agreement and Plan of Merger by and among Targacept, Talos Merger Sub, Inc., and Catalyst dated May 13, 2015.	8-K	000-51173	10.1	May 14, 2015	
3.1	Fourth Amended and Restated Certificate of Incorporation of the Company.	S-8	333-133881	4.1	May 8, 2006	
3.2	Certificate of Amendment to Fourth the Amended and Restated Certificate of Incorporation of the Company.	8-K	000-51173	3.1	Aug. 20, 2015	
3.3	Second Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Company.	8-K	000-51173	3.1	Feb. 10, 2017	
3.4	Bylaws of the Company, as amended.	8-K	000-51173	3.1	Mar. 6, 2015	
3.5	Certificate of Designation of Preferences, Rights and Limitations, filed with the Delaware Secretary of State on April 10, 2017, with respect to the Series A Preferred Stock.	8-K	000-51173	3.1	Apr. 13, 2017	
4.1	Description of Securities.					X
4.2	Warrant to Purchase Stock of Catalyst Biosciences, Inc., issued to Silicon Valley Bank on March 3, 2005.	10-K	000-51173	4.3	Mar. 9, 2016	
4.3	Form of Warrant to Purchase Stock of Catalyst Biosciences, Inc., issued to purchasers of convertible promissory notes.	10-K	000-51173	4.5	Mar. 9, 2016	
10.1**	Catalyst Biosciences, Inc. (formerly Targacept, Inc.) 2015 Stock Incentive Plan (as Amended and Restated Effective June 9, 2016).	DEF 14A	000-51173	Appendix A	Apr. 25, 2016	
10.2**	Catalyst Biosciences, Inc. 2016 Inducement Stock Incentive Plan.	8-K	000-51173	10.1	Apr. 20, 2016	
10.3**	Catalyst's 2004 Stock Plan.	S-4	333-204423	10.31(a)	May 22, 2015	

Exhibit No.	Exhibit title	Incorporated by reference				Filed or Furnished herewith
		Form	File No.	Exhibit No.	Filing Date	
10.4**	Form of Incentive Stock Option Award Notice.	8-K	000-51173	10.1	July 14, 2017	
10.5**	Form of Non-qualified Stock Option Award Notice.	8-K	000-51173	10.2	July 14, 2017	
10.6**	Catalyst Biosciences, Inc. 2018 Omnibus Incentive Plan.	DEF 14A	000-51173	Appendix A	May 11, 2018	
10.7**	Catalyst Biosciences, Inc. 2018 Employee Stock Purchase Plan.	DEF 14A	000-51173	Appendix B	May 11, 2018	
10.8**	Form of Stock Option Award Agreement.	DEF 14A	000-51173	Appendix C	May 11, 2018	
10.9**	Amended and Restated Employment Agreement, dated as of August 28, 2018, by and between Catalyst Biosciences, Inc. and Dr. Nassim Usman, Ph.D.	8-K	000-51173	10.1	Aug. 31, 2018	
10.10**	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.	8-K	000-51173	10.2	Aug. 31, 2018	
10.11**	Amended and Restated Employment Agreement, dated as of August 30, 2018, by and between Catalyst Biosciences, Inc. and Fletcher Payne.	8-K	000-51173	10.3	Aug. 31, 2018	
10.12++	Amended and Restated License Agreement, dated December 17, 2018, by and between Catalyst Biosciences, Inc. and ISU Abxis.	10-K/A	000-51173	10.16	April 29, 2019	
10.13+	Development and Manufacturing Services Agreement, by and between CMC ICOS Biologics, Inc. and Biosciences, Inc., dated as of May 20, 2016.	10-Q	000-51173	10.1	Aug. 4, 2016	
10.14+	Termination Agreement, dated December 8, 2016, between Catalyst Biosciences, Inc. and Wyeth LLC, a wholly-owned subsidiary of Pfizer Inc.	10-K	000-51173	10.16	Mar. 8, 2017	
10.15(a)	Lease Agreement, dated November 8, 2017 by and between BXP 611 Gateway Center, LP and Catalyst Biosciences, Inc..	8-K	000-51173	10.1	Nov. 17, 2017	
10.15(b)	First Amendment to Office Lease, dated as of August 9, 2018, by and between BXP 611 Gateway Center, LP and Catalyst Biosciences, Inc.	8-K	000-51173	10.1	Aug. 15, 2018	

Exhibit No.	Exhibit title	Incorporated by reference				Filed or Furnished herewith
		Form	File No.	Exhibit No.	Filing Date	
10.16++	Clinical Supply Agreement, effective as of October 4, 2019, by and between Catalyst Biosciences, Inc. and Catalent Indiana, LLC.	8-K	000-51173	10.1	October 15, 2019	
10.17++	License and Collaboration Agreement, dated December 18, 2019, by and between Biogen International GMBH and Catalyst Biosciences, Inc.					X
10.18++	Amended and Restated Collaboration Agreement, dated December 18, 2019, by and between Mosaic Biosciences, Inc. and Catalyst Biosciences, Inc.					X
10.19	Cooperation Agreement, dated January 13, 2020, by and between CCUR Holdings, Inc. and certain of its affiliates and Catalyst Biosciences, Inc.	8-K	000-51173	10.1	January 10, 2020	
10.20	Description of Annual Cash Incentive Program.					X
10.21**	Form of Indemnification Agreement between the Company and each of its directors and members of executive management.	8-K	000-51173	10.3	August 31, 2018	
21.1	List of subsidiaries of Catalyst Biosciences, Inc.	10-K	000-51173	21.1	March 9, 2016	
23.1	Consent of EisnerAmper LLP, Independent Registered Public Accounting Firm.					X
24.1	Power of Attorney (included as part of the signature page hereto).					X
31.1	Certification of the Principal Executive and 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.					X
32.1	Certification of the Principal Executive and Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X

Exhibit No.	Exhibit title	Incorporated by reference				Filed or Furnished herewith
		Form	File No.	Exhibit No.	Filing Date	
101	The following materials from the Company's Annual Report on Form 10-K for the year ended December 31, 2019, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets as of December 31, 2019 and December 31, 2018; (ii) the Consolidated Statement of Operations for the years ended December 31, 2019 and 2018; (iii) the Consolidated Statements of Comprehensive Loss for the years ended December 31, 2019 and 2018; (iv) the Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity as of December 31, 2019; (v) the Consolidated Statements of Cash Flows for the twelve months ended December 31, 2019 and 2018; and (vi) the Notes to the Consolidated Financial Statements.					X

** 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.

++ Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit were omitted by means of marking such portions with an asterisk because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

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

CATALYST BIOSCIENCES, INC.

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

Date: February 20, 2020

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ Nassim Usman, Ph.D. **Nassim Usman, Ph.D.**	President and Chief Executive Officer (*Principal Executive and Financial Officer*)	February 20, 2020
/s/ Veronica Cai **Veronica Cai**	Principal Accounting Officer	February 20, 2020
/s/ Augustine Lawlor **Augustine Lawlor**	Chairman of the Board of Directors	February 20, 2020
/s/ Errol B. De Souza, Ph.D. **Errol B. De Souza, Ph.D.**	Director	February 20, 2020
/s/ Jeff Himawan, Ph.D. **Jeff Himawan, Ph.D.**	Director	February 20, 2020
/s/ Andrea Hunt **Andrea Hunt**	Director	February 20, 2020
/s/ Geoffrey Ling, M.D., Ph.D. **Geoffrey Ling, M.D., Ph.D.**	Director	February 20, 2020
/s/ John P. Richard **John P. Richard**	Director	February 20, 2020
/s/ Sharon Tetlow **Sharon Tetlow**	Director	February 20, 2020
/s/ Eddie Williams **Eddie Williams**	Director	February 20, 2020

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF
THE SECURITIES EXCHANGE ACT OF 1934

Catalyst Biosciences, Inc. ("we," "our," "us," or the "Company") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended ("1934 Act"): our common stock. The following summary of the terms of our common stock is based upon our Fourth Amended and Restated Certificate of Incorporation, as amended (our "restated certificate of incorporation") and our bylaws. This summary does not purport to be complete and is subject to, and is qualified in its entirety by express reference to, the applicable provisions of our restated certificate of incorporation and our bylaws, which are filed as exhibits to our Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our restated certificate of incorporation, our bylaws and the applicable provisions of the Delaware General Corporation Law ("DGCL") for more information.

Description of Common Stock

Under our restated certificate of incorporation, we have authority to issue 100,000,000 shares of our common stock, par value $0.001 per share. As of December 31, 2019, 12,040,835 shares of our common stock were issued and outstanding. All shares of our common stock will, when issued, be duly authorized, fully paid and nonassessable.

Dividends. Subject to preferential dividend rights of any other class or series of stock, the holders of shares of our common stock are entitled to receive dividends, including dividends of our stock, as and when declared by our board of directors, subject to any limitations imposed by law and to the rights of the holders, if any, of our preferred stock. We have never paid cash dividends on our common stock, except with respect to a cash dividend paid in connection with the closing of our business combination with Targacept, Inc. We do not anticipate paying periodic cash dividends on our common stock for the foreseeable future. Any future determination about the payment of dividends will be made at the discretion of our board of directors and will depend upon our earnings, if any, capital requirements, operating and financial conditions and on such other factors as the board of directors deems relevant.

Liquidation. In the event we are liquidated, dissolved or our affairs are wound up, after we pay or make adequate provision for all of our known debts and liabilities, each holder of our common stock will be entitled to share ratably in all assets that remain, subject to any rights that are granted to the holders of any class or series of preferred stock.

Voting Rights. For all matters submitted to a vote of stockholders, each holder of our common stock is entitled to one vote for each share registered in his or her name. Except as may be required by law and in connection with some significant actions, such as mergers, consolidations, or amendments to our restated certificate of incorporation that affect the rights of stockholders, holders of our common stock vote together as a single class. There is no cumulative voting in the election of our directors, which means that, subject to any rights to elect directors that are granted to the holders of any class or series of preferred stock, a plurality of the votes cast at a meeting of stockholders at which a quorum is present is sufficient to elect a director.

Other Rights and Restrictions. Subject to the preferential rights of any other class or series of stock, all shares of our common stock have equal dividend, distribution, liquidation and other rights, and have no preference, appraisal or exchange rights, except for any appraisal rights provided by Delaware law. Furthermore, holders of our common stock have no conversion, sinking fund or redemption rights, or preemptive rights to subscribe for any of our securities. Our restated certificate of incorporation and our bylaws do not restrict the ability of a holder of our common stock to transfer his or her shares of our common stock.

The rights, powers, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of holders of shares of any series of preferred stock which we may designate and issue in the future.

Listing. Our common stock is listed on the Nasdaq Capital Market under the symbol “CBIO.”

Transfer Agent and Registrar. The transfer agent for our common stock is American Stock Transfer &Trust Company, LLC. Its address is 6201 15th Avenue, Brooklyn, NY 11219.

Description of Preferred Stock

Under our restated certificate of incorporation, we have authority, subject to any limitations prescribed by law and without further stockholder approval, to issue from time to time up to 5,000,000 shares of preferred stock, par value $0.001 per share, in one or more series. As of December 31, 2019, we had no shares of preferred stock issued and outstanding.

Pursuant to our restated certificate of incorporation, we are authorized to issue “blank check” preferred stock, which may be issued from time to time in one or more series upon authorization by our board of directors. Our board of directors, without further approval of the stockholders, is authorized to fix the designation, powers, preferences, relative, participating optional or other special rights, and any qualifications, limitations and restrictions applicable to each series of the preferred stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes could, among other things, adversely affect the voting power or rights of the holders of our common stock and, under certain circumstances, make it more difficult for a third party to gain control of us, discourage bids for our common stock at a premium or otherwise adversely affect the market price of the common stock.

Certain Effects of Authorized but Unissued Stock

We have shares of common stock and preferred stock available for future issuance without stockholder approval. We may issue these additional shares for a variety of corporate purposes, including future public or private offerings to raise additional capital or to facilitate corporate acquisitions or for payment as a dividend on our capital stock. The existence of unissued and unreserved preferred stock may enable our board of directors to issue shares of preferred stock with terms that could render more difficult or discourage a third-party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, if we issue preferred stock, the issuance could adversely affect the voting power of holders of common stock and the likelihood that holders of common stock will receive dividend payments or payments upon liquidation.

Anti-Takeover Effects of Provisions of Our Charter Documents

Our restated certificate of incorporation provides for our board of directors to be divided into three classes serving staggered terms. Approximately one-third of our board of directors will be elected each year. The provision for a classified board could prevent a party who acquires control of a majority of the outstanding voting stock from obtaining control of the board of directors until the second annual stockholders meeting following the date the acquirer obtains the controlling stock interest. The classified board provision could discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of the Company and could increase the likelihood that incumbent directors will retain their positions. Our restated certificate of incorporation provides that directors may be removed with or without cause by the affirmative vote of the holders of at least 66 2/3% of the voting power of all outstanding stock.

Our restated certificate of incorporation requires that certain amendments to the restated certificate of incorporation and amendments by the stockholders of our bylaws require the affirmative vote of at least 66 2/3% of the voting power of all outstanding stock. These provisions could discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of the Company and could delay changes in management.

Our bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual stockholders meeting, including proposed nominations of persons for election to our board of directors. At an annual stockholders meeting, stockholders may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors. Stockholders may also consider a proposal or nomination by a person who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given to the Secretary of the Company timely written notice, in proper form, of his or her intention to bring that business before the annual stockholders meeting. Our bylaws do not give our board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting of the stockholders. However, our bylaws may have the effect of precluding the conduct of business at a meeting if the proper procedures are not followed. These provisions may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer’s own slate of directors or otherwise attempting to obtain control of the Company.

Our bylaws provide that only our board of directors, the chairperson of the board, the President or the Chief Executive Officer may call a special meeting of stockholders. Because our stockholders do not have the right to call a special meeting, a stockholder could not force stockholder consideration of a proposal over the opposition of our board of directors by calling a special meeting of stockholders prior to such time as a majority of our board of directors, the chairperson of the board, the President or the Chief Executive Officer believed the matter should be considered or until the next annual meeting provided that the requestor met the notice requirements. The restriction on the ability of stockholders to call a special meeting means that a proposal to replace the board also could be delayed until the next annual stockholders meeting.

Our restated certificate of incorporation does not allow stockholders to act by written consent without a meeting. Without the availability of stockholder’s actions by written consent, a holder controlling a majority of our capital stock would not be able to amend our bylaws or remove directors without holding a stockholders’ meeting.

Anti-Takeover Effects of Provisions of Delaware Law

We are subject to the provisions of Section 203 of the DGCL, or Section 203. Under Section 203, we would generally be prohibited from engaging in any business combination with any interested stockholder for a period of three years following the time that this stockholder became an interested stockholder unless:

- prior to this time, our board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding shares owned by persons who are directors and also officers, and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to such time, the business combination is approved by our board of directors and authorized at a special or annual stockholders meeting, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Under Section 203, a “business combination” includes:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder, subject to limited exceptions;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by such entity or person.

Limitation of Liability and Indemnification

Our restated certificate of incorporation provides that our directors shall not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, except for liability for breach of the director’s duty of loyalty to us or our stockholders, for acts or omissions not in good faith or involving intentional misconduct or a knowing violation of law, for payment of dividends or approval of stock purchases or redemptions that are prohibited by the DGCL, or for any transaction from which the director derived an improper personal benefit. Under the DGCL, our directors have a fiduciary duty to us that is not eliminated by this provision of the restated certificate of incorporation and, in appropriate circumstances, equitable remedies such as injunctive or other forms of non-monetary relief will remain available. This provision also does not affect our directors’ responsibilities under any other laws, such as federal securities laws or state or federal environmental laws.

Section 145 of the DGCL empowers a corporation to indemnify its directors and officers against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by them in connection with any action, suit or proceeding brought by third parties by reason of the fact that they were or are directors or officers of the corporation, if they acted in good faith, in a manner they reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe that their conduct was unlawful. The DGCL provides further that the indemnification permitted thereunder shall not be deemed exclusive of any other rights to which the directors and officers may be entitled under the corporation's bylaws, any agreement, a vote of stockholders or otherwise. Our restated certificate of incorporation provides that, to the fullest extent permitted by Section 145 of the DGCL, we shall indemnify any person who is or was a director or officer of us, or is or was serving at our request as a director, officer or trustee of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise, against the expenses, liabilities or other matters referred to in or covered by Section 145 of the DGCL. Our bylaws provide that we will indemnify any person who was or is a party or threatened to be made a party to any proceeding by reason of the fact that such person is or was a director or officer of us or is or was serving at our request as a director, officer or trustee of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise to the fullest extent permitted by the DGCL.

In addition, we have entered into indemnification agreements with each of our directors and with certain of our executive officers. Pursuant to the indemnification agreements, we has agreed to indemnify and hold harmless these directors and officers to the fullest extent permitted by the DGCL. 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 our 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 our best interests, with respect to "short-swing" profit claims under Section 16(b) of the 1934 Act and, with certain exceptions, with respect to proceedings that he or she initiates.

Section 145 of the DGCL also empowers a corporation to purchase insurance for its officers and directors for such liabilities. We maintain liability insurance for our officers and directors.

Exhibit 10.17

Certain information identified by bracketed asterisks ([***]) has been omitted from this exhibit because it is both not material and would be competitively harmful if publicly disclosed.

License and Collaboration Agreement

Between

Biogen International GmbH

and

Catalyst Biosciences, Inc.

Dated December 18, 2019

TABLE OF CONTENTS

SCHEDULES

License and Collaboration Agreement

This License and Collaboration Agreement (this "**Agreement**") is entered into as of December 18, 2019 (the "**Effective Date**") by and between **Biogen International GmbH**, a company organized and existing under the laws of Switzerland and having a principal place of business at Neuhofstrasse 30, Baar, 6340, Switzerland ("**Biogen**") and Catalyst Biosciences, Inc., a Delaware corporation having a principal place of business at 611 Gateway Blvd., Suite 710, South San Francisco, CA 94080 ("**Catalyst**"). Biogen and Catalyst are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Catalyst has certain expertise and proprietary technology relating to anti-complement factor 3 (C3) proteases for the treatment of advanced dry age-related macular degeneration (dAMD), and has developed a lead asset, a novel anti-C3 protease known as "CB 2782," and a pegylated form thereof known as "CB 2782-PEG";

WHEREAS, the Parties are interested in entering into a collaboration to utilize Catalyst's expertise to further optimize and progress the development of CB-2782-PEG and perform other pre-clinical research and manufacturing activities with respect to CB-2782-PEG and other Compounds (as defined below), each in accordance with the terms and conditions set forth in this Agreement; and

WHEREAS, Catalyst desires to (a) grant to Biogen, and Biogen desires to receive from Catalyst, an exclusive, worldwide license under the Licensed Technology to exploit Compounds and Products in the Field in the Territory (as each term is defined below); and (b) assign to Biogen all of Catalyst's rights, title, and interests in and to the Assigned Patent Rights (as defined below).

NOW, THEREFORE, the Parties hereto agree as follows:

ARTICLE 1
DEFINITIONS

1.1 "**Acquiror**" has the meaning set forth in Section 2.4.2 (Exception for Change of Control).

1.2 "**Acquisition Products**" has the meaning set forth in [***].

1.3 "**Additional Cure Period**" has the meaning set forth in Section 12.2.3 (Disputes Regarding Material Breach).

1.4 "**Affiliates**" of a Person means any other Person that (directly or indirectly) is controlled by, controls or is under common control with such Person. For the purposes of this definition, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") as used with respect to a Person, will mean the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise, and "control" will be presumed to exist if either of the following conditions is met: (a) in the case of a corporate entity, direct or indirect ownership of voting securities entitled to cast more than 50% of the votes in the election of directors or (b) in the case of a non-corporate entity, direct or indirect ownership of more than 50% of the equity interests with the power to direct the management and policies of such entity.

1.5 "**Alliance Manager**" has the meaning set forth in Section 4.1.1 (Alliance Managers).

1.6 [***]

1.7 "**Annual Net Sales**" has the meaning set forth in Section 7.3.2 (Sales Milestones).

1.8 "**Applicable Law**" means applicable laws, statutes, treatises, ordinances, rules, regulations, and other pronouncements having the effect of law of any Governmental Authority that may be in effect from time to time, including for clarity any applicable rules, regulations, guidances, and other requirements of any Regulatory Authority that may be in effect from time to time, including GLP and GMP.

1.9 "**Arising IP**" has the meaning set forth in Section 10.1.2 (Arising IP).

1.10 "**Assigned Patent Rights**" has the meaning set forth in Section 10.1.3 (Patent Assignments).

1.11 "**Audited Party**" has the meaning set forth in Section 7.9.1 (Record Retention; Audits).

1.12 "**Auditing Party**" has the meaning set forth in Section 7.9.1 (Record Retention; Audits).

1.13 "**Bankrupt Party**" has the meaning set forth in Section 12.3 (Termination for Insolvency).

1.14 "**Biogen First Right Patent Rights**" has the meaning set forth in Section 10.2.1(a) (Biogen's Rights).

1.15 "**Biogen Indemnified Party**" has the meaning set forth in Section 11.1 (Indemnification by Catalyst).

1.16 "**Biogen Patent Rights**" has the meaning set forth in Section 10.1.3 (Patent Assignments).

1.17 "**Biogen-Prosecuted Patent Rights**" has the meaning set forth in Section 10.2.1(a) (Biogen's Rights).

1.18 "**Biogen Records**" has the meaning set forth in Section 7.9.1 (Record Retention; Audits).

1.19 "**Biogen Technology**" means (a) any Know-How Controlled by Biogen or any of its Affiliates that is (i) necessary for Catalyst to conduct Catalyst Research Activities under the Work Plan, and (ii) actually provided by Biogen to Catalyst for use in such Catalyst Research Activities, and (b) any Patent Rights Controlled by Biogen or any of its Affiliates that Cover or claim such Know-How described in the foregoing clause (a).

1.20 "**Business Day**" means a day that is not: (a) Saturday, Sunday, or a bank or other public holiday in Boston, Massachusetts or San Francisco, California; or (b) December 24 through December 31.

1.21 "**Calendar Quarter**" means the respective periods of three consecutive calendar months ending on March 31st, June 30th, September 30th, or December 31st in any Calendar Year.

1.22 "**Calendar Year**" means any calendar year beginning on January 1st and ending on December 31st.

1.23 "**Catalyst Indemnified Party**" has the meaning set forth in Section 11.2 (Indemnification by Biogen).

1.24 "**Catalyst's Knowledge**" means the actual knowledge, after reasonable investigation, of the individuals listed on Schedule 1.24.

1.25 "**Catalyst-Prosecuted Patent Rights**" has the meaning set forth in Section 10.2.1(b) (Catalyst's Rights).

1.26 "**Catalyst Records**" has the meaning set forth in Section 7.9.1 (Record Retention; Audits).

1.27 "**Change of Control**" means, with respect to a Party, that: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of such Party, or if the percentage ownership of such Third Party in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing at least 50% of the total voting power of all of the then outstanding voting securities of such Party; (b) a merger, consolidation, recapitalization, or reorganization of such Party is consummated that would result in shareholders or equity holders of such Party immediately prior to such transaction owning less than 50% of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; or (c) there is a sale or transfer to a Third Party of all or substantially all of such Party's consolidated assets taken as a whole, through one or more related transactions.

1.28 "**Clinical Trial**" means any clinical trial in humans that is designed to generate data in support or maintenance of an IND or MAA, or other similar marketing application, including any Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, or any post-approval clinical trial in humans.

1.29 "**CMO**" has the meaning set forth in Section 6.2.1 (General).

1.30 "**Collaboration Target**" means complement factor C3.

1.31 "**Collaborative Period**" means the period commencing on the Effective Date and extending until the second anniversary of the expiration or termination of the Research Term.

1.32 "**Combination Product**" means a Product that is (a) sold in the form of a combination that contains or comprises a Compound (the "**Compound Component**") together with one or more other therapeutically active pharmaceutical or biological agents (whether coformulated or copackaged); and (b) sold for a single invoice price (such additional therapeutically active pharmaceutical or biological agent, an "**Other Active**") or (c) defined as a "combination product" by the FDA pursuant to 21 C.F.R. §3.2(e) or its foreign equivalent.

1.33 "**Commercialization**" means any and all activities directed to the marketing, promotion, distribution, offering for sale, sale, having sold, importing, having imported, exporting, having exported, pricing, or other commercialization of a pharmaceutical or biologic product, but excluding activities directed to Manufacturing, Development, or Medical Affairs. "**Commercialize**" and "**Commercializing**," will be construed accordingly.

1.34 "**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by Biogen or its Affiliate with respect to any Development or Commercialization objective, activity, or goal related to a Compound or Product under this Agreement, those efforts that Biogen would normally use to accomplish such objective, activity, or decision, and specifically means the carrying out of Development and Commercialization activities using efforts that Biogen would normally devote to a product at a similar stage in its development or product life and of similar market potential, strategic importance, and profit potential (taking into account payments under this Agreement and any agreements entered into pursuant to Section 7.4.4(b) (Third Party Payments)), based on conditions then prevailing and taking into account efficacy, safety, approved labeling, the competitiveness of alternative products sold by Third Parties in the marketplace, the patent and other proprietary position of the product, the likelihood of

regulatory approval given the regulatory structure involved, and all other relevant factors. Commercially Reasonable Efforts will be determined on a country-by-country and indication-by-indication basis for the applicable Compound or Product, and it is anticipated that the level of effort will change over time, reflecting changes in the status of such Compound or Product (as applicable) and the market or country involved. Catalyst expressly understands and accepts that the use of Commercially Reasonable Efforts may result in Biogen ceasing the Development or Commercialization of a Compound or Product (in whole or in part), and that once Development or Commercialization for a Compound or Product has ceased in compliance with this Agreement, Commercially Reasonable Efforts does not require the continued re-evaluation of whether Development or Commercialization must be re-initiated for such Compound or Product.

1.35 "**Competing Compound**" means [***]

1.36 "**Competing Product**" has the definition set forth in Section 2.4.1 (General).

1.37 "**Compound**" means [***]

1.38 "**Compound Component**" has the meaning set forth in Section 1.32 (Combination Product).

1.39 "**Compulsory License**" has the meaning set forth in Section 7.4.4(a) (Reductions for Patent Expiry, Generic Versions, and Compulsory Licenses).

1.40 "**Confidential Information**" means, with respect to each Party, all Know-How and other information, including proprietary information and materials (whether or not patentable) regarding or embodying such Party's technology, products, business information or objectives, that is communicated by or on behalf of a Party or its Affiliates, Sublicensees, or agents (such Party, the "**Disclosing Party**") to the other Party or its Affiliates, Sublicensees, or agents (such Party, the "**Receiving Party**"), including information disclosed prior to the Effective Date pursuant to the Confidentiality Agreement.

1.41 "**Confidentiality Agreement**" means that certain Mutual Confidentiality Agreement dated October 27, 2017, by and between Biogen Inc. and Catalyst, as amended by Amendment No. 1 thereto dated November 18, 2019.

1.42 "**Control**" or "**Controlled**" means the possession by a Person (whether by ownership, license, or otherwise, other than pursuant to this Agreement) of, (a) with respect to any tangible Know-How, the legal authority or right to physical possession of such tangible Know-How, with the right to provide such tangible Know-How to the other Party on the terms set forth herein, or (b) with respect to Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other Intellectual Property, the legal authority or right to assign or grant a license, sublicense, access, or right to use (as applicable) to the other Party under such Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other Intellectual Property on the terms set forth herein, in each case ((a) and (b)), without breaching or otherwise violating the terms of any arrangement or agreement with a Third Party in existence as of the time Person or its Affiliates would first be required to grant such assignment, access, right to use, licenses, or sublicense.

1.43 "**Cover**," "**Covering**" or "**Covered**" means, with respect to a product, technology, process, method, or mode of administration that, in the absence of ownership of or a license granted under a particular Valid Claim, the manufacture, use, offer for sale, sale, or importation of such product or the practice of such technology, process, method, or mode of administration would infringe such Valid Claim or, in the case of a claim that has not yet issued, would infringe such claim if it were to issue and become a Valid Claim, in each case, [***]

1.44 "**Debarred**" means, with respect to an individual or entity, that such individual or entity has been debarred or suspended under 21 U.S.C. §335(a) or (b), the subject of a conviction described in Section 306 of the FD&C Act, excluded from a federal or governmental health care program, debarred from federal contracting, convicted of or pled *nolo contendere* to any felony, or to any federal or state legal violation (including misdemeanors) relating to prescription drug products or fraud, the subject to OFAC sanctions or on the OFAC list of specially designated nationals, or the subject of any similar sanction of any Governmental Authority in the Territory.

1.45 "**Defaulting Party**" has the meaning set forth in Section 12.2.3 (Disputes regarding Material Breach).

1.46 "**Deliverables**" means any and all deliverables to be generated or provided by Catalyst in connection with the performance of Catalyst Research Activities, as specified in the Work Plan.

1.47 "**Develop**" or "**Development**" means all internal and external research, development, and regulatory activities related to pharmaceutical or biologic products, including (a) research, non-clinical testing, toxicology, testing and studies, non-clinical and preclinical activities, and Clinical Trials, and (b) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct Clinical Trials and to obtain, support, or maintain Regulatory Approval of a pharmaceutical or biologic product and interacting with Regulatory Authorities following receipt of Regulatory Approval in the applicable country or region for such pharmaceutical or biologic product regarding the foregoing, but excluding activities directed to Manufacturing, Medical Affairs, or Commercialization. Development includes development and regulatory activities for additional forms, formulations, or indications for a pharmaceutical or biologic product after receipt of Regulatory Approval of such product. "**Developing**" and "**Developed**" will be construed accordingly.

1.48 "**Development Candidate**" has the meaning set forth in Section 3.8 (Designation of Development Candidates).

1.49 "**Development Candidate Criteria**" means the criteria for Compounds set forth in the Work Plan as "Development Candidate Criteria", which criteria are intended to indicate that such Compounds are appropriate for the commencement of IND-Enabling Studies.

1.50 "**Development Milestone Event**" has the meaning set forth in Section 7.3.1 (Development Milestones).

1.51 "**Development Milestone Payment**" has the meaning set forth in Section 7.3.1 (Development Milestones).

1.52 "**Diligence Trigger**" means [***].

1.53 "**Disclosing Party**" has the meaning set forth in Section 1.40 (Confidential Information).

1.54 [***]

1.55 "**Dollar**" means the U.S. dollar, and "$" will be interpreted accordingly.

1.56 "**Effective Date**" has the meaning set forth in the preamble.

1.57 "**EMA**" means the European Medicines Agency, or any successor agency thereto.

1.58 "**Exclusivity Period**" means: [***]

1.59 "**Executive Officers**" means [***]

1.60 "**Existing In-Licenses**" has the meaning set forth in Section 8.2.14 (Additional Representations and Warranties of Catalyst).

1.61 "**Exploit**" means Develop, have Developed, make, have made, use, have used, perform Medical Affairs, have performed Medical Affairs, offer for sale, have offered for sale, sell, have sold, export, have exported, import, have imported, Manufacture, have Manufactured, Commercialize, or have Commercialized. "**Exploitation**" and "**Exploiting**" will be construed accordingly.

1.62 "**FD&C Act**" means the Federal Food, Drug and Cosmetic Act, as the same may be amended or supplemented from time to time.

1.63 "**FDA**" means the U.S. Food and Drug Administration, or any successor agency thereto.

1.64 "**Field**" means any and all uses.

1.65 "**First Commercial Sale**" means, with respect to any Product in any country or region, the first sale of such Product to a Third Party (other than a Sublicensee) for distribution, use, or consumption in such country or region after receipt of Regulatory Approval (including for clarity, all applicable Reimbursement Approvals) for such Product in such country or region. Sales or transfers of Product for Clinical Trial purposes or other scientific testing purposes, test marketing purposes or programs, any expanded or early access program, any compassionate sales or use program (including named patient program or single patient program), any indigent program or charitable purposes, as free samples or any similar uses, programs, or studies, shall not constitute a First Commercial Sale.

1.66 "**FTE**" means a qualified full-time person, or more than one person working the equivalent of a full-time person, where "full time" is based upon a total of [***] working hours per Calendar Year of scientific or technical work carried out by one or more duly qualified employees of Catalyst. Overtime, and work on weekends, holidays, and the like will not be counted with any multiplier (*e.g.*, time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution.

1.67 "**FTE Costs**" means, for a given Calendar Quarter, the product of (a) the number of FTEs working on the Research Program or other activities for which Catalyst is entitled to be reimbursed hereunder in such Calendar Quarter, as documented by a reliable tracking system, and (b) the FTE Rate.

1.68 "**FTE Rate**" means [***].

1.69 "**GAAP**" means United States generally accepted accounting principles, which principles are currently used at the relevant time and consistently applied by the applicable Party.

1.70 "**Generic Version**" means with respect to a given Product in a given country in the Territory, a product that (a) (i) contains the same active pharmaceutical ingredient as such Product and is approved in reliance, in whole or in part, on a prior Regulatory Approval of such Product or (ii) is otherwise approved in reliance, in whole or in part, on a prior Regulatory Approval of such Product, and (b) is sold or marketed for sale in such country by a Third Party that has not obtained the rights to market or sell such product as a Sublicensee, Subcontractor, or Third Party Distributor of Biogen or any of its Affiliates, Sublicensees, or Subcontractors with respect to such Product. For clarity, a "biosimilar," "follow-on biologic," or "biosimilar biologic product" with respect to a Product in a given country that meets the criteria set forth in subpart (b) constitutes a "Generic Version" with respect to such Product in such country.

1.71 "**GLP**" means all applicable good laboratory practice standards, including, as applicable, as set forth in the then-current good laboratory practice standards promulgated or endorsed by the U.S. Food and Drug Administration, as defined in 21 C.F.R. Part 58, and the equivalent Applicable Law in the region in the Territory.

1.72 "**GMP**" means the then-current good manufacturing practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Parts 210, 211, 601, and 610 as such regulations may be amended from time to time, and analogous Applicable Laws of an applicable Regulatory Authority and all additional Regulatory Authority documents or regulations that replace, amend, modify, supplant, or complement any of the foregoing.

1.73 "**Governmental Authority**" means any court, tribunal, arbitrator, agency, commission, department, ministry, official, authority or other instrumentality of any national, state, county, city or other political subdivision.

1.74 [***]

1.75 "**IND**" means an Investigational New Drug application required pursuant to 21 C.F.R. Part 312 or any comparable filings outside of the United States required to commence human clinical trials in such country or region, and all supplements or amendments that may be filed with respect to the foregoing.

1.76 "**IND-Enabling Study**" means a toxicology study (a) that is conducted using applicable GLP, (b) that is conducted in a species that satisfies applicable regulatory requirements, and (c) the data and results from which are intended to meet the standard necessary for submission thereof as part of an IND with the applicable Regulatory Authority.

1.77 "**Indemnified Party**" has the meaning set forth in Section 11.3 (Procedure for Third Party Claims).

1.78 "**Indemnifying Party**" has the meaning set forth in Section 11.3 (Procedure for Third Party Claims).

1.79 "**Initial Research Term**" has the meaning set forth in Section 3.6.1 (Initial Term).

1.80 "**Initiation**" means [***] dosing of a human subject in a Clinical Trial.

1.81 "**Intellectual Property**" means all Patent Rights, copyrights, design rights, trademarks, trade secrets, Know-How, and all other intellectual property rights (whether registered or unregistered) and all applications and rights to apply for any of the foregoing, anywhere in the world.

1.82 "**Invention**" means any process, invention, method, utility, formulation, composition of matter, article of manufacture, material, creation, discovery or finding, or any improvement thereof, whether patentable or not.

1.83 "**JSC**" has the meaning set forth in Section 4.2.1 (Joint Steering Committee).

1.84 "**Know-How**" means any (a) information or materials, including records, improvements, modifications, techniques, assays, chemical or biological materials, designs, protocols, formulas, data (including physical data, chemical data, toxicology data, animal data, raw data, pre-clinical and clinical data, and analytical and quality control data), dosage regimens, control assays, product specifications, marketing, pricing and distribution costs, Inventions, algorithms, technology, forecasts, profiles, strategies, plans, results in any form whatsoever, know-how, and trade secrets (in each case, whether or not patentable, copyrightable, or otherwise protectable), and (b) any physical embodiments of any of the foregoing.

1.85 "**Liabilities**" has the meaning set forth in Section 11.1 (Indemnification by Catalyst).

1.86 "**Licensed Know-How**" means any and all Know-How that is: (a) owned or otherwise Controlled by Catalyst or any of its Affiliates as of the Effective Date or during the Term and (b) necessary or useful to (i) perform any Research Activities or (ii) Exploit any Compound or Product.

1.87 "**Licensed Patent Rights**" means (a) the Patent Rights set forth on Schedule 1.87 (Existing Licensed Patent Rights); and (b) any and all other Patent Rights that: (i) are owned or otherwise Controlled by Catalyst or any of its Affiliates as of the Effective Date or during the Term, and (ii) Cover (A) the conduct of any Research Activities, or (B) the Exploitation of any Compound or Product.

1.88 "**Licensed Technology**" means all Licensed Know-How and Licensed Patent Rights.

1.89 "**MAA**" means any new drug application, biologics license application, or other marketing authorization application, in each case, filed with the applicable Regulatory Authority in a country or other regulatory jurisdiction, which application is required to commercially market or sell a pharmaceutical or biologic product in such country or jurisdiction (and any amendments thereto), including a New Drug Application and a Biologics License Application submitted to the FDA and any analogous application or submission with any Regulatory Authority outside of the United States.

1.90 "**Major European Market**" means any of France, Germany, Italy, Spain, or the United Kingdom.

1.91 "**Manufacture**" means activities directed to manufacturing, processing, packaging, labeling, filling, finishing, assembly, quality assurance, quality control, testing, and release, shipping, or storage of any pharmaceutical or biologic product (or any components or process steps involving any product or any companion diagnostic), placebo, or comparator agent, as the case may be, including process development, qualification, and validation, scale-up, pre-clinical, clinical, and commercial manufacture and analytic development, product characterization, and stability testing, but excluding activities directed to Development, Commercialization, or Medical Affairs. "**Manufacturing**" will be construed accordingly.

1.92 "**Manufacturing Tech Transfer Plan**" has the meaning set forth in Section 6.3 (Manufacturing Technology Transfer).

1.93 "**Medical Affairs**" means activities conducted by a Party's medical affairs departments (or, if a Party does not have a medical affairs department, the equivalent function thereof), including communications with key opinion leaders, medical education, symposia, advisory boards (to the extent related to medical affairs or clinical guidance), activities performed in connection with patient registries, and other medical programs and communications, including educational grants, research grants (including conducting investigator-initiated studies), and charitable donations to the extent related to medical affairs and do not involve Commercialization of the Products.

1.94 "**Milestone Payments**" has the meaning set forth in Section 7.3.2 (Sales Milestones).

1.95 "**Net Sales**" means with respect to a Product, the gross amount invoiced in a country by Biogen or its Affiliates or Sublicensees (each of the foregoing Persons, a "**Selling Party**") for the sale or other disposition of such Product in such country to Third Parties (including Third Party Distributors), less the following deductions: [***]

1.96 [***]

1.97 "**Non-Defaulting Party**" has the meaning set forth in Section 12.2.3 (Disputes Regarding Material Breach).

1.98 "**Opposed Biogen Patent Right**" means any Biogen-Prosecuted Patent Right that is the subject of any suspected, threatened, or actual (a) infringement, (b) objection, (c) opposition, or (d) challenge by a Third Party, including, for example, declaratory judgment proceedings, *inter partes* review proceedings, post grant review proceedings, patent interference proceedings, *ex parte* and *inter partes* reexamination proceedings, and patent opposition proceedings in a court, patent office, or other administrative authority with competent jurisdiction in any country within the Territory.

1.99 "**Opposed Catalyst Patent Right**" means any Catalyst-Prosecuted Patent Right that is the subject of any suspected, threatened, or actual (a) infringement, (b) objection, (c) opposition, or (d) challenge by a Third Party, including, for example, declaratory judgment proceedings, *inter partes* review proceedings, post grant review proceedings, patent interference proceedings, *ex parte* and *inter partes* reexamination proceedings, and patent opposition proceedings in a court, patent office, or other administrative authority with competent jurisdiction in any country within the Territory.

1.100 "**Other Active**" has the meaning set forth in Section 1.32 (Combination Product).

1.101 "**Other Component**" has the meaning set forth in Section 1.95 (Net Sales).

1.102 "**Out-of-Pocket Costs**" means direct expenses paid by Catalyst or its Affiliates to Third Parties which are specifically identifiable and incurred to conduct Catalyst Research Activities or other activities for which Catalyst is entitled to be reimbursed hereunder, without markup.

1.103 "**Patent Rights**" means any and all (a) patents, (b) patent applications, including all provisional and non-provisional applications, patent cooperation treaty (PCT) applications, national phase applications, substitutions, continuations, continuations-in-part, divisions and renewals, and all patent rights granted thereon, (c) all patents-of-addition, reissues, re-examinations and extensions or restorations by existing or future extension or restoration mechanisms, including supplementary protection certificates and equivalents thereof, (d) inventor's certificates, letters patent, or (e) any other substantially equivalent form of government issued right substantially similar to any of the foregoing described in subsections (a) through (e) above, anywhere in the world.

1.104 "**Patent Term Extension**" has the meaning set forth in Section 10.5 (Patent Term Extensions).

1.105 "**Per Product Annual Net Sales**" has the meaning set forth in Section 7.4.1 (Royalty Payments).

1.106 "**Person**" means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture, Governmental Authority, association or other entity.

1.107 "**Phase I Clinical Trial**" means a clinical trial in humans that generally provides for the first introduction into humans of a pharmaceutical or biologic product with the primary purpose of determining safety, metabolism, and pharmacokinetic properties and clinical pharmacology of such product, in a manner that meets the requirements of 21 C.F.R. § 312.21(a), as amended (or its successor regulation), or, with respect to any other country or region, the equivalent of such a clinical trial in such other country or region.

1.108 "**Phase II Clinical Trial**" mean a clinical trial in humans that is intended to explore the feasibility, safety, dose ranging, or efficacy of a pharmaceutical or biologic product that is prospectively designed to generate sufficient data (if successful) to commence a Phase III Clinical Trial for such product, in a manner that meets the requirements of 21 C.F.R. § 312.21(b), as amended (or its successor regulation), or, with respect to any other country or region, the equivalent of such a clinical trial in such other country or region.

1.109 "**Phase III Clinical Trial**" means a clinical trial in humans of a pharmaceutical or biologic product that the FDA permits to be conducted under an open IND and that is performed to gain evidence with statistical significance of the efficacy of such product in a target population, and to obtain expanded evidence of safety for such product that is needed to evaluate the overall benefit-risk relationship of such product, to form the basis for approval of an MAA by a Regulatory Authority and to provide an adequate basis for physician labeling, in a manner that meets the requirements of 21 C.F.R. § 312.21(c), as amended (or its successor regulation), or, with respect to any other country or region, the equivalent of such a clinical trial in such other country or region. Notwithstanding anything to the contrary set forth in this Agreement, treatment of patients as part of an expanded access program, compassionate sales or use program (including named patient program or single patient program), or an indigent program, in each case, will not be included in determining whether or not a clinical trial is a Phase III Clinical Trial or whether a patient has been dosed thereunder.

1.110 "**Product**" means any product incorporating a Compound.

1.111 "**Prosecuting Party**" means, with respect to any Patent Right, the Party that is responsible for the preparation, filing, prosecution, and maintenance of such Patent Right pursuant to Section 10.2.1 (Right to File and Prosecute) or Section 10.2.2 (Step-In Right), as applicable.

1.112 "**Quarterly Expenses**" has the meaning set forth in Section 7.2.2 (Cost Reports and Invoices).

1.113 "**Receiving Party**" has the meaning set forth in Section 1.40 (Confidential Information).

1.114 "**Regulatory Approval**" means, with respect to a particular country or other regulatory jurisdiction, any approval of an MAA or other approval, product, or establishment license, registration, or authorization of any Regulatory Authority necessary for the commercial marketing or sale of a pharmaceutical or biologic product in such country or other regulatory jurisdiction, including, in each case, Reimbursement Approval in those countries and jurisdictions where required.

1.115 "**Regulatory Authority**" means any applicable Governmental Authority with jurisdiction or authority over the Development, Manufacture, Commercialization, or other Exploitation (including Regulatory Approval or Reimbursement Approval) of pharmaceutical or biologic products in a particular country or other regulatory jurisdiction, and any corresponding national or regional regulatory authorities.

1.116 "**Regulatory Exclusivity**" has the meaning set forth in Section [***].

1.117 "**Regulatory Submissions**" means any filing, application, or submission with any Regulatory Authority in support of the Development, Manufacture, Commercialization, or other Exploitation of a pharmaceutical or biologic product (including to obtain, support, or maintain Regulatory Approval from that Regulatory Authority), and all correspondence or communication with or from the relevant Regulatory Authority, as well as minutes of any material meetings, telephone conferences, or discussions with the relevant Regulatory Authority. Regulatory Submissions include all INDs, MAAs, and other applications for Regulatory Approval and their equivalents.

1.118 "**Reimbursement Approval**" means an approval, agreement, determination, or other decision by the applicable Governmental Authority that establishes prices charged to end-users for pharmaceutical or biologic products at which a particular pharmaceutical or biologic product will be reimbursed by the Regulatory Authorities or other applicable Governmental Authorities in the Territory.

1.119 "**Research Activities**" means, individually or collectively, (a) the activities to be performed by Catalyst under the Research Program as set forth in the Work Plan ("**Catalyst Research Activities**"); and (b) activities to be performed by Biogen under the Research Program as set forth in the Work Plan ("**Biogen Research Activities**").

1.120 "**Research Budget**" has the meaning set forth in Section 3.1.3 (Budget).

1.121 "**Research Program**" has the meaning set forth in Section 3.1.1 (General).

1.122 "**Research Reports**" means the reports required to be provided pursuant this Agreement with respect to the Research Program, including the quarterly reports summarizing the Catalyst Research Activities during the Research Term as described in Section 3.4.1 and research cost reports as described in Section 7.2 (Reimbursement of Research Costs).

1.123 "**Research Term**" has the meaning set forth in Section 3.6.2 (Extension of Research Term).

1.124 "**Residual Knowledge**" has the meaning set forth in Section 9.7 (Residual Knowledge).

1.125 "**Results**" means any and all results, information (including information related to the composition, production, and purification of any Compound(s)), data, presentations, summaries, and analyses that are generated pursuant to, or prepared as a result of, the performance of the activities under the Work Plan, by either or both Parties, as the context requires.

1.126 "**Royalty Term**" has the meaning set forth in Section 7.4.2 (Royalty Term).

1.127 "**Sales Milestone Event**" has the meaning set forth in Section 7.3.2 (Sales Milestones).

1.128 "**Sales Milestone Payment**" has the meaning set forth in Section 7.3.2 (Sales Milestones).

1.129 "**Selling Party**" has the meaning set forth in Section 1.95 (Net Sales).

1.130 "**Subcontractor**" means a Third Party contractor engaged by a Party or any of its Affiliates to perform certain obligations or exercise certain rights of such Party under this Agreement on a fee-for-service basis (including contract research organizations or contract manufacturing organizations), excluding all Sublicensees and Third Party Distributors.

1.131 "**Sublicensees**" means any Third Party to whom a Party or any of its Affiliates grants a sublicense of its rights hereunder to Exploit Compounds or Products, excluding all Subcontractors and Third Party Distributors.

1.132 "**Term**" has the meaning set forth in Section 12.1 (Term).

1.133 "**Terminated Compound or Product**" has the meaning set forth in Section 12.5.3 (Right of Reversion).

1.134 "**Territory**" means all of the countries of the world, and their territories and possessions.

1.135 "**Third Party**" means any Person other than Biogen or Catalyst or their respective Affiliates.

1.136 "**Third Party Acquisition**" has the meaning set forth in Section [***].

1.137 "**Third Party Action**" has the meaning set forth in Section 10.3.1 (Third Party Infringement).

1.138 "**Third Party Claim**" has the meaning set forth in Section 11.3 (Procedure for Third Party Claims).

1.139 "**Third Party Distributor**" means, with respect to a country, any Third Party that (a) purchases its requirements for Products in such country from Biogen or its Affiliates, Sublicensees, or Subcontractors, and (b) is appointed to distribute, market, and resell such Product in such country, even if such Third Party is granted ancillary rights to Develop, package, or obtain Regulatory Approval of such Product in order to distribute, market, or sell such Product in such country.

1.140 "**Valid Claim**" means a claim of (a) an issued and unexpired patent or a supplementary protection certificate, which claim has not been held invalid or unenforceable by a court or other government agency of competent jurisdiction from which no appeal can be or has been taken and has not been held or admitted to be invalid or unenforceable through re-examination, or disclaimer, opposition procedure, nullity suit, or otherwise, or (b) a pending patent application that has not been finally abandoned, finally rejected, or expired; *provided*, *however*, that if a claim of a pending patent application will not have issued within [***] after the earliest filing date from which such claim takes priority, then such claim will not constitute a Valid Claim for the purposes of this Agreement unless and until a patent issues with such claim.

1.141 "**Work Plan**" has the meaning set forth in Section 3.1.2 (Work Plan).

ARTICLE 2
LICENSE GRANTS

2.1 **Licenses to Biogen**.

2.1.1 **Exclusive License**. Catalyst hereby grants to Biogen and its Affiliates a worldwide, royalty-bearing, exclusive (even as to Catalyst, except to the extent necessary for Catalyst to perform its Research Activities under the Work Plan) license, with the right to sublicense (subject to the provisions of Section 2.1.2 (Sublicensing by Biogen)), under the Licensed Technology to (a) perform (or have performed) all Research Activities under the Work Plan, and (b) Exploit all Compounds and Products in the Field in the Territory.

2.1.2 **Sublicensing by Biogen**. Biogen and its Affiliates may grant sublicenses pursuant to a written sublicense agreement (through multiple tiers) under Section 2.1.1 (Exclusive License) to any Affiliate or Third Party. Any such sublicenses will be consistent with the terms of this Agreement and will include, inter alia, audit rights, record-keeping, confidentiality, non-disclosure, and non-use provisions at least as restrictive or protective of the Parties as those set forth in this Agreement, to the extent applicable.

2.2 **Licenses to Catalyst**.

2.2.1 **Collaboration License**. Biogen hereby grants to Catalyst, during the Research Term, a royalty-free, non-exclusive, worldwide license, with the right to sublicense (subject to the provisions of Section 2.2.4 (Sublicensing by Catalyst)), under the Biogen Technology solely for the purpose of performing the Catalyst Research Activities under the Work Plan.

2.2.2 **License Under Assigned Patent Rights**. Effective as of the effective date of the assignment of any Assigned Patent Right pursuant to Section 10.1.3 (Patent Assignments), and subject to Section 2.4 (Exclusivity), Biogen hereby grants to Catalyst a worldwide, perpetual, irrevocable, fully-paid, royalty-free, exclusive (even as to Biogen) license, with the right to sublicense (subject to the provisions of Section 2.2.4 (Sublicensing by Catalyst)), under such Assigned Patent Right for any and all uses except to Exploit any Compounds or Products in the Field.

2.2.3 **License Under Arising IP**. Subject to Section 2.4 (Exclusivity), Biogen hereby grants to Catalyst a worldwide, perpetual, irrevocable, fully-paid, royalty-free, non-exclusive, license, with the right to sublicense (subject to the provisions of Section 2.2.4 (Sublicensing by Catalyst)), under the Arising IP solely for use in connection with Exploiting any compound, large or small molecule, or cell or gene therapy, other than a Compound or Product.

2.2.4 **Sublicensing by Catalyst**. Catalyst may not grant any sublicense of the rights granted pursuant to Section 2.2.1 (Collaboration License) without Biogen's prior written consent. Catalyst may grant sublicenses pursuant to a written sublicense agreement (through multiple tiers) under Section 2.2.2 (License Under Assigned Patent Rights) and Section 2.2.3 (License Under Arising IP) to any Affiliate or Third Party, provided that any such sublicense under Section 2.2.3 (License Under Arising IP) is granted only in connection with the grant of a license under Catalyst's other Intellectual Property with respect to products or compounds that are not Compounds or Products. Any sublicense granted by Catalyst will be consistent with the terms of this Agreement and will include, inter alia, audit rights, record-keeping, confidentiality, non-disclosure, and non-use provisions at least as restrictive or protective of the Parties as those set forth in this Agreement, to the extent applicable.

2.3 **No Implied Licenses**. Except as expressly provided in this Agreement, neither Party will be deemed to have granted any license or other right with respect to any Intellectual Property of such Party.

2.4 **Exclusivity**.

2.4.1 **General**. Subject to Sections 2.4.2 (Exception for Change of Control) and 2.4.3 (Exception for Acquisition by Catalyst), other than in the performance of activities under this Agreement, during the applicable Exclusivity Period, Catalyst will not (and will not permit its Affiliates to), either alone or directly or indirectly with any Affiliate or Third Party: [***] a "**Competing Product**").

2.4.2 **[*****]

2.4.3 **[*****]

ARTICLE 3
COLLABORATION

3.1 **Research Program**.

3.1.1 **General**. During the Research Term, Catalyst and Biogen shall engage in a program of collaborative research activities with respect to the pre-clinical Development of Compounds as set forth in the Work Plan, with the goal of identifying at least one Development Candidate (the "**Research Program**"). All such activities shall be conducted in accordance with the Work Plan and with the terms and conditions set forth in this Agreement.

3.1.2 **Work Plan**. The Parties have agreed upon an initial work plan, which is attached to this Agreement as Schedule 3.1.2, governing the Parties' activities under the Research Program. The initial work plan may be amended from time to time during the Research Term by the JSC (as so amended, the "**Work Plan**").

3.1.3 **Budget**. The Work Plan will include a detailed budget covering the activities contemplated by the Work Plan, which budget may be amended from time to time during the Research Term by the JSC (as so amended, the "**Research Budget**"). With respect to costs to be incurred by Catalyst, the Research Budget will be expressed in terms of FTE Costs and Out-of-Pocket Costs.

3.2 **Diligence; Compliance**. Subject to Section 3.3 (Subcontracting), Catalyst will perform all Catalyst Research Activities. As between the Parties, Biogen will be responsible for performing all Biogen Research Activities, at its own cost and expense. All such activities shall be performed by the applicable Party using reasonable care and skill, in accordance with all Applicable Laws, and in accordance with the Work Plan and otherwise in accordance with this Agreement. Catalyst will not perform any activities with respect to a Compound that are not set forth in the Work Plan.

3.3 **Subcontracting**. Catalyst may subcontract portions of the Catalyst Research Activities to the pre-approved Subcontractors listed in the Work Plan. If Catalyst desires to subcontract or otherwise delegate any other portion of the Catalyst Research Activities, Catalyst must obtain Biogen's prior written consent (not to be unreasonably withheld, conditioned, or delayed). Catalyst shall (a) ensure that all Subcontractors engaged by Catalyst to perform Catalyst Research Activities are obligated to assign all Inventions (or if not feasible, exclusively license such Inventions) arising out of such Catalyst Research Activities to Catalyst to enable Catalyst to comply with its obligations under ARTICLE 10 (Intellectual Property) and (b) to the extent applicable to the subcontracted activities, use commercially reasonable efforts to cause its Subcontractors to provide the technology transfers and support described in Section 5.1 (Technology Transfer).

3.4 **Reports of Research Activities**.

3.4.1 **Reports**. Catalyst will keep Biogen reasonably informed, through the JSC, regarding the status and progress of all Catalyst Research Activities. Without limiting the foregoing, during the Research Term, on a quarterly basis, Catalyst will prepare and deliver to Biogen not later than [***] following conclusion of the applicable [***] written reports describing in reasonable detail the Catalyst Research Activities performed by or on behalf of Catalyst during the applicable Calendar Quarter. Such reports shall be sufficient in content to allow Biogen to reasonably evaluate the progress of the Catalyst Research Activities against the objectives and timelines included therefor in the Work Plan. Each report shall include the information contained in Section 7.2 (Reimbursement of Research Costs). In addition, Catalyst will include in such reports such Deliverables, Results, or other information as may be required under the Work Plan or as may otherwise be reasonably requested in advance by Biogen.

3.4.2 **JSC Review**. The JSC will review these quarterly reports and (a) confer regarding the progress towards the objectives of the Research Program, (b) review relevant Deliverables provided and Results generated in the performance of the Research Activities, (c) consider and advise on any technical issues that may arise, and (d) discuss the Biogen Research Activities (if any) performed by or on behalf of Biogen under the Work Plan during the same period; provided that Biogen will not be obligated to discuss the Biogen Research Activities, or any activities related to the Exploitation of the Compounds or any Product, with the JSC or Catalyst from and after any Change of Control of Catalyst.

3.5 **Records**.

3.5.1 **General**. Catalyst will prepare and maintain, and cause its Affiliates, Sublicensees, and Subcontractors to prepare and maintain, complete and accurate written records of all Catalyst Research Activities in sufficient detail and in good scientific manner, appropriate for scientific, patent, and regulatory purposes, which records will be complete and properly reflect all work done and results achieved in the performance of the Catalyst Research Activities under the Work Plan. In addition, Catalyst will maintain records of FTEs working on the Research Program, FTE Costs and Out-of-Pocket Costs incurred in connection with the performance of Catalyst Research Activities. Catalyst shall retain, and cause its Affiliates, Sublicensees, and Subcontractors to retain, such records for at least three years following the Research Term or such longer period as may be required by Applicable Law.

3.5.2 **Copies and Inspection of Records**. During the Collaborative Period, once every 12 months, during normal business hours and upon reasonable notice of not less than seven Business Days, Biogen will have the right to inspect, at Biogen's sole cost and expense, all records of Catalyst, its Affiliates, Sublicensees, and Subcontractors generated pursuant to, or prepared as a result of, the performance of the Research Activities by or on behalf of Catalyst. Notwithstanding the foregoing, during and after the Collaborative Period, Biogen will have the right to inspect, at Biogen's sole cost and expense, such records more than once every 12 months for reasonable cause. In addition, Catalyst shall promptly provide copies of any such records reasonably requested by Biogen. Biogen will have the right to arrange for its employees or independent consultants and (sub)contractors involved in the performance of activities under this Agreement to (a) visit the offices and laboratories of Catalyst once every 12 months during normal business hours and upon reasonable notice not less than seven Business Days, and (b) discuss with Catalyst's technical personnel and consultants the performance and progress of the Research Activities and applicable Deliverables and associated Results in detail. After preparing or receiving the report for such visit or inspection, Biogen may provide Catalyst with a written summary of Biogen's findings of any deficiencies or other areas of remediation that Biogen identifies during any such visit or inspection, it being understood that failure to achieve a desired or specific result under the Work Plan shall not in and of itself be deemed a deficiency. Catalyst will use diligent efforts to remediate any such deficiencies within 30 days after Catalyst's receipt of such report, at Catalyst's cost and expense.

3.6 **Research Term**.

3.6.1 **Initial Term**. The term of the Research Program shall begin on the Effective Date and expire, subject to Section 3.6.3 (Termination or Expiration of Research Program) on the date that is 30 months thereafter unless extended pursuant to Section 3.6.2 (Extension of Research Term) (the "**Initial Research Term**").

3.6.2 **Extension of Research Term**. Biogen may elect to extend the Initial Research Term for up to two additional 12 month periods by delivering to Catalyst written notice of extension at least three months prior to the expiration of the Initial Research Term or then-current renewal period, such notice to contain a proposed amended Work Plan and Research Budget to cover the activities to be conducted during such extension period (the Initial Research Term, as it may be extended in accordance with this Section 3.6.2 (Extension of Research Term), the "**Research Term**"). Upon receipt of such notice of extension, Catalyst shall have a period of 30 days in which to agree to such extension (such agreement not to be unreasonably withheld, conditioned, or delayed), which it shall do by written notification to Biogen. If Catalyst does not so agree with such proposed extension, no such extension shall be in effect. Notwithstanding anything to the contrary set forth in this Agreement, except as provided under Section 3.6.3, Catalyst will complete all Catalyst Research Activities in accordance with the Work Plan that are ongoing or incomplete at the end of the Research Term (whether the Initial Research Term or extension thereof), and the Research Term will be extended until the completion of all such activities as set forth under the Work Plan. In connection with any extension of the Research Term pursuant to this Section 3.6.2 (Extension of Research Term), the JSC will amend the Work Plan, including the Research Budget, as necessary, to cover the activities to be conducted during such extension period.

3.6.3 **Termination or Expiration of Research Program**.

(a) **Termination by Biogen**. Biogen may terminate the Research Program, at its sole discretion at any time, upon 60 days' prior written notice to Catalyst. In the event of such a termination, Catalyst shall wind-down any on-going Catalyst Research Activities in an expeditious manner and not commence any new Catalyst Research Activities following its receipt of the termination notice. Biogen will reimburse Catalyst in accordance with Section 7.2 (Reimbursement of Research Costs) for any [***]. Catalyst will use commercially reasonable efforts to mitigate such costs.

(b) **No Effect on Agreement**. For the avoidance of doubt, expiration or termination of the Research Program in and of itself shall have no effect on the continued effectiveness of this Agreement which shall continue in full force and effect, subject to ARTICLE 12 (Term and Termination).

(c) **Transfers upon Termination or Expiration**. Without limiting Section 5.1 (Technology Transfer) or Section 6.3 (Catalyst Manufacturing Support), upon the termination or expiration of the Research Term, Catalyst shall transfer or otherwise make available to Biogen to the extent not already in Biogen's possession, all tangible embodiments of Licensed Know-How, Deliverables, Results, and other records generated pursuant to, or prepared as a result of, the Research Program.

3.7 **Reporting Obligations Following a Change in Control**. In the event Catalyst that undergoes a Change of Control, then except for reports required to be provided pursuant to ARTICLE 7 (Payments) hereunder (*i.e.*, royalty reports and notifications of achievement of Sales Milestone Events and Development Milestone Events), all reporting obligations of Biogen (including for example pursuant to this ARTICLE 3 (Collaboration), ARTICLE 4 (Governance), and any diligence or other reports required to be provided pursuant to ARTICLE 5 (Development, Regulatory Matters, and Commercialization)) will terminate on the date such Change of Control closes or otherwise becomes effective.

3.8 **Designation of Development Candidates**. The JSC shall review and discuss from time to time the status of Compounds and whether or not any Compound meets the Development Candidate Criteria, or should otherwise be determined to be appropriate for the commencement of IND-Enabling Studies. Any such Compound so approved by the JSC to have met the Development Candidate Criteria or otherwise be appropriate for the commencement of IND-Enabling Studies shall be deemed a Development Candidate. Any disagreement with respect to whether such Development Candidate Criteria have been met, or whether a Compound otherwise is appropriate for the commencement of IND-Enabling Studies shall be subject to Biogen's final decision-making authority in accordance with Section 4.2.4 (Decision Making Authority). For clarity, at any time during the Term, Biogen shall nonetheless have the right to determine whether any Compound meets the Development Candidate Criteria or otherwise is appropriate for the commencement of IND-Enabling Studies. As used in this Agreement, "**Development Candidate**" means each Compound (a) that meets the Development Candidate Criteria (whether determined by the JSC or Biogen); (b) that does not meet the Development Candidate Criteria but nonetheless is determined by the JSC (or by Biogen) as appropriate for the commencement of IND-Enabling Studies, or (c) for which Biogen otherwise elects to commence IND-Enabling Studies.

ARTICLE 4
GOVERNANCE

4.1 **Alliance Management**.

4.1.1 **Alliance Managers**. Each Party will appoint a single individual who possesses sufficient alliance management experience and is otherwise suitably qualified and that has the requisite decision-making authority, in each case, to act as its alliance manager under this Agreement to support the Research Activities and the Research Program (the "**Alliance Manager**"). The initial Alliance Managers will be appointed within 30 days of the Effective Date. Each Party may change the person designated as its Alliance Manager upon written notice (including via email notification) to the other Party, *provided* that such new Alliance Manager possesses sufficient alliance management experience and otherwise meets the requirements set forth in this Section 4.1.1 (Alliance Managers).

4.1.2 **Roles and Responsibilities**. The Alliance Managers will be responsible for (a) facilitating the flow of information and otherwise promoting communication of the day-to-day work for the Research Program, (b) coordinating the Research Activities, (c) providing a single point of communication for seeking consensus both internally within the respective Party's organization and between the Parties regarding key strategy and planning issues, (d) assisting the integration of teams across functional areas, (e) preparing and disseminating agendas and presentations for the JSC meetings, (f) conducting the meetings of the JSC, and (g) performing such other functions as requested by the JSC.

4.2 **Joint Steering Committee**.

4.2.1 **Formation**. As soon as practicable, but no later than [***] after the Effective Date, the Parties will establish a joint steering committee (the "**JSC**") to oversee the Research Activities. The JSC will be comprised of [***], each of whom will have the appropriate experience and expertise to perform its responsibilities on the JSC, [***]. Each Party will provide notice to the other Party of its initial representatives to the JSC. Either Party may replace its representatives with similarly qualified individuals at any time upon prior written notice to the other Party. If agreed by the JSC on a case-by-case basis, the JSC may invite other non-members to participate in the discussions and meetings of the JSC, *provided* that such participants will have no voting authority at the JSC and that any such non-employee participants are bound by written obligations of non-use and confidentiality no less stringent than those set forth in ARTICLE 9 (Confidentiality). The Alliance Managers will be responsible, on behalf of the JSC, for setting the agenda for meetings of the JSC with input from the other members and for conducting the meetings of the JSC. Neither Alliance Manager will be a member of the JSC, but the Alliance Managers or suitable designees will attend all meetings of the JSC.

4.2.2 **Meetings**. The JSC will meet in person (alternating between a site designated by each of Catalyst and Biogen) or by teleconference at least once every Calendar Quarter, or with such other frequency as the Parties may agree. Specific meeting dates will be determined by agreement of the Parties. Either Party may also call a special meeting of the JSC (by videoconference or teleconference) upon at least 10 Business Days' prior written notice to the other Party if such requesting Party reasonably believes that a significant matter must be addressed before the next regularly scheduled JSC meeting. Biogen will host the first meeting of the JSC at a mutually agreeable time and place no later than 60 days after the Effective Date. Each Party will be responsible for its own expenses relating to attendance at or participation in JSC meetings. The Alliance Managers will prepare and disseminate agendas and presentations no later than five Business Days in advance of each JSC meeting unless otherwise agreed to by the Parties in writing. The Alliance Managers will jointly prepare and circulate minutes for each JSC meeting within 10 Business Days after each such meeting and will ensure that such minutes are reviewed and approved by their respective companies within 30 days thereafter.

4.2.3 **Responsibilities**. The JSC will oversee and monitor the progress of the Research Activities. Within such scope the JSC will, subject to Section 4.2.4 (Decision Making Authority) and Section 4.2.5 (Limits of JSC Decision Making Authority):

(a) review and approve any amendments to the Work Plan and associated Research Budget;

(b) oversee and guide the Research Program, including by discussing the Research Activities conducted since the previous JSC meeting;

(c) oversee and guide the technology transfers contemplated pursuant to this Agreement;

(d) consider and advise on any technical issues that arise under the Research Program;

(e) form such other committees as the JSC may deem appropriate, including individual committees to oversee the Research Activities;

(f) discuss, plan, and coordinate the transition of Manufacturing activities and transfer of Know-How to Biogen that is necessary or useful for the Manufacture of Compounds and Products;

(g) attempt to resolve any disputes on an informal basis; and

(h) perform such other functions as expressly set forth in this Agreement or allocated to the JSC by the written agreement of the Parties.

4.2.4 **Decision Making Authority**. A quorum for a meeting of the JSC will require the presence of at least one representative from each Party. The JSC will endeavor to reach decisions by consensus, with each Party, through its representative members of the JSC, having one vote, provided that a quorum must be present for any decision to be made by the JSC. In the event that the JSC is unable to reach consensus on any decision at the meeting during which the applicable matter is presented to the JSC, then, subject to the terms of this Agreement, including Section 4.2.5 (Limits on JSC Decision Making Authority), Biogen will have final decision making authority with respect to such decision, including any amendment to the Work Plan or Research Budget.

4.2.5 **Limits on JSC Decision Making Authority**. Notwithstanding anything to the contrary set forth in this Agreement, without Catalyst's prior written consent, no decision of the JSC or Biogen (in the exercise of its final decision-making authority on any such matters as set forth in Section 4.2.4 (Decision Making Authority)), in each case, may:

(a) [***]

(b) [***]

(c) require that Catalyst take or decline to take any action that would be reasonably likely to result in a violation of any Applicable Law, the requirements of any Regulatory Authority, or any agreement between Catalyst and any Third Party, or, that would be reasonably likely to result in the infringement, misappropriation, or other violation of any Intellectual Property of any Third Party; or

(d) conflict with this Agreement.

4.3 **Termination of Decision-Making Authority and Disbandment of the JSC**.

4.3.1 **Decision Making Authority**. The JSC's decision-making authority will terminate (a) with respect to a Compound, upon the date on which (i) such Compound has either been (A) designated as a Development Candidate in accordance with Section 3.8 (Designation of Development Candidates); or (B) determined by Biogen to be appropriate for commencement of IND-Enabling Studies, and (ii) Catalyst has completed all assigned Catalyst Research Activities with respect to such Compound; and (b) in its entirety, upon expiration or early termination of the Research Term.

4.3.2 **Disbandment**. The JSC will terminate and disband upon expiration or early termination of the Research Term. Prior to the termination of the JSC, the JSC will have a final meeting to review the results of the all Research Activities and for clarity will have no further authority with respect to any activities under this Agreement.

ARTICLE 5
DEVELOPMENT, REGULATORY MATTERS, AND COMMERCIALIZATION

5.1 **Technology Transfer**.

5.1.1 **Initial Transfer**. Catalyst will make available to Biogen copies of all Licensed Know-How in its Control as of the Effective Date no later than 30 days after the Effective Date.

5.1.2 **Collaborative Period**. Concurrently with Catalyst's delivery to Biogen of a Research Report, Catalyst will make available to Biogen copies of all Licensed Know-How that was generated under the Research Program or otherwise made, conceived, discovered, or otherwise generated or acquired since the prior such report. In addition, after the Research Term and until expiration of the Collaborative Period, from time to time but no less frequently than once per Calendar Quarter, Catalyst will transfer to Biogen any Licensed Know-How either (i) intended to be, but not previously made available to Biogen or (ii) made, conceived, discovered, or otherwise generated or acquired since the previous transfer of such Licensed Know-How.

5.1.3 **Other Support**. After the Collaborative Period, from time to time during the Term [***] Catalyst will transfer to Biogen any Licensed Know-How intended to be, but not previously made available to Biogen. In addition, after the Collaborative Period, upon the reasonable request of Biogen, Catalyst shall make available to Biogen any Licensed Know-How that is [***]. During the Term and until [***], Catalyst will make its personnel reasonably available to Biogen so as to enable Biogen to practice the Licensed Technology in connection with the Exploitation of Compounds and Products. [***]

5.2 **Development and Medical Affairs**. Subject to any applicable decision-making authority of the JSC during the Research Term, Biogen will have sole control over, will bear all costs and expenses of, and will have sole discretion and decision-making authority with respect to, the Development of, and the performance of all Medical Affairs with respect to, Compounds and Products.

5.3 **Regulatory Activities**. Biogen will have sole control over the preparation and submission of all Regulatory Submissions for all Products at its own cost and expense, including all MAAs and applications for obtaining, supporting, and maintaining Regulatory Approvals (including Reimbursement Approvals) for all Products. Biogen may file all such applications in its own name (or in the name of its designee) and, as between the Parties, will own and control all such applications. [***] upon Biogen's reasonable request, Catalyst will reasonably cooperate to assist Biogen in its efforts to prepare and submit any Regulatory Submissions to obtain, support, or maintain Regulatory Approvals for each Product (which assistance must be in accordance with Applicable Law and any other standards of the applicable Regulatory Authorities).

5.4 **Commercialization**. Biogen will have sole control over, will bear all costs and expenses of (except as set forth in ARTICLE 7 (Payments and Royalties)), and, without limiting its obligations under Section 5.5.2 (Commercialization Diligence Obligations), will have sole discretion and decision-making authority with respect to, the Commercialization of all Compounds and Products.

5.5 **Diligence Obligations**.

5.5.1 **Development Diligence Obligations**. Subject to Catalyst's performance of its obligations under the Work Plan, beginning as of the Diligence Trigger, Biogen, itself or through its Affiliates, Sublicensees, or Subcontractors, will use Commercially Reasonable Efforts to [***].

5.5.2 **Commercialization Diligence Obligations**. Biogen, itself or through its Affiliates, Sublicensees, or Subcontractors, will use Commercially Reasonable Efforts to [***].

5.5.3 **Limitation**. The covenants contained in this Section 5.5 (Diligence Obligations) are the only agreements or commitments made by Biogen with respect to the level of efforts or resources to be expended by it, its Affiliates, its Sublicensees or Subcontractors in respect of the Exploitation of any Compound or Product, and except as expressly set forth in this Section 5.5 (Diligence Obligations), such Exploitation shall be in Biogen's sole discretion. For clarity, Biogen will have no other diligence obligations under this Agreement with respect to the Development, Regulatory Approval, Commercialization, or other Exploitation of any Compound or Product except as expressly set forth in this Section 5.5 (Diligence Obligations).

5.6 **Reimbursement for Assistance**. [***].

5.7 **Annual Reports**. Following the Calendar Year in which the expiration or termination of the Research Term occurs, and each Calendar Year thereafter, Biogen shall provide Catalyst with a written report that summarizes at a high level material Development activities performed by Biogen and its Affiliates, Sublicensees, and Subcontractors with respect to Compounds and Products during such Calendar Year within [***] after the end of such Calendar Year; provided that the obligation to provide such reports shall terminate at such time as Biogen no longer has obligations under Section 5.5.1 (Development Diligence Obligations).

ARTICLE 6
MANUFACTURING

6.1 **General Responsibilities**. Following successful manufacturing technology transfer as set forth in Section 6.3 (Manufacturing Technology Transfer) for each relevant Compound or Product, Biogen will have sole responsibility for, and sole decision-making authority with respect to, all Manufacturing activities and associated costs and expenses for the Manufacture of such Compound or Product.

6.2 **Observation by Biogen; Transfer of CMO Agreements**.

6.2.1 **General**. From time to time during the Research Term and until successful manufacturing technology transfer as set forth in Section 6.3 (Manufacturing Technology Transfer), Catalyst will provide Biogen with the opportunity, upon Biogen's reasonable request and during normal business hours, to observe and discuss with relevant personnel of Biogen or any Third Party contract manufacturing organization ("**CMO**") engaged by Catalyst the Manufacturing processes and procedures for Compounds (including to review assays, batch records, and release processes and procedures) for the purpose of enabling Biogen or a CMO designated by Biogen to Manufacture such Compounds and Products that incorporate such Compounds pursuant to Section 6.3 (Manufacturing Technology Transfer).

If Catalyst utilizes a CMO for the Manufacture of any Compound, then Catalyst will take all reasonable actions, including entering into a three-party agreement with Biogen and such CMO, to enable Biogen to exercise its rights under Section 6.3 (Manufacturing Technology Transfer) and this Section 6.2 (Observation by Biogen; Transfer of CMO Agreements).

6.2.2 **Transfer of CMO Agreements**. Without limiting the foregoing, Catalyst agrees that, if requested by Biogen, it will (or cause its Affiliates to, as applicable), to the extent legally permissible: (a) assign to Biogen or its designee any existing agreements with a CMO for the Manufacture of Compounds and all Products that incorporate such Compounds; or (b) assist Biogen or its Affiliate in entering into new agreements directly with such CMO for such Manufacture. If any such existing CMO agreement is assigned to Biogen, Catalyst will be solely responsible for, and will indemnify and hold harmless Biogen and all other Biogen Indemnified Parties from and against any costs and other Liabilities arising from, or relating to, any such CMO agreement as a result of, or in connection with, events or occurrences prior to the date of such assignment (including any payments that accrued prior to the date of such assignment but which do not become payable until after the date of such assignment). Biogen will be solely responsible for, and will indemnify and hold harmless Catalyst and all other Catalyst Indemnified Parties from and against any costs and other Liabilities arising from, or relating to, any such CMO agreement as a result of, or in connection with, events or occurrences on or after the date of such assignment.

6.3 **Manufacturing Technology Transfer**. In addition to the technology transfers provided for in Section 5.1 (Technology Transfer), following designation of a Development Candidate and no later than [***] following Biogen's written request (email is acceptable) with respect to any such Development Candidate, the Parties will develop and agree upon a plan for the transfer of the manufacturing process and related Licensed Know-How then in existence for such Development Candidate (each, a "**Manufacturing Tech Transfer Plan**") that will include all activities necessary to enable Biogen (or a CMO designated by Biogen) to Manufacture the applicable Development Candidate and all Products that incorporate such Development Candidate, utilizing such process. The Parties will perform the activities set forth in the Manufacturing Tech Transfer Plan for each such Development Candidate as quickly as possible following the Parties' agreement thereon, but in any event no later than [***] following such agreement with respect to such plan. Thereafter [***].

6.4 **Reimbursement for Catalyst Manufacturing Support**. [***]

ARTICLE 7
PAYMENTS AND ROYALTIES

7.1 **Upfront Fee**. In consideration of the licenses and rights granted to Biogen and its Affiliates hereunder, Biogen will pay to Catalyst a one-time upfront payment of fifteen million Dollars ($15,000,000) within 10 Business Days after the Effective Date.

7.2 **Reimbursement of Research Costs**.

7.2.1 **Nonbinding Estimates**. Within [***] after the conclusion of each Calendar Quarter during the Research Term, for planning purposes, Catalyst will deliver a summary report containing nonbinding estimates of the FTE Costs and Out-of-Pocket Costs incurred by Catalyst in the performance of Catalyst Research Activities during such Calendar Quarter for which Catalyst expects to request reimbursement.

7.2.2 **Cost Reports and Invoices**. Within [***] after the conclusion of each Calendar Quarter during the Research Term, Catalyst will deliver the quarterly report as described in Section 3.4.1 (Reports). Such report shall include the following information: (a) all FTE Costs and Out-of-Pocket Costs (along with reasonable supporting documentation), in each case, incurred by or on behalf of Catalyst during the applicable Calendar Quarter in the performance of the Catalyst Research Activities during such Calendar Quarter (the "**Quarterly Expenses**") and (b) a reasonable non-binding rolling estimate of the projected FTE Costs and Out-of-Pocket Costs, in each case, to be incurred on a Calendar Quarter-by-Calendar Quarter basis by or on behalf of Catalyst in order to complete the Catalyst Research Activities as set forth under the Work Plan. Such report shall also include a reasonably detailed invoice for the Quarterly Expenses (on a work stream-by-work stream basis) for which Catalyst is seeking reimbursement. Biogen shall reimburse Catalyst for such Quarterly Expenses, provided that, notwithstanding the foregoing, Biogen shall not be obligated to reimburse Catalyst for any Quarterly Expenses which [***] unless such excess costs are approved by the JSC. Payments under this Section 7.2.2 with respect to any Calendar Quarter will be made within [***] following the receipt by Biogen of the report and invoice for the applicable research costs for such Calendar Quarter.

7.2.3 **[***]

7.3 **Milestone Payments**.

7.3.1 **Development Milestones**.

(a) **General**. Biogen will make one-time milestone payments (each, a "**Development Milestone Payment**") to Catalyst upon the first achievement by Biogen or its Affiliates or Sublicensees of each of the development milestone events set forth in TABLE 7.3.1 below for the first Product that is Covered by a Valid Claim (at the time of such achievement) of a Licensed Patent Right, Patent Right within the Arising IP, or Assigned Patent Right (each, a "**Development Milestone Event**"), to achieve the applicable Development Milestone Event. For the avoidance of doubt, each Development Milestone Payment hereunder will be payable only once upon the first achievement of the applicable Development Milestone Event by any Product. No additional Development Milestone Payments will be made for any subsequent achievement of such Development Milestone Event by such Product or any other Product regardless of whether such other Product contains the same Compound.

(b) **Milestone Catch-Up**. If one or more Development Milestone Events involving the Initiation of a Clinical Trial are skipped (*i.e.*, a Development Milestone Event is achieved prior to such a Development Milestone Event involving the Initiation of a Clinical Trial that precedes such first Development Milestone Event in the table below), then such skipped Development Milestone Event(s) will be payable upon achievement of the subsequent Development Milestone Event (*e.g.*, where no Initiation of a Phase II Clinical Trial occurs, but the Initiation of a Phase III Clinical Trial occurs with respect to the same Product, then at the time of payment of the Development Milestone Payment for Initiation of the Phase III Clinical Trial Biogen shall also pay to Catalyst the Development Milestone Payment for Initiation of the Phase II Clinical Trial). For clarity, a Development Milestone Event in one territory will not be deemed to be skipped solely because a subsequent Development Milestone Event was achieved in a different territory (*e.g.*, the First Commercial Sale of a Product in the third Major European Market will not be deemed to trigger a Development Milestone Payment for the First Commercial Sale of any Product in the United States).

(c) **Notification of Achievement**. Biogen will notify Catalyst of the achievement of a Development Milestone Event by Biogen or its Affiliates or Sublicensees no later than [***] after Biogen becomes aware of the achievement thereof. Thereafter, Catalyst will provide Biogen with an invoice for the corresponding Development Milestone Payment. Biogen will pay to Catalyst such Development Milestone Payment no later than [***] after its receipt of the applicable invoice. For clarity, the total Development Milestone Payments that may become due and payable under this Agreement shall in no event exceed [***].

TABLE 7.3.1 – Development Milestones	
Development Milestone Event	***Development Milestone Payment***
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

7.3.2 **Sales Milestones**.

(a) **General**. Biogen will make one-time sales milestone payments (each, a "**Sales Milestone Payment**" and together with the Development Milestone Payments, the "**Milestone Payments**") to Catalyst upon the achievement by Biogen or its Affiliates or Sublicensees of each of the sales-based milestones events (each, a "**Sales Milestone Event**") set forth in TABLE 7.3.2 below with respect to [***] ("**Annual Net Sales**"). Each of the Sales Milestone Payments set forth below will be payable only one time, and, except as otherwise provided in Section 7.3.2(b) (Notification of Achievement), only for the first Calendar Year in which the corresponding Sales Milestone Event is achieved.

(b) **Notification of Achievement**. Biogen will notify Catalyst in writing of the achievement of a Sales Milestone Event by Biogen or its Affiliates or Sublicensees no later than 45 days after the end of the Calendar Year in which such Sales Milestone Payment is achieved. Thereafter, Catalyst will provide Biogen with an invoice for the corresponding Sales Milestone Payment. Biogen will pay to Catalyst such Sales Milestone Payment no later than [***] after its receipt of the applicable invoice. If more than one Sales Milestone Event is achieved by Biogen or its Affiliates or Sublicensees in any Calendar Year, Biogen will only be obligated to pay the highest Sales Milestone Payment corresponding to any Sales Milestone Event that was achieved in such Calendar Year and (except as provided in the next sentence) no other Sales Milestone Payments for such Calendar Year. [***]

TABLE 7.3.2 – Sales Milestones	
Sales Milestone Event	***Sales Milestone Payment***
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

7.4 **Royalties**.

7.4.1 **Royalty Payments**. Subject to the provisions of Section 7.4.4 (Payment Adjustments), on a Product-by-Product and country-by-country basis, Biogen will pay to Catalyst royalties on aggregate Net Sales in each Calendar Year resulting from the sale of a Product in the Territory during the applicable Royalty Term for such Product in each country (each, the "**Per Product Annual Net Sales**") in the amounts set forth in TABLE 7.4.1 below.

TABLE 7.4.1 – Marginal Royalty Rates	
Per Product Annual Net Sales	***Marginal Royalty Rate (% of Per Product Annual Net Sales)***
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Each marginal royalty rate set forth in TABLE 7.4.1 above will apply only to that portion of the Per Product Annual Net Sales of a given Product in the Territory during a given Calendar Year that falls within the indicated range. For example, [***]

7.4.2 **Royalty Term**. On a Product-by-Product and country-by-country basis, Biogen's obligation to pay royalties will begin upon the First Commercial Sale of a Product in a country and will expire upon the later of (a) the expiration of the last-to-expire Valid Claim of a (i) Licensed Patent Right, (ii) Patent Right within the Arising IP; and (iii) Assigned Patent Right, in each case (of (i)-(iii)) Covering the composition of matter of such Product in such country; or (b) the tenth anniversary of the First Commercial Sale of the first Product in such country (the "**Royalty Term**"). Upon expiration of the Royalty Term for a given Product in a given country: (i) no further royalties will be payable in respect of sales of such Product in such country, (ii) sales of such Product in such country will not be included in the calculation of aggregate Net Sales under Section 7.3.2 (Sales Milestones) (*i.e.*, for purposes of determining whether a Sales Milestone Event has been achieved) or for purposes of calculating the royalty tiers pursuant to Section 7.4.1 (Royalty Payments) and (iii) the licenses granted under Section 2.1.1 (Exclusive License) with respect to the Exploitation of such Product in such country will automatically become fully paid-up, perpetual, irrevocable, and royalty-free. For clarity, only a single royalty will be payable on the sale of a Product regardless of the number of Valid Claims Covering such Product during the applicable Royalty Term.

7.4.3 **Royalty Reports; Payments**.

(a) **Royalty Reports**. No later than [***] after the end of each Calendar Quarter during which any royalty payments are owed, Biogen will submit to Catalyst a written report of Net Sales of Products sold, in the currency for which such Products were sold (and, if the currency of sale was not Dollars, also in Dollars), by or on behalf of Biogen and its Affiliates and Sublicensees during such Calendar Quarter, and the royalty payments payable on such Net Sales, in sufficient detail to permit confirmation of the accuracy of royalty payments paid hereunder.

(b) **Royalty Payments**. Royalties will be payable on a Calendar Quarter basis. Biogen will make any such payments within [***] after the end of the Calendar Quarter during which the applicable Net Sales of Products occurred.

7.4.4 **Payment Adjustments**.

(a) **Reductions for Patent Expiry, Generic Versions, and Compulsory Licenses**. Subject to Section 7.4.4(c) (Maximum Payment Reductions), the royalties payable under Section 7.4 (Royalties) with respect to Net Sales of a Product in a country shall be reduced as follows:

(i) upon the expiration of the last to expire Valid Claim of a Licensed Patent Right, Patent Right within the Arising IP, and Assigned Patent Right, in each case Covering the composition of matter of such Product in such country, the royalties payable pursuant to Section 7.4 (Royalties) with respect to Net Sales of such Product in such country will be reduced by [***] for the remainder of the Royalty Term for such Product in such country (if any); and

(ii) upon the earlier of (A) the date on which a Third Party first sells a Generic Version of such Product in such county, or (B) the date on which a Third Party sells any product that contains the same Compound as such Product in such country under a compulsory license granted or ordered to be granted by a competent Governmental Authority (a "**Compulsory License**"), the royalties payable pursuant to Section 7.4 (Royalties) with respect to Net Sales of such Product in such country will be reduced by an additional [***] of the royalties otherwise payable pursuant to Section 7.4 (Royalties) (calculated after giving effect to any adjustment pursuant to Section 7.4.4(a)(i)) for the remainder of the Royalty Term for such Product in such country (if any) [***].

(b) **Third Party Payments**. Without limiting Biogen's rights or Catalyst's responsibilities under Section 7.4.5 (Third Party Agreements), if Biogen or any Affiliate or Sublicensee thereof enters into an agreement with a Third Party to obtain rights (whether by acquisition or license) under a Patent Right or other Intellectual Property owned or controlled by such Third Party, and such rights are necessary or useful to Exploit one or more Compounds or Products (but not any Other Active of any Combination Product), then, subject to Section 7.4.4(c) (Maximum Payment Reductions), Biogen may offset against the royalties due to Catalyst an amount equal to [***] of the amounts paid to such Third Party under such agreement (including any upfront payments, milestone payments, royalties (whether based on net sales or profits)); provided that if such agreement also includes a license under Intellectual Property that Covers products other than any Compound or Compound Component of any Product, such reduction shall only apply to an appropriately allocated portion of such payments (such allocation to be done in good faith by Biogen). [***].

(c) **Maximum Payment Adjustments**. In no event will the royalties payable to Catalyst in a given Calendar Quarter be reduced by more than [***] of the aggregate amount that would otherwise be payable to Catalyst in respect of such royalties in such Calendar Quarter (as set forth in TABLE 7.4.1) as a result of the reductions permitted pursuant to Section 7.4.4(a) (Reductions for Patent Expiry, Generic Versions, and Compulsory Licenses) and Section 7.4.4(b) (Third Party Payments). Biogen may carry forward any such reductions permitted under Section 7.4.4(a) (Reductions for Patent Expiry, Generic Versions, and Compulsory Licenses) and Section 7.4.4(b) (Third Party Payments) that are incurred or accrued in a Calendar Quarter but are not applied against royalties due to Catalyst in such Calendar Quarter as a result of the foregoing floor. Biogen may apply such amounts against royalties due to Catalyst in any subsequent Calendar Quarter (subject to the minimum floor set forth in this Section 7.4.4(c) (Maximum Royalty Adjustments)) until the full amount of such reduction has been fully applied against royalties due to Catalyst.

(d) **Compulsory Licenses**. Notwithstanding any other provision hereof, in no event will the royalties payable under this Section 7.4 (Royalties) on the sale of any Product by a Sublicensee pursuant to a Compulsory License exceed the royalty actually received by Biogen or its Affiliates from such Sublicensee with respect to such sale.

7.4.5 **Third Party Agreements**. Catalyst will be solely responsible for (i) all obligations (including any royalty or other payment obligations, including those which relate to the Licensed Technology or Assigned Patent Rights) under any agreement between Catalyst or any Affiliate thereof and any Third Party that is in effect as of the Effective Date or that Catalyst or any Affiliate thereof enters into during the Term and (ii) all payments to inventors (other than inventors that are representatives of Biogen) of Licensed Technology, Assigned Patent Rights, Results, and Deliverables, including payments under inventorship compensation laws.

7.5 **Payment Method**. All payments to be made between the Parties under this Agreement will be made in Dollars and may be paid by wire transfer in immediately available funds to a bank account designated by Catalyst; *provided* that in no event will Biogen be obligated to make payments under this Agreement to any Person organized in any jurisdiction outside of the U.S. without Biogen's prior written consent. All undisputed invoiced amounts are due within [***] following the date of the invoice, unless a different time period is specified herein.

7.6 **Currency Exchange**. Biogen's then-current standard exchange rate methodology will be employed for the translation of foreign currency sales into Dollars.

7.7 **Late Payments**. If a Party does not receive payment of any undisputed sum due to it on or before the due date set forth under this Agreement, then simple interest will thereafter accrue on the sum due to such Party from the due date until the date of payment at a per-annum rate of one percentage point over the then-current prime rate reported in *The Wall Street Journal* or the maximum rate allowable under Applicable Law, whichever is lower.

7.8 **Taxes**.

7.8.1 **Responsibility**. Except as expressly set forth in Section 7.8.2 (Withholding Taxes), Catalyst will pay any and all taxes levied on account of all payments it receives under this agreement.

7.8.2 **Withholding Taxes**. Catalyst will provide such information and documentation to Biogen as are reasonably requested by Biogen to determine if any withholding taxes apply to any payments to be made by Biogen to Catalyst under this Agreement. Solely to the extent that Applicable Law requires that taxes be withheld with respect to any such payments to be made by Biogen to Catalyst under this Agreement, Biogen will: (a) deduct those taxes from the remittable payment, (b) pay the taxes to the proper taxing authority, and (c) send evidence of the obligation together with proof of tax payment to Catalyst on a reasonable and timely basis following such tax payment. Any such payments made to any taxing authority in accordance with the foregoing shall be deemed to have been made to Catalyst in satisfaction of the applicable payment obligation as contemplated in this Agreement. Each Party agrees to reasonably cooperate with the other Party in claiming refunds or exemptions from such deductions or withholdings under any relevant agreement or treaty that is in effect.

7.9 **Financial Audits**.

7.9.1 **Record Retention; Audits**. Each Party will keep (and will cause its Affiliates and Sublicensees to keep) complete and accurate records pertaining to (a) in the case of Biogen [***] (the "**Catalyst Records**"), in each case ((a) and (b)), in reasonable detail to permit the other Party to confirm the accuracy of all payments or costs reported, for at least the preceding [***]. Upon reasonable (but in any case no less than [***]) advance notice by one Party (the "**Auditing Party**") to the other Party (the "**Audited Party**") and not more than [***], the Audited Party and its Affiliates will permit, and will cause their Sublicensees to permit, an independent certified public accounting firm of internationally recognized standing, selected by the Auditing Party and reasonably acceptable to the Audited Party, to have access during normal business hours to such of the records of the Audited Party and its Affiliates and, if applicable, their Sublicensees, as may be reasonably necessary to verify the accuracy of (i) in the case of Biogen as the Audited Party [***] and (ii) in the case of Catalyst as the Audited Party, [***]. The accounting firm will enter a confidentiality agreement reasonably acceptable to the Audited Party governing the use and disclosure of the Audited Party's information disclosed to such firm, and such firm will disclose to the Auditing Party only whether information provided by the Audited Party to the Auditing Party as described in clauses (a) and (b) above was accurate and the specific details concerning any discrepancies, which information will be Confidential Information of the Audited Party.

7.9.2 **Audit Disputes**. Any disputes with respect to the findings of such accounting firm may be referred by either Party to the dispute resolution procedure set forth in Section 13.8 (Dispute Resolution). If either Party is found to have been underpaid any amounts payable to such Party hereunder or to have overpaid to the other Party any amounts payable hereunder, then such first Party will be entitled to receive any undisputed discrepancy, plus interest as set forth in Section 7.7 (Late Payments), no later than [***] after delivery to the Parties of the final report of such accounting firm. For clarity, in the case of Biogen, all or any portion of the amount of such discrepancy may be set of against any other payments owed to Catalyst under this Agreement. The fees charged by such accounting firm will be paid by the Auditing Party; *provided* that if the audit discloses a net underpayment of amounts owed or over-reporting of expenses by the Audited Party of more than [***] of total amounts owed or expenses reported by the Audited Party for any Calendar Year period covered by the audit, then, in addition to the payment of the underpaid amount (or reimbursement of the overpaid amount, as applicable), the Audited Party will pay the reasonable fees and expenses charged by such accounting firm. The Auditing Party will treat all financial information disclosed by its accounting firm pursuant to this Section 7.9 (Financial Audits) as Confidential Information of the Audited Party for purposes of ARTICLE 9 (Confidentiality) of this Agreement, and will cause its accounting firm to do the same.

ARTICLE 8
REPRESENTATIONS, WARRANTIES, AND COVENANTS

8.1 **Mutual Representations and Warranties of the Parties**. Each Party represents and warrants to the other Party as of the Effective Date that:

8.1.1 it is duly organized, validly existing and in good standing under the Applicable Law of the jurisdiction of its incorporation and has all requisite corporate power and authority to enter into this Agreement and to perform its obligations, in each case, under this Agreement;

8.1.2 the execution of this Agreement and the performance by such Party of its obligations hereunder have been duly authorized;

8.1.3 this Agreement has been duly executed and delivered on behalf of such Party, and is valid, legally binding, and enforceable against such Party in accordance with its terms;

8.1.4 the performance of this Agreement by such Party does not create a breach or default under any other agreement to which it is a Party;

8.1.5 the execution, delivery, and performance of this Agreement by such Party does not conflict with any agreement, instrument, or understanding, oral or written, to which it is a party or by which it is bound, nor violate any Applicable Law or regulation of any Governmental Authority; and

8.1.6 it has obtained all necessary government authorizations, consents, approvals, licenses, exemptions of, or filings or registrations with Governmental Authorities, under any Applicable Law currently in effect, that are or will be necessary for the transactions contemplated by this Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Agreement.

8.2 **Additional Representations and Warranties of Catalyst**. Catalyst represents and warrants to Biogen as of the Effective Date that:

8.2.1 it has the full right, power, and authority to grant all of the licenses and rights granted under this Agreement;

8.2.2 (a) Schedule 1.87 (Existing Licensed Patent Rights) sets forth a complete and accurate list of all Patent Rights existing as of the Effective Date that are owned or otherwise Controlled by Catalyst or any of its Affiliates and Cover the performance of the Research Activities or the Exploitation of any Compound; and (b) except as otherwise noted on Schedule 1.87 (Existing Licensed Patent Rights), Catalyst exclusively owns all rights, title, and interests in and to such Patent Rights, and where Catalyst does not exclusively own any such Patent Right, Schedule 1.87 (Existing Licensed Patent Rights) identifies the owner of such Patent Right and the Existing In-License pursuant to which Catalyst (or its Affiliate) Controls such Patent Right;

8.2.3 the documents, data, and information that are included in the Licensed Know-How listed on Schedule 8.2.3 (Licensed Know-How) constitute all of the Know-How owned or otherwise Controlled by Catalyst or any of its Affiliates as of the Effective Date that is necessary to perform its obligations under the Research Program;

8.2.4 there are no pending or threatened in writing actions, suits, claims, arbitrations, or other proceedings, that the practice of the Licensed Technology by Catalyst or its Affiliates or licensees has infringed, misappropriated, or otherwise violated, or would infringe, misappropriate, or otherwise violate, any of the Intellectual Property of any Third Party;

8.2.5 there are no claims, judgments, or settlements against or pending, or amounts with respect thereto, owed by Catalyst or any of its Affiliates, with respect to the Licensed Technology, and Catalyst has not received written notice threatening any such claims, judgments, or settlements;

8.2.6 to Catalyst's Knowledge, practice by Catalyst or Biogen under the Licensed Technology of the activities set forth in the Work Plan, including the manufacture, use or sale by Catalyst or Biogen (or their respective Affiliates or Sublicensees) of the Compounds referred to as CB-2963, CB-2782 or CB-2782-PEG, in each case, for use in the Research Program as contemplated under this Agreement, does not and will not (as of the Effective Date) infringe any issued patent of any Third Party or, if and when issued, any claim within any published patent application of any Third Party;

8.2.7 Catalyst has received no written notice that any Third Party has challenged the ownership, scope, duration, validity, enforceability, priority, or right to use any Licensed Patent Rights (including, by way of example, through the institution of or written threat of institution of interference, *inter partes* review, reexamination, protest, opposition, nullity, or similar invalidity proceeding before the United States Patent and Trademark Office or any foreign patent authority or court);

8.2.8 to Catalyst's Knowledge, no Third Party is infringing, misappropriating, or otherwise violating, or threatening to infringe, misappropriate, or otherwise violate the Licensed Technology;

8.2.9 all fees required to be paid by Catalyst in any jurisdiction in order to maintain the Licensed Patent Rights have been timely paid and, to Catalyst's Knowledge, the Licensed Patent Rights are valid, subsisting, and enforceable;

8.2.10 Catalyst has not previously assigned, transferred, conveyed, or granted any license or other rights under the Licensed Technology in any way that would conflict with or limit the scope of any of the rights or licenses to be granted to Biogen hereunder;

8.2.11 Catalyst is the sole and exclusive (i) legal, beneficial, and record owner of all Patent Rights set forth on Schedule 1.87 (Existing Licensed Patent Rights) and Know-How listed on Schedule 8.2.3 (Licensed Know-How); or (ii) holder of a legal and valid license to all such Patent Rights and Know-How, in each case, free and clear of all liens and encumbrances of any type;

8.2.12 Catalyst has obtained from all individuals who participated as of the Effective Date in any respect in the invention or authorship of any Licensed Technology effective written assignments of all ownership rights of such individuals in such Licensed Technology; and no Person who claims to be an inventor of an invention claimed in a Licensed Patent Right is not identified as an inventor of such invention in the filed patent documents for such Licensed Patent Right;

8.2.13 the inventorship of the Licensed Patent Rights is properly identified on each issued patent or patent application in the Licensed Patent Rights;

8.2.14 there are no Third Party agreements pursuant to which Catalyst Controls or purports to Control any of the Licensed Technology, other than the agreements expressly disclosed in Schedule 8.2.14 (Existing In-Licenses) (the "**Existing In-Licenses**"), true and complete copies of which have been provided to Biogen;

8.2.15 no written notice of default or termination has been received or given under any agreement pursuant to which Catalyst Controls any Licensed Technology (including under any Existing In-License) and all such agreements are in full force and effect, and no act or omission by Catalyst or its Affiliates has occurred that constitutes a default or provides a right to terminate any such agreement;

8.2.16 Catalyst and its Affiliates have taken commercially reasonable measures consistent with industry practices to protect the secrecy, confidentiality, and value of all Licensed Know-How that constitutes trade secrets under Applicable Law (including requiring all employees, consultants, and independent contractors to execute binding and enforceable agreements requiring all such employees, consultants, and independent contractors to maintain the confidentiality of such Licensed Know-How) and to Catalyst's Knowledge, such Licensed Know-How has not been used by, or disclosed to, any Third Party except pursuant to such confidentiality agreements and there has not been a breach by any party to such confidentiality agreements;

8.2.17 Neither Catalyst nor any of its Affiliates has entered into a government funding relationship that would result in any payment obligations to any Governmental Authority or any rights to any Compound, Product or Licensed Technology residing in any Governmental Authority; the Licensed Technology and the Exploitation thereof are not subject to overriding obligations to the United States federal government as set forth in Public Law 96 517 (35 U.S.C. § 200 -204), as amended, or any similar obligations under the Applicable Laws of any state or other country;

8.2.18 all information disclosed to Biogen by Catalyst as of the Effective Date relating to the Licensed Technology, and the materials and methods to be employed by Catalyst in the performance by or on behalf of Catalyst of the Research Activities under the Work Plan and otherwise under this Agreement is, at the time of disclosure, accurate in all material respects; and

8.2.19 Catalyst has not intentionally failed to furnish Biogen with any information requested by Biogen, or intentionally concealed from Biogen any information in its possession relating to the Licensed Technology or any Compound, in each case, that Catalyst reasonably believes would be material to Biogen's decision to enter into this Agreement and undertake the commitments and obligations set forth herein.

8.3 **Covenants of Catalyst**. Catalyst covenants to Biogen that:

8.3.1 during the Term, Catalyst will not, and will cause its Affiliates not to: (a) assign, transfer, convey, or grant any license or other rights to any rights, title, and interests in or to the Licensed Technology in any way that would conflict with or limit the scope of any of the rights or licenses granted hereunder; or (b) incur or permit to exist, with respect to any Licensed Technology, any lien, encumbrance, charge, security interest, mortgage, Liability, or other restriction (including in connection with any indebtedness);

8.3.2 Catalyst will, and will cause its Affiliate to, remain in compliance in all respects with the Existing In-Licenses and it will not without Biogen's written consent, terminate, amend, or waive any rights under, any Existing In-License in a manner that adversely affects the rights granted hereunder or Catalyst's ability to fully perform its obligations hereunder, and it will provide prompt notice to Biogen of any alleged breach or default or request for amendment of any Existing In-License. If Biogen makes any payments to the Third Party counter party of any Existing In-License in connection with the cure or other resolution of such alleged breach or default of Catalyst, then, notwithstanding anything to the contrary set forth in this Agreement, Biogen may credit the full amount of such payments against any Milestone Payments, royalties, or other amounts payable to Catalyst under this Agreement;

8.3.3 Catalyst will, and will ensure that its Affiliates, Sublicensees, Subcontractors, and agents obtain written agreements from any and all Persons involved in or performing any Research Activities by or on behalf of Catalyst that assign such Persons' rights, title, and interests in and to any Licensed Technology, Results, or Deliverables to Catalyst prior to any such Person performing such activities;

8.3.4 in the performance of activities under this Agreement, Catalyst will not employ or use any Person who: (a) has ever been Debarred or is subject to debarment or convicted of a crime for which an entity or person could be Debarred; or (b) has ever been under indictment for a crime for which a person or entity could be so Debarred; and

8.3.5 during the Research Term, Catalyst will maintain sufficient resources to perform the Research Activities for which it is responsible under this Agreement in accordance herewith.

8.4 **Covenants of Biogen**. Biogen covenants to Catalyst that during the Term, except to the extent the same would not be reasonably likely to prevent Biogen from complying with its obligations under this Agreement in any material respect, Biogen will not, and will cause its controlled Affiliates not to: (i) assign or transfer its ownership of any Assigned Patent Rights to any Third Party; or (ii) incur or permit to exist, with respect to any Assigned Patent Rights, any lien, encumbrance, charge, security interest, mortgage, Liability, or other restriction (including in connection with any indebtedness).

8.5 **DISCLAIMER OF WARRANTIES**. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTIES OF TITLE, NON-INFRINGEMENT, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE. IN PARTICULAR, BIOGEN DOES NOT MAKE ANY REPRESENTATION OR EXTEND ANY WARRANTY THAT THE COMPOUNDS OR PRODUCTS WILL BE SUCCESSFULLY DEVELOPED OR COMMERCIALIZED HEREUNDER AND CATALYST DOES NOT MAKE ANY REPRESENTATION OR EXTEND ANY WARRANTY THAT THE PERFORMANCE OF THE CATALYST RESEARCH ACTIVITIES WILL RESULT IN THE IDENTIFICATION OF A DEVELOPMENT CANDIDATE.

8.6 **LIMITATION OF LIABILITY**. EXCEPT FOR DAMAGES RESULTING FROM BREACHES OF SECTION 2.1 (LICENSES TO BIOGEN), SECTION 2.2 (LICENSES TO CATALYST), SECTION 2.4 (EXCLUSIVITY), ARTICLE 9 (CONFIDENTIALITY), OR INDEMNIFIABLE CLAIMS UNDER ARTICLE 11 (INDEMNIFICATION; INSURANCE), IN NO EVENT WILL EITHER PARTY HAVE ANY CLAIMS AGAINST OR LIABILITY TO THE OTHER PARTY WITH RESPECT TO ANY LOST PROFITS OR REVENUES, OR INDIRECT, PUNITIVE, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES ARISING UNDER OR IN CONNECTION WITH THIS AGREEMENT UNDER ANY THEORY OF LIABILITY, EVEN IF SUCH PARTY HAS BEEN INFORMED OR SHOULD HAVE KNOWN OF THE POSSIBILITY OF SUCH DAMAGES.

ARTICLE 9
CONFIDENTIALITY

9.1 **Confidential Information**. It is understood and agreed by the Parties that:

9.1.1 The terms and conditions of this Agreement will be considered Confidential Information of both Parties and kept confidential by each of the Parties in accordance with this ARTICLE 9 (Confidentiality).

9.1.2 The Licensed Technology which relates solely to the Exploitation of Compounds or Products, unpublished Assigned Patent Rights, the Biogen Technology, all reports provided pursuant to Section 7.4.3(a) (Royalty Reports), all Research Reports, and all Deliverables and Results will each be considered the Confidential Information of Biogen, with Biogen deemed to be the Disclosing Party in respect thereof and Catalyst deemed to be the Receiving Party with respect thereto.

9.2 **Non-Disclosure and Non-Use Obligation**. Except as otherwise expressly set forth herein, the Receiving Party will, during the Term and for a period of [***] thereafter, keep the Confidential Information of the Disclosing Party confidential using at least the same degree of care with which the Receiving Party holds its own confidential information (but in no event less than a reasonable degree of care) and will not (a) disclose such Confidential Information to any Person without the prior written approval of the Disclosing Party, except, solely to the extent necessary to exercise its rights or perform its obligations under this Agreement, to its employees, Affiliates, Sublicensees, and Subcontractors,

consultants, or agents who have a need to know such Confidential Information, all of whom will be similarly bound by confidentiality, non-disclosure, and non-use provisions at least as restrictive or protective of the Parties as those set forth in this Agreement and for whom the Disclosing Party will be responsible, or (b) use such Confidential Information for any purpose other than for the purposes contemplated by this Agreement. The Receiving Party will cause the foregoing Persons to comply with the restrictions on use and disclosure and other provisions of this ARTICLE 9 (Confidentiality). Each Party will promptly notify the other Party of any misuse or unauthorized disclosure of the other Party's Confidential Information.

9.3 **Return of Confidential Information**. Upon the expiration or termination of this Agreement, the Receiving Party will return or destroy all Confidential Information of the Disclosing Party to the Disclosing Party that is in the Receiving Party's possession or control (other than any Confidential Information required to continue to exercise a Party's rights that survive termination of this Agreement), *provided*, however, copies may be retained and stored solely for the purpose of determining its obligations under this Agreement, subject to the non-disclosure and non-use obligation under this ARTICLE 9 (Confidentiality). In addition, the Receiving Party will not be required to return or destroy Confidential Information contained in any computer system back-up records made in the ordinary course of business; *provided* that such Confidential Information may not be accessed without the Disclosing Party's prior written consent or as required by Applicable Law, or as required to continue to exercise a Party's rights that survive termination of this Agreement.

9.4 **Exemptions**. Information of a Disclosing Party will not be Confidential Information of such Disclosing Party to the extent that the Receiving Party can demonstrate through competent evidence that such information: (a) is already in the possession of the Receiving Party at the time of its receipt from the Disclosing Party and not through a prior disclosure by or on behalf of the Disclosing Party, as evidenced by contemporaneous written records, (b) is generally available to the public before its receipt from the Disclosing Party, (c) became generally available to the public or otherwise part of the public domain after its disclosure by the Disclosing Party and other than through any act or omission of the Receiving Party or any of its Affiliates or disclosure in breach of this Agreement, including pursuant to Section 9.8.2 (Publication Rights), (d) is subsequently disclosed to the Receiving Party or any of its Affiliates without obligation of confidentiality by a Third Party who may rightfully do so and is not under a conflicting obligation of confidentiality to the Disclosing Party, or (e) is developed independently by employees, subcontractors, consultants or agents of the Receiving Party or any of its Affiliates without use of or reliance upon the Disclosing Party's Confidential Information, as evidenced by contemporaneous written records. No combination of features or disclosures will be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

9.5 **Permitted Disclosures**. In addition to the exceptions contained in Sections 9.2 (Non-Disclosure and Non-Use Obligation) and 9.4 (Exemptions), the Receiving Party may disclose Confidential Information of the Disclosing Party to the extent (and solely to the extent) that such disclosure is reasonably necessary in the following instances:

9.5.1 the prosecution and maintenance of Assigned Patent Rights and Licensed Patent Rights, in each case, as contemplated by this Agreement;

9.5.2 Regulatory Submissions and other filings with Governmental Authorities (including Regulatory Authorities), as necessary for the Exploitation of a Compound or Product;

9.5.3 disclosure of the existence and applicable terms of this Agreement to actual or bona fide potential investors, acquirors, Sublicensees, lenders, and other financial or commercial partners, and their respective attorneys, accountants, banks, investors, and advisors, solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, sublicense, debt transaction, collaboration or other transaction; provided that, in each such case, such Third Parties are bound by obligations of confidentiality, non-disclosure, and non-use provisions at least as restrictive or protective of the Parties as those set forth in this Agreement or otherwise customary for such type and scope of disclosure, and any such disclosure is limited (e.g., redacted) to the maximum extent practicable for the particular context in which it is being disclosed;

9.5.4 to comply with Applicable Law (whether generally or in pursuit of an application for listing of securities) including the United States Securities and Exchange Commission or equivalent foreign agency or regulatory body, or otherwise required by judicial or administrative process, *provided that* in each such event, as promptly as reasonably practicable and to the extent not prohibited by Applicable Law or judicial or administrative process, such Party will notify the other Party of such required disclosure and provide a draft of the proposed disclosure to the other Party reasonably in advance of such filing or disclosure for the other Party's review and comment. The non-disclosing Party will provide any comments as soon as practicable, and the disclosing Party will consider in good faith any timely comments provided by the non-disclosing Party. Confidential Information that is disclosed in order to comply with Applicable Law or by judicial or administrative process pursuant to this Section 9.5.4, in each case, will remain otherwise subject to the confidentiality and non-use provisions of this ARTICLE 9 (Confidentiality) with respect to the Party disclosing such Confidential Information, and such Party will take all steps reasonably necessary, including seeking of confidential treatment, or a protective order for a period of at least five years (to the extent permitted by Applicable Law or Governmental Authority), to ensure the continued confidential treatment of such Confidential Information, and each Party will be responsible for its own legal and other external costs in connection with any such filing or disclosure pursuant to this Section 9.5.4;

9.5.5 to prosecute or defend litigation so long as there is 30 days' prior written notice given by the Receiving Party before filing, and to enforce Patent Rights in connection with the Receiving Party's rights and obligations pursuant to this Agreement; and

9.5.6 to allow the Receiving Party to exercise its rights and perform its obligations hereunder, *provided* that such disclosure is covered by terms of confidentiality and non-use at least as restrictive as those set forth herein.

9.6 **Use of Name and Logo**. Subject to Section 9.8.1 (Announcements), neither Catalyst nor Biogen will use the other Party's or its Affiliates' name or logo in any label, press release, or product advertising, or for any other promotional purpose, without first obtaining the other Party's written consent.

9.7 **Residual Knowledge**. Notwithstanding anything to the contrary set forth in this Agreement, Confidential Information will not include any knowledge, experience, or Know-How that is retained in the unaided memory of any authorized representative of the Receiving Party after having access to such Confidential Information ("**Residual Knowledge**"). Any use made by the Receiving Party of any such Residual Knowledge is on an "as is, where is" basis, with all faults and all representations and warranties disclaimed and at its sole risk.

9.8 **Publications**.

9.8.1 **Announcements**. Catalyst shall have the right to issue an initial press release announcing this Agreement in the form of the press release set forth on Schedule 9.8.1. Except as may be expressly permitted under Section 9.5 (Permitted Disclosures), neither Party will make any other public announcement or disclosure regarding this Agreement without the prior written approval of the other Party. For clarity, nothing in this Agreement will prevent Biogen, its Affiliates, or its Sublicensees from making any scientific publication or public announcement or disclosure concerning the Exploitation of any Compound or Product under this Agreement; *provided* that, except as permitted under Section 9.5 (Permitted Disclosures), Biogen will not disclose any of Catalyst's Confidential Information in any such publication or announcement without obtaining Catalyst's prior written consent to do so. After the issuance by a Party of a press release or other public disclosure by a Party in accordance with this Section 9.8.1 (Announcements), such Party may make subsequent public disclosures reiterating such information without having to obtain the other Party's prior consent and approval so long as the information in such subsequent press release or other public announcement remains true, correct, and the most current information with respect to the subject matters set forth therein.

9.8.2 **Publication Rights**. Biogen will be the exclusive owner of any publication rights with respect to the Results, the Compounds, and the Products, and will have the sole and exclusive right to publish on or otherwise publicly disclose such Results, Compounds, and Products, provided that, during the Collaborative Period, with respect to the publication of any Results or any other pre-clinical data pertaining to the Compounds, Catalyst has a reasonable opportunity not less than [***] prior to the date of submission for publication to review the proposed publication and provide comments, which such comments Biogen shall consider in good faith, and *provided further*, that if such comments involve a redaction of Catalyst Confidential Information, Biogen shall incorporate such comments, and if such comments involve the identification of patentable material in such proposed publication, Biogen shall delay publication for up to [***] until the appropriate Party seeks patent protection for such information. Any such publication shall acknowledge, as appropriate, the contribution of Catalyst, its employees, Sublicensees and Subcontractors.

ARTICLE 10
INTELLECTUAL PROPERTY

10.1 **Ownership**.

10.1.1 **Background Technology**. Subject to Section 10.1.3 (Patent Assignments), each Party will be and will remain the owner of any Intellectual Property that it (a) developed or owned prior to the Effective Date or (b) independently develops or acquires during the Term outside the scope of the Research Program.

10.1.2 **Arising IP**. Regardless of inventorship, Biogen shall solely own: (i) any Inventions made, conceived, discovered or otherwise generated by either Party or its Affiliates' employees, agents, or Subcontractors in the course of performance of the Research Program and all Intellectual Property with respect to such Inventions ("**Arising IP**"); and (ii) all Deliverables and Results.

10.1.3 **Patent Assignments**.

(a) If requested in writing by Biogen, on a Development Candidate-by-Development Candidate basis and effective as of [***], Catalyst will and hereby does assign to Biogen [***] "**Assigned Patent Rights**." For clarity, at any time during the Term prior to such assignment, such Patent Rights constitute "Licensed Patent Rights," and, upon such assignment, such Patent Rights will no longer constitute "Licensed Patent Rights," except where otherwise expressly provided in this Agreement. Collectively, the Assigned Patent Rights and any Patent Rights constituting Arising IP are referred to herein as the "**Biogen Patent Rights**."

(b) Any grants of a license by Biogen under any of the Assigned Patent Rights shall be consistent with the license grant in Section 2.2.2 (License Under Assigned Patent Rights), and with the other terms and conditions of this Agreement, including termination under ARTICLE 12 (Term and Termination), and any Third Party licensee of such rights shall be deemed a "Sublicensee" for purposes of this Agreement (including royalty payments upon such Third Party's Net Sales) notwithstanding Biogen's ownership of the Assigned Patent Rights.

10.1.4 **Disclosure of Inventions by Personnel**. Each Party will ensure that any personnel involved in the performance of Research Activities on behalf of such Party, its Affiliates or Subcontractors are obligated to inform such Party about any Invention made, conceived, discovered, or otherwise generated individually or jointly by or on behalf of such personnel in the performance of such Research Activities. Catalyst will promptly inform Biogen of any such Inventions by or on behalf of Catalyst, its Affiliates or Subcontractors.

10.1.5 **Inventorship**. Inventorship of patentable inventions conceived or reduced to practice during the course of performance of activities pursuant to this Agreement will be determined in accordance with U.S. patent laws.

10.2 **Patent Prosecution and Maintenance**.

10.2.1 **Right to File and Prosecute**.

(a) **Biogen's Rights**. Biogen will have (i) the sole right (but not the obligation) to prepare, file in its name, prosecute, and maintain all Biogen Patent Rights, and (ii) the first right (but not the obligation) to prepare, file, prosecute, and maintain all Patent Rights listed in Schedule 1.87 but not listed under the heading "SUBJECT TO ASSIGNMENT" (the Patent Rights described in the foregoing clause (ii), the "**Biogen First Right Patent Rights**" and the Patent Rights described in clauses (i) and, where Biogen has elected to prosecute, (ii), collectively, the "**Biogen-Prosecuted Patent Rights**"). Biogen will be the Prosecuting Party with respect to all Biogen-Prosecuted Patent Rights. Biogen will be responsible for and pay all future costs and expenses incurred in connection with the preparation, filing, prosecution, and maintenance of the Biogen-Prosecuted Patent Rights and will keep Catalyst reasonably informed as to material developments with respect to the preparation, filing, prosecution, issuance, and maintenance of the Biogen First Right Patent Rights, including providing to Catalyst notice in advance of abandoning any such Biogen First Right Patent Rights, and considering in good faith Catalyst's reasonable comments thereto with respect to those claims Covering products or compounds which are not Compounds or Products.

(b) **Catalyst's Rights**. Catalyst will have the first right (but not the obligation) to prepare, file in its name, prosecute, and maintain all other Licensed Patent Rights (*i.e.*, those Licensed Patent Rights not addressed in subpart (a) above) (where Catalyst has elected to so prosecute, the "**Catalyst-Prosecuted Patent Rights**"). Catalyst will be the Prosecuting Party with respect to all Catalyst-Prosecuted Patent Rights. Catalyst will be responsible for and pay all future costs and expenses incurred in connection with the preparation, filing, prosecution, and maintenance of the Catalyst-Prosecuted Patent Rights and will keep Biogen reasonably informed as to material developments with respect to the preparation, filing, prosecution, issuance, and maintenance of the Catalyst-Prosecuted Patent Rights, including providing notice in advance of abandoning any such Catalyst-Prosecuted Patent Rights.

10.2.2 **Step-In Right**. If, during the Term, the Prosecuting Party decides that it is no longer interested in the preparation, filing, prosecution, or maintenance of a particular Biogen First Right Patent Right (with respect to Biogen as the Prosecuting Party) or Catalyst-Prosecuted Patent Right (with respect to Catalyst as the Prosecuting Party), then it will promptly provide written notice to the non-Prosecuting Party of such decision. Within [***] following receipt of such written notice, the non-Prosecuting Party may, upon written notice to the Prosecuting Party, elect to assume the preparation, filing, prosecution, and maintenance of such Patent Right at the non-Prosecuting Party's sole cost and expense. In such event, and notwithstanding anything to the contrary in this Section 10.2 (Patent Prosecution and Maintenance), the Party assuming such rights will be responsible for 100% of the costs and expenses of the preparation, filing, prosecution, and maintenance of such Patent Right as of the election date, and such Party assuming such rights will thereafter be deemed the "Prosecuting Party" with respect to such Patent Right for all purposes under this Agreement. If no such notice from the non-Prosecuting Party is received within such [***] period, the Prosecuting Party may allow the applicable Patent Right to lapse by non-response or non-payment.

10.2.3 **Cooperation**. The non-Prosecuting Party will (a) obtain and deliver to the Prosecuting Party any necessary documents for the Prosecuting Party to exercise its rights to prepare, prosecute, defend, and maintain all Patent Rights pursuant to Section 10.2.1 (Right to File and Prosecute) or Section 10.2.2 (Step-In Right), as applicable, (b) render all signatures that will be necessary in connection with all such patent filings, and (c) assist the Prosecuting Party in all other reasonable ways that are necessary for the issuance of those Patent Rights for which such Prosecuting Party is responsible, as well as for the preparation, prosecution, defense, and maintenance of such Patent Rights.

10.3 **Patent Enforcement**.

10.3.1 **Third Party Infringement**. During the Term, the Parties will promptly inform each other in writing if either Party becomes aware of any Opposed Biogen Patent Right or Opposed Catalyst Patent Right and will, as applicable, provide any available evidence of such suspected, threatened or actual infringement, objection, opposition or challenge with such notification (each, a "**Third Party Action**").

10.3.2 **Third Party Actions**.

(a) **By Biogen**. During the Term, Biogen will have the sole right (except as provided below), but not the obligation, to enforce or defend any Opposed Biogen Patent Right against such Third Party Action, at Biogen's sole discretion and at Biogen's sole cost and expense. Where Biogen desires to enforce or defend such Opposed Biogen Patent Right but is unable to do so due to Applicable Law or regulation (even as the assignee or exclusive licensee of such Patent Right), then Biogen may request that Catalyst join as a named party in such action or that Catalyst enforce or defend such Patent Right against such Third Parties, at Biogen's sole cost and expense. Biogen will take the lead in the control and conduct of any such enforcement or defense under this Section 10.3.2(a) (By Biogen) and Catalyst will reasonably assist Biogen in any such enforcement or defense action under this Section 10.3.2(a) (By Biogen) at Biogen's expense. Biogen will keep Catalyst reasonably informed of any such enforcement or defense.

(b) **By Catalyst**. During the Term, Catalyst will have the first right, but not the obligation, to enforce or defend any Opposed Catalyst Patent Right against such Third Party Action, at Catalyst's sole discretion and at Catalyst's sole cost and expense. Where Catalyst desires to enforce or defend such Opposed Catalyst Patent Right but may not do so due to Applicable Law or regulation (even as the assignee or exclusive licensee of such Patent Right), then upon Catalyst's reasonable request, Biogen shall join as a named party in such action or itself enforce or defend such Opposed Catalyst Patent Right against such Third Parties, at Catalyst's sole cost and expense. Catalyst will take the lead in the control and conduct of any such enforcement or defense under this Section 10.3.2(b) (By Catalyst) and will keep Biogen reasonably informed of any such enforcement or defense, and Biogen will reasonably assist Catalyst in any such enforcement or defense action under this Section 10.3.2(b) (By Catalyst) at Catalyst's expense. Catalyst will keep Biogen reasonably informed of any such enforcement or defense. If Catalyst does not bring any legal action within [***] after first becoming aware of such infringement or after notice of such infringement was provided pursuant to Section 10.3.1, then Biogen shall have the right to bring and control any legal action in connection with such Third Party Action, at its sole cost and expense.

(c) **Cooperation**. At the request and sole cost and expense of the Party defending or enforcing the Third Party Action under Section 10.3.2(a) or 10.3.2(b), the other Party shall provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party to the action if required. In connection with any such proceeding, the Party bringing the action under Section 10.3.2(a) or 10.3.2(b) shall not enter into any settlement admitting the invalidity of, or otherwise impairing the other Party's rights in, the Opposed Biogen Patent Right or Opposed Catalyst Patent Right without the prior written consent of the other Party, which shall not be unreasonably withheld.

10.3.3 **Patent Listing**. Biogen will have the full and exclusive right, in its sole discretion, to determine and control the listing of any Patent Right (including any Assigned Patent Right or Licensed Patent Right) in connection with the Regulatory Approval of any Product, including in the then-current edition of the United States Food and Drug Administration publications (i) "List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations" (commonly referred to as the purple book); (ii) "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the orange book), or in equivalent patent listings in any other country within the Territory.

10.3.4 **Recoveries**. Any amount recovered in any action under Section 10.3.2 (Third Party Actions), including any amount recovered in any settlement of such Third Party Action, will first be used to reimburse each Party's costs and expenses with respect to such action, which reimbursement will be first allocated to the Party controlling such action's costs and expenses, and then, to the extent such costs and expenses exceed such recovered amount, to the other Party's costs and expenses. Any such recoveries in excess of such costs and expenses shall be shared by the Parties as follows [***].

10.4 **Defense of Claims**. Catalyst will promptly inform Biogen in writing if Catalyst receives written notice, or otherwise becomes aware, of alleged infringement, misappropriation, or other violation of a Third Party's Intellectual Property based upon Catalyst's performance of its obligations or exercise of its rights hereunder. Except as otherwise set forth under this Agreement (including under ARTICLE 11 (Indemnification; Insurance)), Catalyst will have the sole right (and the obligation) to defend against any such claim brought against it. Catalyst will keep Biogen advised of all material developments in the conduct of any proceedings in defending any claim of alleged infringement, misappropriation, or other violation related to any Compounds or Products and will reasonably cooperate with Biogen in the conduct of such defense. In no event may Catalyst settle any such infringement, misappropriation, or other violation claim in a manner that would limit the rights of Biogen or impose any obligation on Biogen, in each case, without Biogen's prior written consent, which consent will not be unreasonably withheld, conditioned, or delayed.

10.5 **Patent Term Extensions**. Biogen will have the full and exclusive right and discretion to determine and control all filings of requests for patent term extensions, supplementary protection certificates, or equivalents thereto, in any country in the Territory, for any Patent Rights that Cover any Compound or Product (hereinafter "**Patent Term Extensions**"). All costs and expenses relating to the Patent Term Extensions will be born solely by Biogen. Upon request of Biogen and at Biogen's cost and expense, Catalyst will provide support, assistance, and all necessary documents, in full executed form as needed, to Biogen for the purpose of supporting, filing, obtaining, and maintaining Patent Term Extensions.

10.6 **Summary of Activities**. Upon the request of either Party, the Prosecuting Party will provide to the other Party, no more frequently than on an annual basis, a written report summarizing all material activities undertaken by such Prosecuting Party in the preceding Calendar Year with respect to the preparation, filing, prosecution, maintenance, enforcement, and defense of the Biogen-Prosecuted Patent Rights or Catalyst-Prosecuted Patent Rights (as applicable) in the exercise of the rights granted to such Prosecuting Party under this ARTICLE 10 (Intellectual Property). Such report will be considered the Confidential Information of the Prosecuting Party.

ARTICLE 11
INDEMNIFICATION; INSURANCE

11.1 **Indemnification by Catalyst**. Catalyst will indemnify, defend, and hold harmless Biogen, its Affiliates, Sublicensees, and each of its and their respective employees, officers, directors, and agents (each, a "**Biogen Indemnified Party**") from and against any and all liabilities, losses, damages, expenses (including reasonable attorneys' fees and expenses), and costs (collectively, "**Liabilities**") that the Biogen Indemnified Party may be required to pay to one or more Third Parties resulting from or arising out of:

11.1.1 the negligence or willful misconduct of Catalyst or any other Catalyst Indemnified Party;

11.1.2 the breach by Catalyst of any of its representations, warranties, covenants, or agreements under this Agreement;

11.1.3 any claim that Catalyst misappropriated any trade secrets or inappropriately used or disclosed the confidential information owned or possessed by any Third Party in the conduct of the Catalyst Research Activities; or

11.1.4 any claims of any nature arising out of any Exploitation of any Compound or Product by or on behalf of Catalyst prior to the Effective Date or after the effective date of termination of this Agreement (or the effective date of termination of such Compound or Product in the event of partial termination);

11.1.5 The obligation to indemnify, defend, and hold harmless a Biogen Indemnified Party pursuant to Section 11.1.1, 11.1.2, 11.1.3, or 11.1.4 shall not apply to any such Liabilities to the extent that (a) Biogen is obligated to indemnify, defend, and hold harmless a Catalyst Indemnified Party pursuant to this Agreement; or (b) such Liabilities are caused by the negligence or willful misconduct of Biogen or any Biogen Indemnified Party.

11.2 **Indemnification by Biogen**. Biogen will indemnify, defend, and hold harmless Catalyst, each of its Affiliates, and each of its and its Affiliates' employees, officers, directors, and agents (each, a "**Catalyst Indemnified Party**") from and against any and all Liabilities that the Catalyst Indemnified Party may be required to pay to one or more Third Parties resulting from or arising out of:

11.2.1 the negligence or willful misconduct of Biogen or any other Biogen Indemnified Party;

11.2.2 any claims of any nature arising out of (a) the Exploitation of any Compound or Product by or on behalf of Biogen, its Affiliates or Sublicensees or (b) any Biogen Research Activities performed by or on behalf of Biogen, in each case ((a)-(b)), other than by any Catalyst Indemnified Party; or

11.2.3 the breach by Biogen of any of its representations, warranties, covenants, or agreements under this Agreement.

11.2.4 The obligation to indemnify, defend, and hold harmless a Catalyst Indemnified Party pursuant to Section 11.2.1, 11.2.2, or 11.2.3 shall not apply to any such Liabilities to the extent that (a) Catalyst is obligated to indemnify, defend, and hold harmless a Biogen Indemnified Party pursuant to this Agreement; or (b) such Liabilities are caused by the negligence or willful misconduct of Catalyst or any Catalyst Indemnified Party.

11.3 **Procedure for Third Party Claims**. If a Party is seeking indemnification under Section 11.1 or 11.2, as applicable (the "**Indemnified Party**"), it shall inform the other Party (the "**Indemnifying Party**") of the claim for Liabilities giving rise to the obligation to indemnify pursuant to Section 11.1 or 11.2, as applicable (the "**Third Party Claim**"), as soon as reasonably practicable after receiving notice of the Third Party Claim (provided, however, any delay or failure to provide such notice shall not constitute a waiver or release of, or otherwise limit, the Indemnified Party's rights to indemnification under Section 11.1 or 11.2, as applicable, except to the extent that such delay or failure materially prejudices the Indemnifying Party's ability to defend against the relevant Third Party Claims). The Indemnifying Party shall have the right to assume the defense of any such Third Party Claim for which the Indemnified Party is seeking indemnification pursuant to Section 11.1 or 11.2, as applicable. The Indemnified Party shall cooperate with the Indemnifying Party and the Indemnifying Party's insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party's cost and expense. The Indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any Third Party Claim that has been assumed by the Indemnifying Party. The Indemnifying Party shall not settle any Third Party Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, conditioned, or delayed; provided, however, that the Indemnifying Party shall not be required to obtain such consent if the settlement (a) involves only the payment of money which is fully paid by the Indemnifying Party and will not result in the Indemnified Party (or other Biogen Indemnified Parties or Catalyst Indemnified Parties, as applicable) becoming subject to injunctive or other similar type of relief, (b) does not require an admission by the Indemnified Party (or other Biogen Indemnified Parties or Catalyst Indemnified Parties, as applicable), (c) includes an unconditional release of the Indemnified Party (or other Biogen Indemnified Parties or Catalyst Indemnified Parties, as applicable) from all Liability on claims that are the subject matter of such proceeding, and (d) does not materially adversely affect any Intellectual Property owned or controlled by the Indemnified Party or any rights or licenses granted to the Indemnified Party under this Agreement. The Indemnified Party shall not settle or compromise any such Third Party Claim without the prior written consent of the Indemnifying Party, not to be unreasonably withheld, conditioned, or delayed. If the Parties cannot agree as to the application of Section 11.1 or 11.2, as applicable, to any Third Party Claim, pending resolution of the dispute pursuant to Section 13.8 (Dispute Resolution), the Parties may conduct separate defenses of such Third Party Claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 11.1 or 11.2, as applicable, upon resolution of the underlying claim. In each case, the Indemnified Party shall reasonably cooperate with the Indemnifying Party, and shall make available to the Indemnifying Party all pertinent information under the control of the Indemnified Party, which information shall be subject to ARTICLE 9 (Confidentiality).

11.4 **Insurance**. Catalyst will purchase and maintain, through an appropriate, reputable insurance provider, insurance coverage in the amount of five million Dollars ($5,000,000) for each claim and ten million Dollars ($10,000,000) in the aggregate to cover claims against Biogen in connection with this Agreement, including any indemnification obligations under this ARTICLE 11 (Indemnification; Insurance).

ARTICLE 12
TERM AND TERMINATION

12.1 **Term**. This Agreement will commence upon the Effective Date and, if not otherwise terminated earlier pursuant to this ARTICLE 12 (Term and Termination), will continue, on a Product-by-Product and country-by-country basis, in full force and effect until the expiration of the Royalty Term applicable to such Product and such country (the "**Term**").

12.2 **Termination for Cause**.

12.2.1 **By Biogen**. In the event of a material breach of this Agreement by Catalyst, which material breach remains uncured for [***] measured from the date of written notice of such material breach provided by Biogen that identifies the material breach, Biogen may terminate this Agreement in whole or with respect to one or more Compounds or Products by written notice of termination to Catalyst provided within [***] of the expiration of such [***] period.

12.2.2 **By Catalyst**. In the event of a material breach of this Agreement by Biogen, which material breach remains uncured for [***] measured from the date of written notice of such material breach provided by Catalyst that identifies the material breach, Catalyst may terminate this Agreement solely with respect to those Compounds or Products to which such material breach relates by written notice of termination to Biogen provided within [***] of the expiration of such [***].

12.2.3 **Disputes Regarding Material Breach**. If a Party (the "**Defaulting Party**") is alleged to have, but disputes that it, materially breached this Agreement by the other Party (such other Party, the "**Non-Defaulting Party**"), then the issue of whether the Non-Defaulting Party may properly terminate this Agreement or applicable portion hereof on expiration of the applicable cure period will be resolved in accordance with Section 13.8 (Dispute Resolution). If as a result of such dispute resolution process, it is determined that the Defaulting Party committed a material breach of this Agreement and the Defaulting Party does not cure such material breach within [***] after the date of such determination [***] (the "**Additional Cure Period**"), then the Non-Defaulting Party will have the right to terminate this Agreement or applicable portion hereof by written notice of termination to the Defaulting Party provided within [***] of the expiration of the Additional Cure Period. This Agreement will remain in full force and effect during the pendency of any such dispute resolution proceeding and the cure periods set forth in Section 12.2.1 (By Biogen) or Section 12.2.2 (By Catalyst), as applicable, and any Additional Cure Period, in each case, will be tolled during any such dispute resolution proceeding. If as a result of such dispute resolution proceeding it is determined that the Defaulting Party did not commit such material breach, then no termination will be effective, and this Agreement will continue in full force and effect.

12.3 **Termination for Insolvency**. To the extent permitted by Applicable Law, either Party may terminate this Agreement upon the filing or institution of bankruptcy, reorganization, liquidation, or receivership proceedings, upon the appointment of a receiver or trustee over all or substantially all property, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, however, that in the case of any involuntary bankruptcy proceeding such right to terminate will only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within [***] after the filing thereof. In the event of any termination pursuant to this Section 12.3 (Termination for Insolvency):

12.3.1 All rights and licenses now or hereafter granted by either Party (the "**Bankrupt Party**") to the other Party under or pursuant to this Agreement are, for all purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined in the U.S. Bankruptcy Code. Upon the filing or institution of bankruptcy, reorganization, liquidation, or receivership proceedings, upon the appointment of a receiver or trustee over all or substantially all property, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the Bankrupt Party, the Bankrupt Party agrees that the other Party, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Bankrupt Party will, during the Term, create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, to the extent feasible, of all intellectual property rights licensed under this Agreement. Each Party acknowledges and agrees that "embodiments" of intellectual property rights within the meaning of Section 365(n) include laboratory notebooks, cell lines, product samples, and inventory, research studies and data, all Regulatory Approvals (and all applications for Regulatory Approval) and rights of reference therein, the Assigned Patent Rights, Licensed Technology, Results, and all information related to the Licensed Technology. If (A) a case under the U.S. Bankruptcy Code is commenced by or against the Bankrupt Party, (B) this Agreement is rejected as provided in the U.S. Bankruptcy Code, and (C) the other Party elects to retain its rights hereunder as provided in Section 365(n) of the U.S. Bankruptcy Code, the Bankrupt Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) will:

(a) provide the other Party with all such intellectual property rights (including all embodiments thereof) held by the Bankrupt Party and such successors and assigns, or otherwise available to them, immediately upon the other Party's written request. Whenever the Bankrupt Party or any of its successors or assigns provides to the other Party any of the intellectual property rights licensed hereunder (or any embodiment thereof) pursuant to this Section 12.3 (Termination for Insolvency), the other Party will have the right to perform the Bankrupt Party obligations hereunder with respect to such intellectual property rights, but neither such provision nor such performance by the other Party will release the Bankrupt Party from liability resulting from rejection of the license or the failure to perform such obligations; and

(b) not interfere with the other Party's rights under this Agreement, or any agreement supplemental hereto, to such intellectual property rights (including such embodiments), including any right to obtain such intellectual property rights (or such embodiments) from another entity, to the extent provided in Section 365(n) of the U.S. Bankruptcy Code.

12.3.2 All rights, powers, and remedies of the other Party provided in this Section 12.3 (Termination for Insolvency) are in addition to and not in substitution for any other rights, powers, and remedies now or hereafter existing at law or in equity (including the U.S. Bankruptcy Code) in the event of the commencement of a case under the U.S. Bankruptcy Code with respect to the Bankrupt Party. The Parties intend the following rights to extend to the maximum extent permitted by Applicable Law, and to be enforceable under Section 365(n) of the U.S. Bankruptcy Code:

(a) the right of access to any intellectual property rights (and all embodiments thereof) of the Bankrupt Party, or any Third Party with whom the Bankrupt Party contracts to perform any obligation of the Bankrupt Party under this Agreement, and, in the case of any such Third Party, that is necessary for the Exploitation of Compounds or Products; and

(b) the right to contract directly with any Third Party to complete the contracted work.

12.4 **Termination for Convenience**. Biogen will be entitled to terminate this Agreement, in whole or with respect to one or more Compounds or Products, at its sole discretion at any time upon 60 days' prior written notice to Catalyst.

12.5 **Effects of Termination**.

12.5.1 **Generally**. Upon early termination of the Agreement in whole or with respect to one or more Compounds or Products:

(a) Except as provided in Section 12.5.3 (Right of Reversion), the Receiving Party will promptly return to the other Party or destroy all Confidential Information of the other Party (or, in the case of partial termination, all such Confidential Information of the Disclosing Party that is related solely to the terminated Compound or Product) in accordance with Section 9.3 (Return of Confidential Information).

(b) Effective as of the effective date of termination by Catalyst pursuant to Section 12.2.2 (By Catalyst) or Section 12.3 (Termination for Insolvency) or a termination by Biogen pursuant to Section 12.4 (Termination for Convenience), [***].

(c) All licenses granted by a Party to the other Party under this Agreement with respect to any terminated Compound or Product will immediately terminate (except for any licenses which are perpetually granted).

(d) Notwithstanding subsection 12.5.1(c), Biogen, its Affiliates and Sublicensees shall have the right to continue to sell their existing inventories of Products for a period not to exceed [***] after the effective date of such termination, provided that Catalyst is paid royalties with respect thereto, to the extent entitled, in accordance with ARTICLE 7 (Payments and Royalties).

(e) [***]

(f) [***]

12.5.2 **Knowledge Transfer**. If this Agreement is terminated by Biogen pursuant to Section 12.2.1 (By Biogen) or Section 12.3 (Termination for Insolvency), then to the extent not already provided pursuant to Section 5.1 (Technology Transfer) or Section 6.3 (Manufacturing Technology Transfer) by the effective date of termination of this Agreement, Catalyst will promptly transfer to Biogen, on a Product-by-Product basis, all Results and Deliverables, the costs of which transfer will be borne [***].

12.5.3 **Right of Reversion**. [***]

12.6 **Alternative Remedy in Lieu of Termination**. If Biogen has the right to terminate this Agreement pursuant to Section 12.2.1 (By Biogen), then in addition to any other remedies available to Biogen at law or in equity, in lieu of terminating this Agreement Biogen may, in its sole discretion, exercise an alternative remedy as follows: [***]

12.7 **Rights Accruing Prior to Expiration or Termination**. Except as set forth in Section [***] above, expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination. Except as set forth in Section [***] above, any expiration or termination of this Agreement will be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to expiration or termination, including any payment obligation that accrued prior to the effective date of such expiration or termination.

12.8 **Survival**. The following provisions, as well as any other provisions which expressly or by their nature are intended to survive termination or expiration, will survive termination or expiration of this Agreement: ARTICLE 9 (Confidentiality) (but if a time period for survival is specified therein, then only for such time period) but excluding Section 9.8 (Publications); ARTICLE 11 (Indemnification; Insurance); ARTICLE 13 (Miscellaneous); and Sections 2.3 (No Implied Licenses); 7.2 (Reimbursement of Research Costs) solely with respect to costs and expenses incurred prior to the effective date of termination; 7.5 (Payment Method); 7.6 (Currency Exchange); 7.7 (Late Payments); 7.8 (Taxes); 7.9 (Financial Audits); 8.5 (Disclaimer of Warranties); 8.6 (Limitation of Liability); 10.1 (Ownership); 12.3 (Termination for Insolvency); 12.5 (Effects of Termination); 12.7 (Rights Accruing Prior to Expiration or Termination) and 12.8 (Survival). Furthermore, any other provisions required to interpret the Parties' rights and obligations under this Agreement (*e.g.*, ARTICLE 1 (Definitions)) shall survive to the extent required.

ARTICLE 13
MISCELLANEOUS

13.1 **Assignment**. Neither this Agreement nor any interest hereunder will be assignable by Catalyst without the prior written consent of Biogen, except as follows: (a) Catalyst may, subject to the terms of this Agreement, assign its rights and obligations under this Agreement in whole to its successor-in-interest in connection with the sale of all or substantially all of its assets to which this Agreement relates, whether in a merger, acquisition, or similar transaction or series of related transactions, *provided* that such sale is not primarily for the benefit of its creditors, and (b) Catalyst may assign its rights and obligations under this Agreement to any of its Affiliates, *provided* that Catalyst will remain liable for all of its rights and obligations under this Agreement. Biogen may freely assign this Agreement or any interest hereunder in whole or in part, provided that Biogen will remain liable for all of its rights and obligations under this Agreement. Each Party will promptly notify the other Party of any assignment or transfer under the provisions of this Section 13.1 (Assignment), other than in the case of Biogen, any such assignment or transfer to an Affiliate thereof. This Agreement will be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing herein will be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 13.1 (Assignment) will be null, void, and of no legal effect.

13.2 **Entire Agreement; Amendments**. This Agreement sets forth the entire agreement between the Parties and supersedes all previous and contemporaneous negotiations, representations, or agreements, written or oral, regarding the subject matter hereof, and any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, with respect to the subject matter hereof, including the Confidentiality Agreement, are superseded by the terms of this Agreement. This Agreement may be amended only by an instrument in writing duly executed on behalf of the Parties.

13.3 **Force Majeure**. Neither Party will be liable or deemed in default for failure to perform any duty or obligation that such Party may have under this Agreement where such failure has been occasioned by any act of God, fires, earthquakes, strikes and labor disputes, acts of war, terrorism, civil unrest, or intervention of any Governmental Authority, and occurring without its fault or negligence; *provided* that the Party affected will promptly notify the other of the force majeure condition and will exert all reasonable efforts to eliminate, cure, or overcome any such causes and to resume performance of its obligations as soon as possible.

13.4 **Waiver; Remedies not Exclusive**. The failure of either Party to require performance by the other Party of any of that other Party's obligations under this Agreement will in no manner affect the right of such Party to enforce the same at a later time. No waiver by any Party of any condition, or of the breach of any provision, term, representation or warranty contained in this Agreement will be deemed to be or construed as a further or continuing waiver of any such condition or breach, or of any other condition or

of the breach of any other provision, term, representation, or warranty hereof. Except as set forth in Section [***] above, the remedies provided in this Agreement are not exclusive and the Party suffering from a breach or default of this Agreement may pursue all other remedies, both legal and equitable, alternatively, or cumulatively.

13.5 **Severability**. If any provision or portion thereof in this Agreement is for any reason held to be invalid, illegal, or unenforceable, then the same will not affect any other portion of this Agreement and its validity, as it is the intent of the Parties that this Agreement will be construed in such fashion as to maintain its existence, validity, and enforceability to the greatest extent possible. In any such event, this Agreement will be construed as if such provision or portion thereof had never been contained in this Agreement, and there will be deemed substituted therefore such provision as will most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by Applicable Law unless doing so would have the effect of materially altering the rights and obligations of the Parties in which event this Agreement may be terminated by mutual written agreement of the Parties.

13.6 **Notices**. All notices that are required or permitted hereunder will be in writing and sufficient if delivered by internationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, and in each case, addressed as follows (with a courtesy copy sent by email, which will not constitute notice):

If to Catalyst:

Catalyst Biosciences, Inc.
611 Gateway Blvd., Suite 710
South San Francisco, CA 94080
Attention: Jeff Landau
E-mail: jlandau@catbio.com

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

Cooley LLP
3175 Hanover Street
Palo Alto, CA 94304
Attention: Barbara Kosacz

If to Biogen:

Biogen International GmbH
c/o Biogen MA Inc.
225 Binney Street
Cambridge, MA 02142
Attention: Chief Legal Officer
E-mail: legaldepartment@biogen.com

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

Hogan Lovells US LLP
390 Madison Ave
New York, NY 10017
Attention: Adam H. Golden

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given: (a) on the Business Day after dispatch if sent by internationally-recognized overnight courier; or (b) on the fifth Business Day after dispatch if sent by registered or certified mail, postage prepaid, return receipt requested.

13.7 **Governing Law**. This Agreement, and all claims arising under or in connection therewith, notwithstanding scope and validity of any patent or patent application as below, will be governed by and interpreted in accordance with the substantive laws of the State of New York, without regard to conflict of law principles thereof. Any legal action related to the scope and validity of any patent or patent application relating to this Agreement brought by the Parties hereto may be conducted in any appropriate forum under the applicable laws of the country of such patent or patent application.

13.8 **Dispute Resolution**.

13.8.1 **Escalation**. Any dispute arising out of or in connection with this Agreement (except for disputes arising at the JSC, which will be resolved pursuant to Section 4.2.4 (Decision Making Authority)) will be settled, if possible, through good faith negotiations between the Parties. If the Parties are unable to settle such dispute within [***] after first considering such dispute, then such dispute will be referred to the Parties' respective Executive Officers. The Executive Officers of both Parties will in good faith attempt to resolve such dispute. Such resolution, if any, of a referred issue will be final and binding on the Parties. All negotiations pursuant to this Section 13.8 (Dispute Resolution) are confidential and will be treated as compromise and settlement negotiations for purposes of applicable rules of evidence. If the Executive Officers cannot resolve such dispute within [***] after referral of such dispute to the Executive Officers, then either Party will have the right to pursue any and all remedies available at law or equity, consistent with Section 13.8.2 (Jurisdiction; Venue). Notwithstanding any other provision of this Agreement, the Parties will be entitled to seek equitable relief, including injunction or specific performance, as a remedy for any breach or threatened breach of this Agreement, in any court having jurisdiction and without first having complied with the procedures set forth in this Section 13.8 (Dispute Resolution). Such remedies will not be deemed to be the exclusive remedies for a breach (or threatened breach) of this Agreement but will be in addition to all other remedies available at law or equity. Neither Party will raise as a defense or objection to the request or granting of such relief that any breach of this Agreement is or would be compensable by an award of money damages.

13.8.2 **Jurisdiction; Venue**. Subject to the last sentence in Section 13.7 (Governing Law), each Party irrevocably submits to the exclusive jurisdiction of the federal courts (or if such courts do not have subject matter jurisdiction, the state courts) sitting in the Borough of Manhattan, New York, for the purposes of any suit, action, or other proceeding arising out of this Agreement or out of any transaction contemplated hereby. Each Party agrees to commence any such action, suit, or proceeding in such federal courts (or if such courts do not have subject matter jurisdiction, the state courts). Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit, or proceeding arising out of this Agreement or the transactions contemplated hereby in such courts, and hereby and thereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit, or proceeding brought in any such court has been brought in an inconvenient forum. Each Party irrevocably consents to service of process in the manner provided under Section 13.6 (Notices) or by first class certified mail, return receipt requested, postage prepaid. THE PARTIES EXPRESSLY, IRREVOCABLY, AND UNCONDITIONALLY WAIVE AND FOREGO ANY RIGHT TO TRIAL BY JURY.

13.9 **Relationship of the Parties**. Nothing in this Agreement is intended or will be deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the Parties. No Party will incur any debts or make any commitments for the other. There are no express or implied third-party beneficiaries hereunder (except for Biogen Indemnified Parties and Catalyst Indemnified Parties for purposes of Section 11.1 (Indemnification by Catalyst) or Section 11.2 (Indemnification by Biogen), as applicable).

13.10 **Performance by Affiliates**. Each Party recognizes that the other Party may perform some or all of its obligations under this Agreement through Affiliates to the extent permitted under this Agreement; *provided*, *however*, that such other Party will remain responsible for the performance by its Affiliates as if such obligations were performed by such other Party.

13.11 **Interpretation**. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" will be deemed to be followed by the phrase "without limitation," (c) the word "will" will be construed to have the same meaning and effect as the word "shall," (d) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any Person will be construed to include the Person's successors and assigns, (f) the words "herein," "hereof," and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections or Schedules will be construed to refer to Sections or Schedules of this Agreement, and references to this Agreement include all Schedules hereto, (h) in case of inconsistencies between this Agreement and any Schedule hereof, the terms of this Agreement will prevail unless agreed to explicitly that the Schedule should prevail, (i) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement, (j) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent," or "approve" or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (k) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, (l) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or," (m) references to any Sections include Sections and subsections that are part of the related Section (*e.g.*, a section numbered "Section 2.2" would be part of "Section 2", and references to "Section 2.2" would also refer to material contained in the subsection described as "Section 2.2(a)"), and (n) references herein to pharmaceutical products, therapies, or active ingredients include biologics and biopharmaceutical products, therapies, or active ingredients, as applicable.

13.12 **Further Assurances**. Each of Catalyst and Biogen agrees to duly execute and deliver, or cause to be duly executed or delivered, such further instruments and do and cause to be done such further acts, including the filing of additional assignments, agreements, documents and instruments, as the other Party may at any time and from time to time reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes of, or to better assure and confirm unto such other Party its rights and remedies under, this Agreement.

13.13 **Expenses**. Except as otherwise expressly provided in this Agreement, each Party shall pay the fees and expenses of its respective lawyers and other experts and all other expenses and costs incurred by such Party incidental to the negotiation, preparation, execution, and delivery of this Agreement.

13.14 **Counterparts**. This Agreement may be executed in counterparts, all of which taken together will be regarded as one and the same instrument. Counterparts may be delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal ESIGN Act of 2000, and any counterpart so delivered will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

[Signature page follows]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized officers.

BIOGEN INTERNATIONAL GMBH

By: /s/ Fred Lawson
(Signature)

Name: Fred Lawson

Title: Director

Date: December 18, 2019

CATALYST BIOSCIENCES, INC.

By: /s/ Nassim Usman
(Signature)

Name: Nassim Usman, Ph.D.

Title: President and CEO

Date: December 18, 2019

Certain information identified by bracketed asterisks ([***]) has been omitted from this exhibit because it is both not material and would be competitively harmful if publicly disclosed.

MOSAIC BIOSCIENCES, INC.

AMENDED AND RESTATED COLLABORATION AGREEMENT

This Amended and Restated Collaboration Agreement ("**Agreement**") is entered into as of this 18th day of December 2019 ("**Amendment No. 2 Effective Date**"), by and between Mosaic Biosciences, Inc., a Delaware corporation, with its principal place of business located at 3415 Colorado Ave., Boulder, CO 80303 ("**Mosaic**"), and Catalyst Biosciences, Inc., a Delaware corporation, with its principal place of business located at 611 Gateway Blvd. Suite 710, South San Francisco, CA 94080 USA ("**Catalyst**"). Mosaic and Catalyst may be referred to individually herein as a "**Party**" and collectively as the "**Parties**".

Whereas, the Parties entered into that certain Collaboration Agreement, dated as of October 10, 2017 (the "**Effective Date**"), to identify novel products as set forth in that Collaboration Agreement (the "**Original Agreement**");

Whereas, the Parties entered into that certain Amendment to the Collaboration Agreement, dated as of December 21, 2018 (the "**First Amendment**");

Whereas, the Parties desire to amend and restate the Original Agreement in its entirety, together with the First Amendment; and

NOW THEREFORE, for and in consideration of the covenants, conditions, and undertakings hereinafter set forth, it is agreed by and between the Parties as follows:

1. DEFINITIONS

1.1 "**Affiliate**" means shall mean, in the case of Catalyst or Mosaic (as the case may be) any entity which controls, is controlled by or is under common control with Mosaic or Catalyst. For purposes of this definition only, "control" shall mean beneficial ownership (direct or indirect) of at least fifty percent (50%) of the shares of the subject entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, in the election of the corresponding managing authority).

1.2 "**Approval**" shall mean all approvals, registrations or authorizations of any governmental entity that are necessary for the manufacturing, use, storage, import, transport and sale of a Product in a regulatory jurisdiction. For countries where governmental approval is required for pricing or reimbursement for the Product to be reimbursed by national health insurance, Marketing Approval shall not be deemed to occur until such pricing or reimbursement approval is obtained; provided, that Approval shall be deemed to have occurred in such country where government approval of pricing has not been obtained if, at any time, the Party undertakes a full commercial launch of such Product in the country without obtaining pricing approval.

1.3 "**BLA**" means a Biologic License Application (as defined in the U.S. Federal Food, Drug and Cosmetics Act and the regulations promulgated thereunder (21 C.F.R. §§ 600-680) in the United States or a comparable filing in any other jurisdiction (*i.e.*, an application submitted to a Regulatory Authority that must be made prior to importing, marketing and selling a biological product).

1.4 [***]

1.5 "**Change of Control**" means, with respect to either Party, any of the following: (a) the sale or disposition of all or substantially all of the assets of such Party or its direct or indirect parent corporation to a third party, (b) the acquisition by a third party which constitutes one person, as such term is used in Section 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), together with any such person's "affiliates" or "associates," as such terms are defined in the Exchange Act, other than an employee benefit plan (or related trust) sponsored or maintained by such party or any of its Affiliates, of more than 50% of the outstanding shares of voting capital stock of such party or its direct or indirect parent corporation, or (c) the merger or consolidation of such party or its direct or indirect parent corporation with or into another corporation, other than, in the case of this clause (c), an acquisition or a merger or consolidation of such party or its direct or indirect parent corporation in which holders of shares of the voting capital stock of such party or its direct or indirect parent corporation, as the case may be, immediately prior to the acquisition, merger or consolidation will have at least fifty percent (50%) of the ownership of voting capital stock of the acquiring third party or the surviving corporation in such merger or consolidation, as the case may be, immediately after the merger or consolidation.

1.6 "**Cumulative Net Sales**" means the cumulative total Net Sales of the respective Product in the Territory by Catalyst or its Affiliates over the entire Royalty Term, but not including any sales of the respective Product by any Sublicensee.

1.7 "**Distributor**" shall mean a third party, other than a Sublicensee, to which Catalyst or an Affiliate of Catalyst has granted the right to market, promote, advertise, detail, sell or distribute Products in the Territory.

1.8 "**GAAP**" means United States generally accepted accounting principles, consistently applied.

1.9 "**Indication**" means each separate and distinct disease, disorder, illness, health condition, or interruption, cessation or disruption of a bodily function, system, tissue type or organ, for which Approval is required.

1.10 "**Intellectual Property**" is defined in Section 8.1 hereof.

1.11 "**EU Major Market**" means Germany, France, Spain, Italy and the UK.

1.12 "**Materials**" is defined in Section 6.4 hereof.

1.13 "**Mosaic Intellectual Property**" means: (i) all patents and all reissues, renewals, re-examinations, and extensions thereof, and patent applications therefor, and any divisions or continuations, in whole or in part, thereof, which claim or otherwise cover the composition, formulation, manufacture, sale or use of a Product(s), that are owned or acquired by Mosaic or its Affiliates, or that cover inventions made by or under authority of Mosaic or its Affiliates,

prior to or during the term of this Agreement; and all material confidential information and tangible materials related to the development, formulation, manufacture, sale or use of a Product, including, but not limited to: pharmaceutical, chemical, biological and biochemical compositions; and technical data and information; available descriptions, if any, of assays, methods and processes; the results of tests, including without limitation screening results, SAR data, optimization data, in vitro and in vivo data; preclinical, clinical and research, manufacturing processes and procedures; analytical and quality control data; and plans, specifications and/or other documents containing said information and data; in each case which are owned or acquired by Mosaic prior to the Effective Date or discovered, developed or acquired by or under authority of Mosaic or its Affiliates during the term of this Agreement.

1.14 "**Net Sales**" means [***].

1.15 "**Phase 1 Clinical Trial**" shall mean human clinical trials, the principal purpose of which is preliminary determination of safety in healthy individuals or patients (for example, as described in 21 C.F.R. §312.21, or similar clinical study in a country other than the United States).

1.16 "**Phase 2 Clinical Trial**" means a human clinical trial for which the primary endpoints include a determination of dose ranges and a preliminary determination of efficacy in patients being studied (for example, as described in 21 C.F.R. §312.21, or similar clinical study in a country other than the United States).

1.17 "**Phase 3 Clinical Trial**" means a pivotal human clinical trial, which is sufficiently powered and designed to establish safety and efficacy of one or more particular doses in patients being studied and to provide the statistical basis for Approval for the respective drug (for example, as described in 21 C.F.R. § 312.21, or similar clinical study in a country other than the United States).

1.18 "**Product**" means any product targeting C3 that incorporates the Materials for use in ophthalmologic indications (a "**C3 Product**") [***].

1.19 "**Regulatory Authority**" means any national (*e.g.*, the FDA), supra-national (*e.g.*, the EMA), or other governmental entity in any jurisdiction of the world involved in the granting of Approval for pharmaceutical products.

1.20 "**Research**" is defined in Section 2.6 hereof.

1.21 "**Research Plan**" means the plan for the Research to be conducted by the Parties as described in Article 2 of this Agreement.

1.22 "**Royalty Term**" means, with respect to a particular Product in a country, the period commencing on the Effective Date and continuing until the later of (a) expiration or abandonment of the last Valid Claim among the Collaboration IP and/or Mosaic Intellectual Property covering such Product in the particular country (on a Product-by-Product and country-by-country basis), or (b) [***] after the first commercial sale of any Product in the Territory.

1.23 "**Sublicense Income**" shall mean amounts received [***].

1.24 "**Sublicensee**" means a non-Affiliate third party to whom Catalyst has granted (i) the right to distribute a Product made in accordance with this Agreement, provided that such third party has primary responsibility for the marketing and promotion of such Product in its distribution territory and has the right to record sales of such Product for its account or (ii) the right to make and sell a Product, with respect to Products made and sold by such third party, within the scope of the license hereunder. For clarity, Sublicensee shall exclude any Distributor, wholesaler or reseller of Product which are not primarily responsible for marketing or promotion of the Product. In addition, Catalyst and Mosaic shall not be deemed Sublicensees of the other, nor shall either Party be deemed to be acting "under authority" of the other Party.

1.25 "**Territory**" means any country or territory in the world in which Catalyst or its Affiliates are commercializing a Product, either directly or through a Distributor.

1.26 "**Third Party IP**" is defined in Section 10.5 hereof.

1.27 "**Valid Claim**" means a claim of an issued and unexpired patent within the patents covering a Product in a specific country, which claim has not lapsed, been canceled or become abandoned and has not been declared invalid or unenforceable by a court or other appropriate body of competent jurisdiction from which no appeal can be or has been taken, and which has not been admitted to be invalid or unenforceable through reissue, reexamination, disclaimer or otherwise.

2. Performance of Research

2.1 **General**. Mosaic agrees to provide to Catalyst the services requested by Catalyst, at Catalyst's discretion from time to time, and agreed to by Mosaic (the "**Services**"). The specific services shall be detailed from time to time in one or more work plans to be signed by the Parties and attached hereto as consecutively numbered Exhibits (e.g., 2.1.1, 2.1.2 etc.). The initial draft scope of Services is attached hereto as Exhibit A, and the work plans will be consistent with the draft scope of Services set forth on Exhibit A. Each work plan shall include a description of the specific Services to be provided, the budget for such services, and the anticipated timeline.

2.2 **Performance of the Services**. Mosaic shall use all commercially reasonable efforts to render the Services in a timely and professional manner consistent with industry standards, by the completion dates agreed upon by the Parties and in accordance with this Agreement, and to provide timely delivery of any deliverables. Subject to the foregoing, the manner and means by which Mosaic chooses to complete the Services are in Mosaic's sole discretion and control. In performing the Services, Mosaic agrees to provide its own personnel, equipment, tools and other materials at its own expense, except for External Costs as described in an applicable work plan and except for any Catalyst Materials. Mosaic may not subcontract or otherwise delegate its obligations under this Agreement without Catalyst's prior written consent. References to "Research" or the "Research Plan" in the Agreement shall refer to the Services and applicable work plans, respectively, following the Amendment No. 2 Effective Date.

2.3 No Conflict of Interest. Mosaic agrees, during the term of this Agreement, not to accept work or enter into any agreement or accept any obligation that conflict(s) with Mosaic's obligations under this Agreement or the scope of Services rendered for Catalyst. Mosaic represents and warrants that, to the best of its knowledge, there is no other existing agreement or duty on Mosaic's part inconsistent with this Agreement.

3. INTENTIONALLY OMITTED

4. COMPENSATION. In consideration of the Services, Mosaic shall be paid on a fee-for-service basis for all Services performed under this Agreement as set forth in each applicable work plan. All reasonable out-of-pocket expenses will be reimbursed to Mosaic by Catalyst. Out-of-pocket expenses will be invoiced on a pass-through basis. Documentation for out-of-pocket expenses will be provided via expense reports. All undisputed invoices shall be payable within [***] of receipt by Catalyst. Should Catalyst disagree with the accuracy of an invoice, Catalyst shall notify Mosaic of such inaccuracy within [***] of receipt of the applicable invoice. Catalyst agrees to pay for any invoice items not in dispute. Catalyst reserves the right to withhold payment of the invoice items in dispute until the dispute is resolved by the Parties.

5. RECORDS; INSPECTION

5.1 General. Each Party and its Affiliates shall keep complete, true and accurate books of accounts and records for the purpose of determining payments due pursuant to this Agreement. Such books and records shall be kept for at least [***] years following the end of the calendar quarter to which they pertain. Such records will be open, for such [***] year period, for inspection at the principal place of business of such Party or its Affiliates, as the case may be, ("Audited Party") during such [***] year period by an independent auditor chosen by the other Party ("**Auditing Party**") and reasonably acceptable to the Audited Party for the purpose of verifying the amounts payable by Audited Party hereunder. All such inspections may be made no more than once each calendar year, at reasonable times and on reasonable notice. The independent auditor shall be obligated to execute a reasonable confidentiality agreement prior to commencing any such inspection.

6. PROPRIETARY INFORMATION; MATERIALS

6.1 Proprietary Information. Each of Catalyst and Mosaic understands that the Research may involve access by the other Party to confidential, proprietary or trade secret information or materials of Catalyst or Mosaic, as applicable (each a "**Disclosing Party**") (or their respective affiliates, licensors, suppliers, vendors, clients, customers or any other third party to whom the Disclosing Party owes a duty of confidentiality), in whatever form, tangible or intangible, whether disclosed or provided to the other Party before or after the execution of this Agreement (collectively, "**Proprietary Information**"). Proprietary Information further includes, without limitation, any trade secrets and know-how, and any: information, ideas or materials of a technical or creative nature, such as inventions, improvements, discoveries, developments, techniques, processes, research and development plans and results, reports, drawings, designs, specifications, works of authorship, data, formulas, files, patent applications, and other materials and concepts relating to Catalyst's or Mosaic's respective business, services, processes or technology.

6.2 Restrictions on Use and Disclosure. Each of Catalyst and Mosaic agrees that, during the term of this Agreement and thereafter, it shall (a) hold Proprietary Information of the other Party in trust and confidence; (b) not use Proprietary Information of the other Party in any manner or for any purpose not expressly set forth in this Agreement; (c) not reproduce such Proprietary Information of the other Party except to the extent reasonably required to fulfill its obligations hereunder; and (d) not disclose, deliver, provide, disseminate or otherwise make available to any third party, directly or indirectly, any Proprietary Information of the other Party without first obtaining such Party's express written consent. Each Party may disclose Proprietary Information of the other Party only to employees and agents who have a need to know such Proprietary Information, and who are each obligated by a written agreement to comply with confidentiality provisions no less restrictive than those set forth in this Agreement. Each Party shall take at least the same degree of care that it uses to protect its own confidential and proprietary information of similar nature and importance (but in no event less than reasonable care) to protect the confidentiality and avoid the unauthorized use, disclosure, publication or dissemination of Proprietary Information of the other Party.

6.3 Exclusions. The foregoing obligations in Section 6.2 shall not apply to any Proprietary Information (a) is or has become generally known or available other than by any act or omission of the non-Disclosing Party; (b) was rightfully known by the non-Disclosing Party prior to the time of first disclosure to the Disclosing Party; (c) is independently developed by the non-Disclosing Party without the use of Proprietary Information of the Disclosing Party; or (d) is rightfully obtained without restriction from a third party who has the right to make such disclosure and without breach of any duty of confidentiality to the Disclosing Party. In addition, either Party may use or disclose Proprietary Information of the other Party to the extent (i) approved in advance in writing by the Disclosing Party or (ii) if legally compelled to disclose such Proprietary Information, provided that non-Disclosing Party shall use reasonable efforts to give advance notice of such compelled disclosure to the Disclosing Party, and shall cooperate with the Disclosing Party in connection with any efforts to prevent or limit the scope of such disclosure and/or use of the Proprietary Information.

6.4 Materials.

(a) Catalyst is willing to transfer to Mosaic, and Mosaic is willing to receive, the materials specified on Exhibit B hereto ("**Materials**"), for the sole purpose of conducting the Research at the facilities of Mosaic. Materials include the original biological and/or other materials transferred to Mosaic, as well as any derivatives, formulations, conjugates, progeny, or improvements developed by Mosaic therefrom, and any combination of the foregoing with other substances. All Materials shall be deemed the Proprietary Information of Catalyst.

(b) **Limitation of Use**. The Materials will be used only for the performance of the Research, solely by Mosaic in Mosaic's laboratory or other locations set forth in the Research Plan under suitable containment conditions. The Materials shall not be used for any other purposes. Mosaic shall not use, or authorize use of, the Materials on or in humans for any purpose under any circumstances.

(c) **Control of Materials**. Mosaic agrees to retain control over the Materials and not to transfer the Materials to any person or entity other than Catalyst without the prior written approval of Catalyst. Catalyst reserves the right to distribute similar Materials to others and to use such Materials for its own purposes. Mosaic agrees to return all Materials and products or materials derived from such Material to Catalyst on completion of the Research Plan or at any earlier time that Catalyst may request.

(d) **Warranty**. Catalyst represents and warrants to Mosaic that, to the best of its knowledge, the use of the Materials by Mosaic, as contemplated in the Research Plan, will not infringe the Intellectual Property rights of any third party The Materials are being made available in order to further research concerning it. EXCEPT AS OTHERWISE SET FORTH IN THIS SECTION 7.4(d), (a) THE MATERIALS ARE BEING SUPPLIED TO MOSAIC "AS IS", WITH NO WARRANTIES, EXPRESS OR IMPLIED, AND CATALYST EXPRESSLY DISCLAIMS ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NONINFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY, and (b) Catalyst disclaims all representations that use of the Materials by Mosaic will not infringe any patent or other proprietary right of any third party.

7. LICENSE

7.1 Mosaic hereby grants to Catalyst an exclusive, worldwide, sublicensable, license under any Mosaic Platform Improvements and Mosaic Intellectual Property to the extent necessary to make, have made, use, offer for sale, sell, import, export, research, develop, or otherwise exploit any Products.

7.2 During the term of the Research Plan, Catalyst hereby grants to Mosaic a non-exclusive, worldwide, non-sublicensable, license under any Catalyst Intellectual Property to the extent necessary to conduct the Research contemplated hereunder.

7.3 [***]

8. INTELLECTUAL PROPERTY. Ownership and prosecution of all Intellectual Property that was first conceived prior to the Amendment No. 2 Effective Date shall be governed by Section 8.1 through Section 8.4 of the Original Agreement, which is hereby incorporated by reference. Ownership, prosecution and enforcement of any Intellectual Property that is first conceived on or after the Amendment No. 2 Effective Date shall be governed by the provisions below.

8.1 **Independent IP**. Each Party shall retain and own all right, title and interest in and to all data, results, information, patent rights, know-how, or other intellectual property rights ("**Intellectual Property**") controlled by such Party or its Affiliates as of the Amendment No. 2 Effective Date or acquired, in-licensed or generated, invented or discovered by such Party or its Affiliates outside the performance of the Services and without use of the other Party's Proprietary Information.

8.2 IP Developed under the Research. All Intellectual Property generated, invented or discovered in the performance of the Services by or on behalf of Mosaic or the Parties jointly shall be owned as follows:

(a) Any Intellectual Property acquired, in-licensed or generated, invented or discovered by Mosaic or its Affiliates in the performance of the Services that is related to Mosaic's platform technology consisting of Mosaic's proprietary thiol-ene click chemistry and modular polymer technology, excluding any materials which incorporate, modify, or improve Collaboration IP or Catalyst Materials ("**Mosaic Platform Improvements**") shall be owned by Mosaic. Mosaic will not use any Mosaic Platform Improvements in connection with the Services without Catalyst's prior written consent.

(b) Any Intellectual Property acquired, in-licensed or generated, invented or discovered by a Party or its Affiliates in the performance of the Services other than Mosaic Platform Improvements ("**Catalyst IP**") shall be owned by Catalyst.

(c) During the term of the Agreement, Mosaic agrees not to conduct research or development activities specifically directed toward [***] or any derivatives thereof either alone or with third parties, other than the Research conducted under this Agreement or in connection with licenses to [***] granted to Mosaic under [***], provided, however, that such restriction will only apply to or be binding to Mosaic prior to a Mosaic Change of Control.

8.3 Assignments. Each Party hereby assigns and transfers to the other Party all of its right, title and interest in and to such Intellectual Property as is necessary to give effect to Section 8.2 and agrees to take, and to cause its employees, agents, investigators, consultants, advisors, collaborators and independent contractors to take, all further acts reasonably required to evidence such assignment and transfer.

8.4 Patent Prosecution.

(a) Each Party shall have the sole right and discretion, at its expense, to prepare, file, prosecute, and maintain ("**Prosecution**") any patent applications and patents constituting, in the case of Mosaic, Mosaic Platform Improvements, and, in the case of Catalyst, Catalyst IP. Each Party shall keep the other Party informed as to such Prosecution of such patent rights, including providing such other Party drafts of patent applications, responses and other filings in advance of their submission to the respective patent offices, and providing such other Party copies of any correspondence with or notices from the patent offices. Mosaic shall duly consider and follow any reasonable comments provided by Catalyst with respect to Prosecution of the Mosaic Platform Improvements pertaining to Products.

(b) In the event Mosaic does not desire to undertake or continue the filing, prosecution or maintenance ("**Prosecution**") of any item of Mosaic Platform Improvements, Mosaic shall notify Catalyst at least [***] prior to any required action (or such shorter period as is reasonably practicable for non-extendable deadlines). In such event, Catalyst shall have the right, but not the obligation, to control the Prosecution of such item of Mosaic Platform Improvements, and Mosaic shall cooperate with Catalyst with respect thereto. Catalyst shall keep Mosaic reasonably informed of such Prosecution as requested by Mosaic. It is understood that, in the event Catalyst takes

over Prosecution of any Mosaic Platform Improvements in accordance with this Section 8.5(b), Catalyst shall have complete discretion with respect to any decisions regarding such Prosecution, and shall not owe any duties, express or implied, to Mosaic with respect to such decisions.

8.5 Enforcement. If Catalyst or Mosaic reasonably believes that any Mosaic Platform Improvements or Catalyst IP is infringed or misappropriated in the Territory by a third party with respect to a product that competes with a Product, or is subject to a declaratory judgment action arising from such infringement in the Territory (collectively, "**Infringements**"), Mosaic or Catalyst (respectively) shall promptly notify the other Party. Catalyst shall have the sole right (but not the obligation) to enforce the Catalyst IP in the Territory with respect to any Infringement, or defend any declaratory judgment action with respect thereto (for purposes of this Section 8.6, an "**Enforcement Action**"). Mosaic shall reasonably cooperate with Catalyst initiating the Enforcement Action (including joining as a party plaintiff to the extent necessary and requested by Catalyst). Unless otherwise agreed, all amounts recovered in the Enforcement Action, after reimbursing the Parties for its costs and expenses incurred in such Enforcement Action, shall be treated as Sublicense Income.

9. Representations and Warranties

9.1 Mosaic Representations and Warranties. Mosaic represents, warrants and covenants that: (a) Mosaic has the full power and authority to enter into this Agreement and to perform its obligations hereunder, without the need for any consents, approvals or immunities not yet obtained; (b) Mosaic's execution of and performance under this Agreement shall not breach any oral or written agreement with any third party or any obligation owed by Mosaic to any third party to keep any information or materials in confidence or in trust; , and (c) any persons involved in the development of Research services have executed (or prior to any such involvement, shall execute) a written agreement with Mosaic in which such persons (i) assign to Mosaic all right, title and interest in and to the Collaboration IP in order that Mosaic may fully grant the rights to Catalyst as provided herein and (ii) agree to be bound by confidentiality and non-disclosure obligations no less restrictive than those set forth in this Agreement; (e) Mosaic has the right to grant the rights and assignments granted herein, without the need for any assignments, releases, consents, approvals, immunities or other rights not yet obtained.

9.2 Catalyst Representations and Warranties. Catalyst represents, warrants and covenants that: (a) Catalyst has the full power and authority to enter into this Agreement and to perform its obligations hereunder, without the need for any consents, approvals or immunities not yet obtained; and (b) Catalyst's execution of and performance under this Agreement shall not breach any oral or written agreement with any third party or any obligation owed by Catalyst to any third party to keep any information or materials in confidence or in trust.

9.3 Mutual Disclaimers. Except as otherwise expressly set forth herein each Party hereby disclaims all warranties of any kind, whether express, implied, statutory or otherwise, with respect to any Proprietary Information or other information or materials supplied by such Party to the other Party hereunder, including, without limitation, any warranties with respect to any specifications for or infringement of any third party rights by the deliverables required or Intellectual Property licensed hereunder.

10. ROYALTIES AND MILESTONES

10.1 Development Milestones. Catalyst agrees to pay Mosaic upon the occurrence of each of the following milestones [***] achieved by Catalyst or its Affiliates (but not, for clarity, by any Sublicensees) with respect to each Product, on a Product-by-Product and Indication-by-Indication basis, in accordance with this Section 10.1, provided, that at the time any such development milestone is achieved, that Catalyst is responsible for the development or regulatory activity with respect to such Product triggering such milestone. [***].

For Products:

DEVELOPMENT MILESTONES FOR PRODUCTS	PAYMENT Indication 1	PAYMENT Indication 2	PAYMENT Indication 3
[***]	[***]	[***]	[***]

[***]

DEVELOPMENT MILESTONES FOR [***]	PAYMENT Indication 1	PAYMENT Indication 2	PAYMENT Indication 3
[***]	[***]	[***]	[***]

If (i) Catalyst has entered into a Sublicense with respect to a Product, and been paid a development milestone by its Sublicensee which was shared with Mosaic as Sublicense Income and (ii) Catalyst later achieves a Development Milestone corresponding to the one achieved by its Sublicensee, then the Development Milestone payment set forth above for any such Development Milestone shall be reduced by an amount equal to the share of Sublicense Income paid by Catalyst to Mosaic with respect to the development milestone achieved by the Sublicensee, but in no event will such reduction result in any obligation of Mosaic to pay Catalyst any amount by which its share of Sublicense Income exceeds the applicable Development Milestone.

10.2 Commercial Milestones.

(a) If Catalyst or its Affiliates commercialize a Product, Catalyst agrees to pay a set of commercialization milestones with respect to each such Product, on a Product-by-Product basis, based on the Cumulative Net Sales thereof, as follows:

COMMERCIALIZATION MILESTONES	PAYMENT
[***]	[***]

10.3 **Royalties**. In consideration of Mosaic's contributions to the Research and the licenses granted to Catalyst hereunder, beginning with the first commercial sale of Products in a country of the Territory by Catalyst, its Affiliates or Sublicensees, Catalyst shall pay Mosaic a running royalty of: [***].

10.4 **Sublicense Revenue Sharing**. In consideration of Mosaic's contributions to the Research and the licenses granted to Catalyst hereunder, Catalyst shall pay Mosaic a share of Sublicense Income of [***] of Catalyst's Sublicense Income, paid in accordance with Article 11 below.

10.5 **Third Party Royalty Sharing**.

(a) In the event Catalyst, its Affiliates or Sublicensees pays royalties on their sales of Products in the Territory, which are in consideration for patent rights, trade secrets or other intellectual property or technology obtained from a non-Affiliate third party, or in the event Catalyst is required to reimburse Mosaic for royalties owed by Mosaic to a non-Affiliate third party for such patent rights, trade secrets, or other intellectual property or technology pursuant to Section 10.5(b), in each case that are necessary for the development, manufacture or commercialization of a Product ("**Third Party IP**"), Catalyst will be entitled to deduct [***] of any royalties paid by Catalyst in any calendar quarter for such Third Party IP, provided that in no case will the royalties or share of Sublicense Income, as applicable, payable by Catalyst to Mosaic be reduced by [***] of the amounts otherwise owed to Mosaic hereunder during such calendar quarter.

(b) Each Party shall promptly notify the other Party of any applicable Third Party IP and the method of calculating royalties owed thereunder to the respective third party. Mosaic agrees not to incorporate into any Product being developed under this Agreement any Third Party IP, which Mosaic has in-licensed or of which Mosaic is otherwise aware, without Catalyst's prior written approval. If after the Effective Date, Mosaic acquires from a third party any Third Party IP within the Mosaic Intellectual Property that is subject to a royalty to such third party which Catalyst would be required to reimburse under this Section 11.5(b), then Mosaic shall promptly notify Catalyst, specifying the applicable royalty rate and the method of calculation. Catalyst may elect upon written notice at any time to exclude such Third Party IP from the Mosaic Intellectual Property, and upon such notice, Catalyst shall thereafter not be licensed under Section 8.1 with respect to such Third Party IP ("**Excluded Third Party IP**") and shall not be obligated to share in the payment of royalties therefor under this Section 11.5. If Catalyst does not elect to exclude such Third Party IP from the Mosaic Intellectual Property, then Catalyst shall reimburse Mosaic for any royalties owed for such Third Party IP, subject to Catalyst's right to deduct a portion of those royalties from amounts owed to Mosaic pursuant to Section 10.5(a) hereof. The Parties shall discuss from time to time at the JSC whether any Third Party IP is necessary or desirable to obtain with respect to the Products.

10.6 [***]

11. PAYMENTS; BOOKS AND RECORDS

11.1 Quarterly Royalty Reports. Commencing on the first commercial sale of Products in the Territory, Catalyst shall make quarterly reports to Mosaic within thirty [***] after the end of each calendar quarter, which reports shall include, in reasonable detail, (a) a calculation of any Net Sales in such quarter and an itemization of any deductions or adjustments applicable to such Net Sales by the categories set forth in Section 1.15; and (b) any Sublicense Income received by Catalyst during such quarter. Concurrently with making such report, Mosaic shall remit payment to Catalyst for any royalty due under Article 10 above.

11.2 Payment Method. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the payee. All dollar amounts specified in this Agreement, and all payments made hereunder, are and shall be made in U.S. dollars. Any payments due under this Agreement which are not paid by the date such payments are due under this Agreement shall bear interest to the extent permitted by applicable law at the prime rate per annum quoted by the Bank of America, or its successor, on the first business day after such payment is due, plus an additional [***], calculated on the number of days such payment is delinquent. This Section 11.2 shall in no way limit any other remedies available to either Party.

11.3 Currency Conversion. If any currency conversion shall be required in connection with the calculation of amounts payable hereunder, such conversion shall be made using the buying rate for conversion of the foreign currency into U.S. dollars, quoted for current transactions reported by Bank of America, or its successor, for the last business day of the calendar quarter to which such payment pertains.

11.4 Taxes. Each Party shall bear and, except as otherwise expressly provided in this Section 11.4, pay any and all taxes, duties, levies, and other similar charges (and any related interest and penalties), however designated, imposed on that Party as a result of the existence or operation of this Agreement. If laws or regulations require that taxes be withheld, the paying Party will (i) deduct those taxes from the remittable payment, (ii) timely pay the taxes to the proper taxing authority, and (iii) send proof of payment to the other Party within [***] following that payment. Each Party shall cooperate with the other and furnish the other Party with appropriate documents to secure application of the most favorable rate of withholding tax under Law (or exemption from such withholding tax payments, as applicable).

12. TERMINATION

12.1 Term. This Agreement shall commence on the Effective Date and continue until the earlier of (a) expiration of all payment obligations under this Agreement, or (b) termination by either Party in accordance with this Article 12. This Agreement may be renewed by mutual written agreement of the Parties. Upon expiration of this Agreement, the license granted to Catalyst pursuant to Section 7.1 shall continue as a perpetual, irrevocable, paid-up, royalty-free, nonexclusive license.

12.2 Termination for Convenience. Catalyst may terminate this Agreement at its convenience, with or without cause, upon [***] prior written notice to Mosaic.

12.3 **Termination for Cause**. If either Party materially defaults in any of its obligations under this Agreement, the non-defaulting Party, at its option shall have the right to terminate this Agreement by written notice unless the defaulting Party remedies the default within [***] calendar days after receipt of written notice of such default.

12.4 **Effect of Termination**. Upon the effective date of any termination of this Agreement, Mosaic shall promptly cease performing any Research under this Agreement. Upon any termination of this Agreement for any reason, Catalyst agrees to pay Mosaic compensation due for Research actually rendered and Mosaic External Costs incurred under the Research Plan, in accordance with Article 3. If this Agreement is terminated for any reason other than by Mosaic for Catalyst's material breach, or upon Mosaic's sole option following termination by Mosaic for Catalyst's material breach, then (a) the license granted by Mosaic to Catalyst under Section 7.1 shall survive such termination, (b) Catalyst's obligations to pay Mosaic under Article 10 shall survive; provided that if Catalyst terminates this Agreement for Mosaic's material breach, then Catalyst's obligations to pay Mosaic under Article 10 shall survive at the rate applicable as of the date of termination [***].

12.5 **Survival**. Articles 1, 5, 6, 13, and 14 and Sections 8.1, 8.2, 8.3, 9.3, 12.4, 12.5 and 12.6 shall survive the expiration or termination of this Agreement. Termination of this Agreement by either Party shall not act as a waiver of any breach of this Agreement and shall not act as a release of either Party from any liability for breach of such Party's obligations under this Agreement. Neither Party shall be liable to the other for damages of any kind solely as a result of terminating this Agreement in accordance with its terms, and termination of this Agreement by a Party shall be without prejudice to any other right or remedy of such Party under this Agreement or applicable law.

12.6 **Delivery of Materials**. Upon any termination of this Agreement or at any time upon Catalyst's request, each Party shall promptly return to the other Party any and all of the other Party's Proprietary Information, including, with respect to Catalyst, any Materials. Upon any termination, Mosaic shall also promptly deliver all results of the Research Plan then in progress.

13. Limitation of Liability

To the extent permitted by applicable law: in no event shall either Party be liable to the other Party under any legal theory for any special, indirect, consequential, exemplary or incidental damages, however caused, arising out of or relating to this Agreement, even if such Party has been advised of the possibility of such damages; and (b) in no event shall either Party's aggregate liability arising out of or relating to this Agreement (regardless of the form of action giving rise to such liability, whether in contract, tort or otherwise) exceed the fees paid and payable by Catalyst hereunder.

14. General Provisions

14.1 Independent Contractor Relationship. Mosaic's relationship with Catalyst shall be that of an independent contractor and nothing in this Agreement should be construed to create a partnership, joint venture, agency or employer-employee relationship between the Parties. Mosaic is not the agent of Catalyst and is not authorized and shall not have any authority to make any representation, contract or commitment on behalf of Catalyst, or otherwise bind Catalyst in any respect whatsoever.

14.2 Governing Law; Venue. This Agreement is to be construed in accordance with and governed by the internal laws of the State of Delaware without giving effect to any choice of law rule that would cause the application of the laws of any jurisdiction other than the internal laws of the State of Delaware to the rights and duties of the Parties. Any legal suit, action or proceeding arising out of or relating to this Agreement shall be commenced in a state or federal court in the State of Delaware, and each Party hereto irrevocably submits to the exclusive jurisdiction and venue of any such court in any such suit, action or proceeding.

14.3 Severability. If the application of any provision of this Agreement to any particular facts or circumstances shall for any reason be held to be invalid, illegal or unenforceable by a court, arbitration panel or other tribunal of competent jurisdiction, then (a) the validity, legality and enforceability of such provision as applied to any other particular facts or circumstances, and the other provisions of this Agreement, shall not in any way be affected or impaired thereby and (b) such provision shall be enforced to the maximum extent possible so as to effect the intent of the Parties. If, moreover, any provision contained in this Agreement shall for any reason be held to be excessively broad as to duration, geographical scope, activity or subject, it shall be construed by limiting and reducing it, so as to be enforceable to the extent compatible with applicable law.

14.4 Assignment. Neither Party shall be entitled to assign, sell, transfer, delegate or otherwise dispose of, whether voluntarily or involuntarily, this Agreement and any of its rights or obligations of this Agreement, without the prior written consent of the other Party, except that this Agreement may be assigned by either Party (including an assignment by operation of law) without the prior written consent of the other Party in connection with a Change of Control of such Party, and may be assigned by Catalyst without the prior written consent of Mosaic to: (i) an Affiliate or (ii) to an acquirer of all or substantially all of the business or assets of Catalyst to which this Agreement relates. Except as provided herein, any purported assignment, transfer or delegation by a Party shall be null and void. Subject to the foregoing, this Agreement shall be binding upon and shall inure to the benefit of the Parties and their respective successors and permitted assigns.

14.5 Notices. Any notice, request, demand, or other communication required or permitted hereunder shall be in writing, shall reference this Agreement and shall be deemed to be properly given: (a) when delivered personally; (b) when sent by facsimile, with written confirmation of receipt by the sending facsimile machine; (c) five (5) business days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (d) two (2) business days after deposit with a private industry express courier, with written confirmation of receipt. All notices shall be sent to the address set forth on the preamble to this Agreement and to the notice of the person executing this Agreement (or to such other address or person as may be designated by a Party by giving written notice to the other Party pursuant to this Section 14.5).

14.6 Legal Fees. If any legal action, including, without limitation, an action for arbitration or injunctive relief, is brought relating to this Agreement or the breach hereof, the prevailing Party in any final judgment or arbitration award, or the non-dismissing Party in the event of a voluntary dismissal by the Party instituting the action, shall be entitled [***].

14.7 Equitable Relief. Each Party recognizes that the covenants contained in Sections 6 and 8 hereof are reasonable and necessary to protect the legitimate interests of the other Party, that each Party would not have entered into this Agreement in the absence of such covenants, and that the other Party's breach or threatened breach of such covenants may cause irreparable harm and significant injury, the amount of which shall be extremely difficult to estimate and ascertain, thus, making any remedy at law or in damages inadequate. Therefore, each Party agrees that the other party shall be entitled, without the necessity of posting of any bond or security, to seek the issuance of injunctive relief by any court of competent jurisdiction enjoining any breach or threatened breach of such covenants and for any other relief such court deems appropriate. This right shall be in addition to any other remedy available at law or in equity.

14.8 Waiver. The waiver by either Party of a breach of or a default under any provision of this Agreement shall not be effective unless in writing and shall not be construed as a waiver of any subsequent breach of or default under the same or any other provision of this Agreement, nor shall any delay or omission on the part of either Party to exercise or avail itself of any right or remedy that it has or may have hereunder operate as a waiver of any right or remedy.

14.9 Construction. This Agreement has been negotiated by the Parties and shall be interpreted fairly in accordance with its terms and without any construction in favor of or against either Party.

14.10 Captions and Section Headings. The captions and section and paragraph headings used in this Agreement are inserted for convenience only and shall not affect the meaning or interpretation of this Agreement.

14.11 Counterparts. This Agreement may be executed (including, without limitation, by facsimile signature) in one or more counterparts, with the same effect as if the Parties had signed the same document. Each counterpart so executed shall be deemed to be an original, and all such counterparts shall be construed together and shall constitute one Agreement.

14.12 Entire Agreement; Amendment. This Agreement (including the Exhibits attached hereto, which are incorporated herein by reference) is the final, complete and exclusive agreement of the Parties with respect to the subject matter hereof and supersedes and merges all prior or contemporaneous representations, discussions, proposals, negotiations, conditions, communications and agreements, whether written or oral, between the Parties relating to the subject matter hereof and all past courses of dealing or industry custom, including the Original Agreement, which Original Agreement shall be deemed null and void and of no further force or effect whatsoever following the date hereof. No modification of or amendment to this Agreement shall be effective unless in writing and signed by each of the Parties.

[*Signature Page Follows*]

In witness whereof, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

Catalyst Biosciences, Inc.		**Mosaic Biosciences, Inc.**	
By:	**/s/ Nassim Usman**	**By:**	**/s/ Marty Stanton**
Name:	**Nassim Usman, Ph.D.**	**Name:**	**Marty Stanton, Ph.D.**
Title:	**President and CEO**	**Title:**	**CEO**
Date:	**December 18, 2019**	**Date:**	**December 18, 2019**

Exhibit 10.20

Description of Annual Cash Incentive Program

Catalyst Biosciences, Inc. (the “Company”) maintains an incentive award program (the “Program”) under which its named executive officers and certain other employees are eligible to receive an annual cash incentive bonus. Under the terms of the Program, each eligible employee is assigned a target bonus percentage of his or her base salary. The target bonus percentages for the Company’s executive officers are determined by the Compensation Committee of the Board of Directors. At or about the beginning of each fiscal year, the Compensation Committee establishes performance objectives for the Company for that year and ascribes, for each performance objective, a percentage weighting, target criteria for achievement. The performance objectives typically relate to some of the following areas — the progression or advancement of the Company’s product candidates, development program execution or outcomes, the enhancement of the Company’s product portfolio, business development, alliance management, operations, capital or operational efficiency, financial factors, or other matters.

Following the end of the fiscal year, the Compensation Committee determines the achievement level for the Program for that year. In making its determination, the Compensation Committee evaluates which achievement criteria have been met, if any, for each performance objective, the circumstances surrounding any performance objective or associated criteria that has not been met and whether to award all or any portion of the weighting ascribed to that performance objective(s), and whether to make any adjustment based on other Company accomplishments that occurred during the year.

For the Company’s named executive offices and other employees participating in this program, 100% of the annual cash incentive bonus is generally determined based on the achievement level for the Program determined by the Compensation Committee as described above. Accordingly, the annual cash incentive bonus for a particular year for each employee in this group is determined by multiplying the amount of his or her base salary received for that year times his or her assigned target bonus percentage times the achievement level for the Program determined by the Compensation Committee, provided that the Compensation Committee reserves the right to make individualized adjustments based on specific facts and circumstances.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Catalyst Biosciences, Inc. on Form S-8 (Nos. 333-133881, 333-133882, 333-160331, 333-185888, 333-189143, 333-206523, 333-206526, 333-212345, 333-219301, and 333-225902), and Form S-3 (Nos. 333-222644 and 333-228970) of our reports dated February 20, 2020, on our audits of the consolidated financial statements as of December 31, 2019 and December 31, 2018, and for each of the years then ended, and the effectiveness of Catalyst Bioscience Inc.'s internal control over financial reporting as of December 31, 2019, which reports are included in this Annual Report on Form 10-K to be filed on or about February 20, 2020.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Iselin, New Jersey
February 20, 2020

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934,
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 subsidiary, 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; and

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: February 20, 2020

/s/ Nassim Usman, Ph.D.

Nassim Usman, Ph.D.
President and Chief Executive Officer
(Principal Executive and Financial Officer)

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of Catalyst Biosciences, Inc. (the "Company") for the year ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Nassim Usman, President and Chief Executive Officer (Principal Executive and Financial 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: February 20, 2020

/s/ Nassim Usman, Ph.D.

Nassim Usman, Ph.D.
President and Chief Executive Officer
(Principal Executive and Financial Officer)