

PROSPECTUS SUPPLEMENT
(To Prospectus dated February 14, 2019)

8,700,000 Shares



Common Stock

We are offering shares of our common stock, par value \$0.001 per share, in this offering.

Our common stock trades on the Nasdaq Capital Market under the symbol "CBIO." On January 25, 2021, the last reported sale price of the common stock on the Nasdaq Capital Market was \$6.83 per share.

Investing in our securities involves a high degree of risk. Before making an investment decision, please read the information under the heading "**Risk Factors**" beginning on page S-21 of this prospectus supplement and in the documents incorporated by reference into this prospectus supplement and the accompanying prospectus.

	Per Share	Total
Public offering price	\$ 5.75	\$ 50,025,000
Underwriting discounts and commissions(1)	\$ 0.345	\$ 3,001,500
Proceeds, before expenses, to us	\$ 5.405	\$ 47,023,500

(1) See "Underwriting" beginning on page S-59 of this prospectus supplement for a description of the compensation payable to the underwriters, including reimbursement of certain expenses.

We have granted the underwriters an option for a period of 30 days from the date of this prospectus supplement to purchase up to 1,305,000 additional shares of our common stock at the public offering price less underwriting discounts and commissions. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be \$3,451,725 and the total proceeds to us, before expenses, will be \$54,077,025. See "Underwriting" for more information.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock against payment on or about January 29, 2021.

Sole Lead Active Bookrunner

Piper Sandler

Bookrunner

Raymond James

The date of this prospectus supplement is January 26, 2021

TABLE OF CONTENTS

	<u>Page</u>
Prospectus Supplement	
About This Prospectus Supplement	S-1
Prospectus Supplement Summary	S-2
The Offering	S-19
Risk Factors	S-21
Cautionary Note Regarding Forward Looking Information	S-57
Use of Proceeds	S-57
Dividend Policy	S-58
Dilution	S-59
Underwriting	S-60
Legal Matters	S-65
Experts	S-65
Where You Can Find More Information	S-65
Incorporation of Certain Information By Reference	S-66
Prospectus	
About This Prospectus	1
Our Company	2
Cautionary Note Regarding Forward-Looking Information	3
Risk Factors	5
Use of Proceeds	5
Description of Capital Stock	6
Additional Information Concerning Our Capital Stock	11
Description of Debt Securities	14
Description of Warrants	21
Description of Units	23
Plan of Distribution	25
Legal Matters	27
Experts	27
Where You Can Find More Information	28

ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts. The first part is the prospectus supplement, including the documents incorporated by reference herein, which describes the specific terms of this offering and also adds to and updates the information contained in the accompanying prospectus and the documents incorporated by reference therein. The second part, the accompanying prospectus, including the documents incorporated by reference therein, provides more general information, some of which may not apply to this offering. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. Before you invest, you should carefully read this prospectus supplement, the accompanying prospectus and the information incorporated by reference herein and therein, as well as the additional information described in this prospectus supplement under “Where You Can Find More Information” and “Incorporation of Certain Information By Reference.” This prospectus supplement may add, update or change information contained in the accompanying prospectus. To the extent that any statement we make in this prospectus supplement is inconsistent with statements made in the accompanying prospectus or any documents incorporated by reference therein, the statements made in this prospectus supplement will be deemed to modify or supersede those made in the accompanying prospectus and such documents incorporated by reference therein. However, if any statement in one of these documents is inconsistent with a statement in another document with a later date that is incorporated by reference herein, the statement in the document having the later date modifies and supersedes the earlier statement.

Neither we nor the underwriters have authorized anyone to provide you with any information or to make any representation, other than those contained or incorporated by reference in this prospectus supplement and the accompanying prospectus, which together we sometimes refer to generally as the prospectus, or in any free writing prospectus prepared by us or on our behalf or to which we have referred you. Neither we nor the underwriters take any responsibility for, and provide no assurance as to the reliability of, any other information that others may give you. You should assume that the information appearing in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and any free writing prospectus is accurate only as of the date of those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates.

We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the offering of the common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus supplement outside the United States. This prospectus supplement does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

Unless the context indicates otherwise, as used in this prospectus supplement and the accompanying prospectus, the terms “Company,” “Catalyst,” “we,” “us” and “our” refer to Catalyst Biosciences, Inc., a Delaware corporation, and its subsidiary, taken as a whole, unless otherwise noted.

This prospectus supplement, the accompanying prospectus and the information incorporated herein and therein by reference includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included or incorporated by reference into this prospectus supplement or the accompanying prospectus are the property of their respective owners.

PROSPECTUS SUPPLEMENT SUMMARY

Company Overview

We are a research and clinical development biopharmaceutical company focused on addressing unmet medical needs in disorders of the complement and coagulation systems. Proteases are the natural regulators of these biological systems. We engineer proteases to create both improved or novel molecules to improve treatment of diseases that result from dysregulation of the complement and coagulation cascades. Our protease engineering platform has generated two late-stage clinical programs including marzeptacog alfa (activated) (“MarzAA”), a subcutaneously (“SQ”) administered next-generation engineered coagulation Factor VIIa (“FVIIa”) for the treatment of episodic bleeding in subjects with rare bleeding disorders. Our complement pipeline includes a preclinical program partnered with Biogen International GmbH (“Biogen”) for dry age-related macular degeneration (“AMD”), an improved complement factor I protease for SQ prophylaxis in patients with complement factor I (“CFI”) deficiency and C4b-degraders designed to target disorders of the classical complement pathway as well as other complement programs in development.

The product candidates generated by our protease engineering platform have improved functional properties such as longer half-life, improved specificity, higher potency and increased bioavailability. These characteristics allow for the potential for improved efficacy, SQ administration of recombinant coagulation factors and complement inhibitors, or less frequently dosed intravitreal therapeutics.

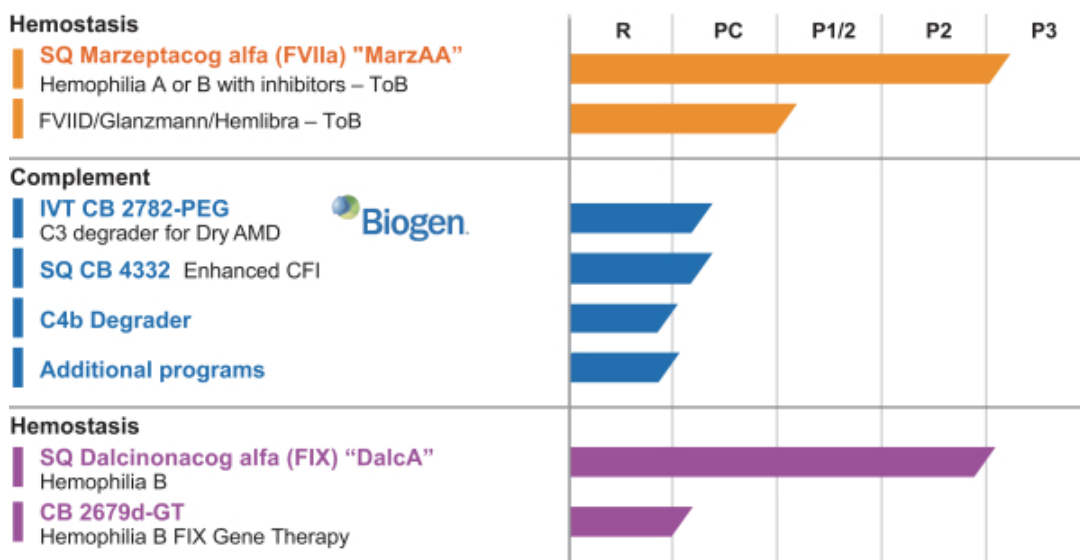
Our most advanced product candidate is MarzAA, a next-generation SQ FVIIa that is entering a registrational Phase 3 trial (MAA-304) in patients with Hemophilia A or B with inhibitors. We also plan to initiate a Phase 1/2 trial of MarzAA in Factor VII Deficiency, Glanzmann Thrombasthenia, and Hemophilia A with inhibitor patients on prophylaxis Hemlibra for treatment of episodic bleeding (MAA-202).

Our complement portfolio is led by the development candidates CB 4332 and CB 2782-PEG. CB 4332 is a wholly-owned first-in-class improved CFI intended for lifelong prophylactic SQ administration in individuals with CFI deficiency. CB 2782-PEG is a potential best-in-class C3 degrader product candidate in preclinical development for the treatment of dry AMD that we have licensed to Biogen. We have several engineered protease programs in discovery or early non-clinical development. These programs all target diseases caused by deficient regulation of the complement system.

Our next most advanced hemophilia product candidate is dalcinonacog alfa (“DalcA”), a next-generation SQ FIX, which has shown efficacy and safety in a Phase 2b clinical trial in individuals with Hemophilia B. We have a discovery stage Factor IX gene therapy construct, CB 2679d-GT for Hemophilia B, that has demonstrated superiority compared with the Padua FIX variant in preclinical models.

[Table of Contents](#)

The following table summarizes our current development programs.



Both MarzAA and DalcA have received orphan drug designation in the U.S. and in the European Union (“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. In addition, the U.S. Food and Drug Administration (the “FDA”) has granted Fast Track designation for MarzAA for the treatment of episodic bleeding in patients with Hemophilia A or Hemophilia B with inhibitors. 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 \$4.0 billion: \$2.2 billion for the Factor VIIa market and \$1.8 billion for the Factor IX (“FIX”) market.

In the CB 4332, enhanced CFI program, we intend to commence enrollment of an observational trial in mid-2021 to measure CFI activity and genotype patients who have diseases related to CFI deficiency in order to identify those who would benefit from CB 4332 treatment. This will prepare us for a P1/2 clinical study of CB 4332 in 2022. CB 4332 is designed to restore the normal complement system in patients with dysregulated or aberrant CFI. There are currently no approved options for protein replacement therapy in CFI deficiency, nor are there any in clinical development. We estimate that the market for CB 4332 in patients with atypical hemolytic uremic syndrome (“aHUS”), complement 3 glomerulopathy (“C3G”) and immune complex mediated membranoproliferative glomerulonephritis (“IC-MPGN”) is approximately \$500 million, with additional potential opportunities for patients who are CFI deficient with indications outside of nephrology, such as to prevent severe infections and recurrent inflammatory histopathologies. The size of the market for these potential opportunities is estimated to be approximately \$12.0 billion by 2026. This patient population is likely significantly underdiagnosed and appears to be growing as more awareness about the clinical manifestation of complete CFI deficiency emerge. There are a number of dry AMD patients who have genetic abnormalities in their CFI gene that may be an important driver of their disease.

Additionally, we are currently developing a portfolio of next generation specific complement degraders based on CB 4332 and designed to target disorders of the classical or alternative pathways.

There are currently no approved drugs for treating dry AMD. Dry AMD is estimated to have a \$5.0 billion market opportunity which could grow to over \$18.0 billion by 2028 with no approved drugs on the market. We entered into an exclusive worldwide license and collaboration agreement with Biogen in late 2019 for the development and commercialization of CB 2782-PEG. We received a \$15.0 million upfront payment from Biogen in January 2020 and are eligible to receive up to \$340.0 million in milestone payments and tiered royalties for worldwide net sales of this product candidate up to low double-digits.

We are experiencing operational and other challenges as a result of the novel coronavirus disease (“COVID-19”) global pandemic, which have delayed our enrollment in MAA-304 and MAA-202, and which may delay or halt our development in our programs. See the section entitled “Risk Factors” for further discussion of the current and expected impact on our business and development programs.

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.

Hemophilia Management and Opportunities for a New Paradigm with SQ Therapy. Current hemophilia treatments involve on-demand management of acute bleeding episodes or prophylactic treatment using factor replacement or bypassing 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 bypassing agents to achieve coagulation in the absence of effective factor levels.

Currently, two types of IV bypassing treatments exist: recombinant activated coagulation factor VII (rFVIIa: NovoSeven RT and SEVENFACT) and activated prothrombin complex concentrates (*e.g.*, FEIBA). rFVIIa is currently the leading bypassing agent for on-demand treatment in inhibitor complicated hemophilia. rFVIIa 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. NovoSeven RT sales for 2019 were \$1.2 billion. 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. All of these bypassing agents are administered intravenously, making them cumbersome to administer and have relatively short half-lives, often requiring multiple infusions to treat a bleed. Although FEIBA is approved for prophylaxis, it must be administered by IV infusion every other day and the rFVIIa products are generally not used for routine prophylaxis.

[Table of Contents](#)

We believe SQ dosing is the future in hemophilia and other rare benign hematology indications. Our nonclinical and 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 the potential 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. In late 2018 Hemlibra®, a bispecific antibody mimicking FVIIIa, was approved for SQ prophylaxis in Hemophilia A with or without inhibitors but cannot treat breakthrough bleeding.

MarzAA Clinical Development. We are initiating a registrational Phase 3 trial (MAA-304) for our most advanced product candidate, MarzAA, a potent, subcutaneously administered, next-generation Factor VIIa variant.

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 were 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.

In 2019, we successfully completed a Phase 2 open-label SQ prophylaxis trial that met all primary and secondary end points. The Phase 2 trial was designed to evaluate the efficacy of MarzAA in preventing bleeding episodes. The primary endpoint assessed 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 or neutralizing antibody formation. Daily SQ administration for 50 days at an individual’s final dose of MarzAA significantly reduced the mean 6-month pre-study ABR from 19.8 to 1.6 during treatment ($p < 0.01$). Additionally, the Proportion of Days with Bleeding (“PDB”), was significantly reduced from a 6-month pre-treatment mean of 12.3% to 0.8% during treatment ($p < 0.01$). 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 level. Subcutaneous treatment with MarzAA demonstrated an acceptable safety profile and was well tolerated. No anti-drug antibodies or inhibitors to MarzAA or thrombotic events were detected after administration of a total of 517 SQ doses. Subcutaneous administration prolonged the half-life of MarzAA to 16.6 hours so that trough levels of MarzAA before the next SQ dose are projected to be sufficient to provide bleed prevention.

We completed a Phase 1/2 PK/PD study (MAA-102) in 2020, to evaluate the pharmacokinetics and pharmacodynamics of ascending single dose levels of MarzAA and twice and thrice dosing of 60 µg/kg at 3-hourly intervals in individuals with Hemophilia A or B with or without inhibitors. The purpose of the trial was to determine if the timing and peak levels achieved were sufficient to treat episodic or breakthrough bleeding with SQ dosing and determine if increasing dose levels resulted in dose proportional pharmacokinetics. This trial, together with population pharmacokinetic simulations and preclinical studies of spontaneous joint bleeding, confirm that we have optimized dosing for the registrational Phase 3 trial (MAA-304). We reported final data from the trial at the International Society on Thrombosis and Haemostasis in July 2020, which demonstrated that MarzAA reaches target levels estimated to effectively treat episodic and breakthrough bleeds. In addition to prophylaxis efficacy in patients, multiple preclinical studies suggest that MarzAA has the potential to be used for treatment of episodic bleeding and supports further clinical testing to assess effectiveness to achieve hemostasis in the treatment of bleeding events in individuals with hemophilia with inhibitors or for other conditions.

Across all clinical studies we have treated a total of 46 subjects ranging from single IV to 44-97 days of daily SQ with no MarzAA anti-drug antibodies (ADAs) detected and an ISR rate of <1%.

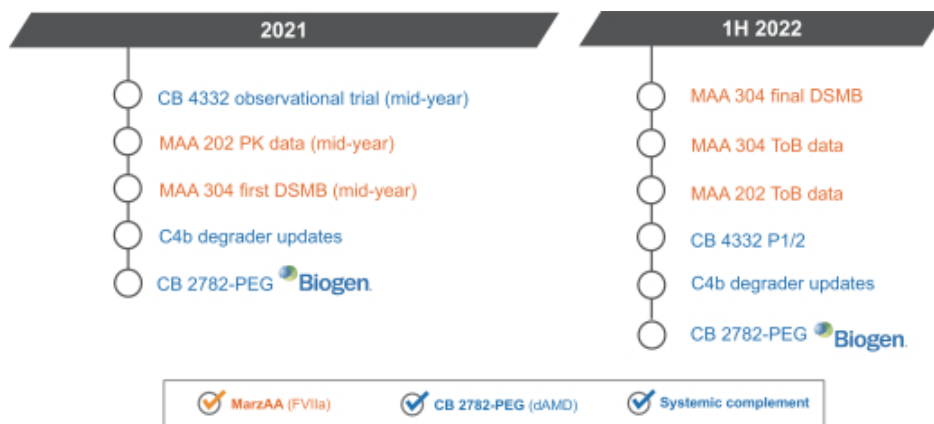
Table of Contents

In December 2020, we announced that the FDA had granted Fast Track designation for MarzAA. The Fast Track program is designed to facilitate and expedite the development and review of drug candidates that have demonstrated the potential to address an unmet medical need in treating serious diseases or conditions. A drug candidate with Fast Track designation is eligible for greater access to the FDA as well as a priority review and rolling review of the marketing application. We believe the FDA Fast Track designation validates MarzAA's potential to improve patient care. As the only SQ delivered therapy in development for on-demand treatment of bleeding events, MarzAA is uniquely positioned to become an important addition to the treatment landscape.

The Phase 3 registration trial – MAA-304 – is an open-label, global, multi-center, randomized, cross-over study, designed to evaluate the safety and efficacy of MarzAA for on-demand treatment of spontaneous or traumatic bleeding episodes, in adolescents and adults with congenital Hemophilia A or B with inhibitors, compared with Standard of Care, either IV rFVIIa or IV FEIBA. The study will enroll approximately 60 subjects to treat 244 eligible bleeding episodes with each treatment. The primary endpoint is hemostatic efficacy using a standard 4-point assessment scale at the 24-hour timepoint. The study will assess the effectiveness of SQ MarzAA, using up to three doses to treat a bleeding episode, compared with the Standard of Care. We plan to submit our first report to the Data and Safety Monitoring Board (“DSMB”) in 2021 and our final DSMB report in the first half of 2022.

We also plan to initiate a Phase 1/2 trial (MAA-202) of MarzAA for treatment of bleeding in Factor VII Deficiency, Glanzmann Thrombasthenia, and in individuals with Hemophilia A with inhibitors treated with Hemlibra in 2021 and to report interim PK data mid-year.

Anticipated Milestones for our product candidates are listed below:

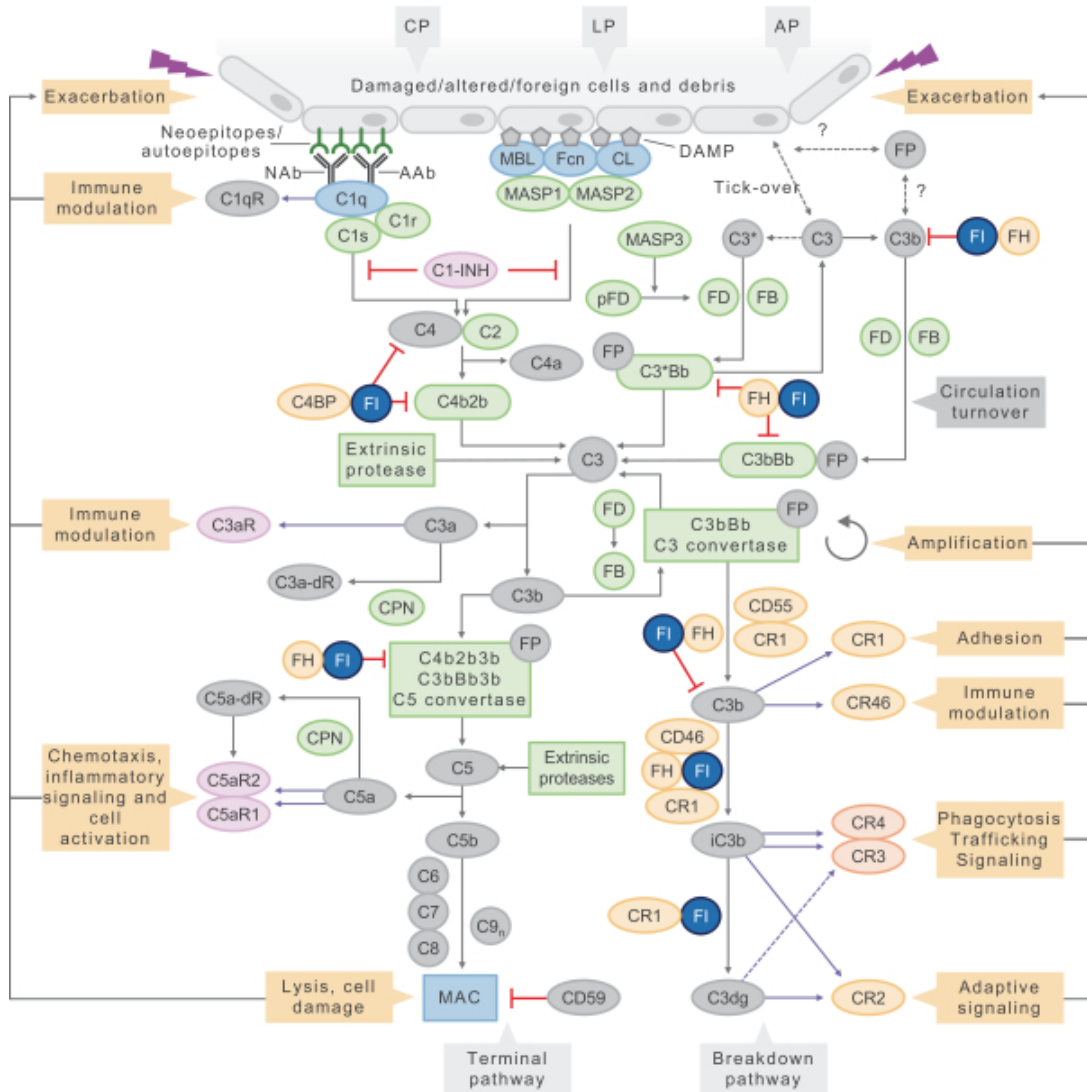


Interplay of On-demand Treatment of Bleed and Prophylaxis for Hemophilia Management. Our preclinical data has shown that SQ injections of MarzAA given one minute after injury, to mirror on-demand therapy, significantly reduced bleeding in animal models of Hemophilia A. In mice, reduction of bleeding 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. Moreover, SQ MarzAA was efficacious as a stand-alone therapy for treating spontaneous bleeding in rats and dogs with congenital Hemophilia A. Rats and dogs with hemophilia A present with spontaneous unprovoked bleeding as is seen in humans with hemophilia. These findings suggest that MarzAA has the potential to be used on-demand by SQ administration 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 or other rare bleeding disorders.

[Table of Contents](#)

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, when 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 is associated with increased risk of 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 by an IV infusion to treat a bleeding event. Ideally, add-on therapy for patients on SQ Hemlibra should be given subcutaneously. We believe MarzAA provides a potential SQ solution to this problem as a SQ rescue therapy for hemophilia patients experiencing breakthrough bleeds while on prophylaxis with SQ agents such as Hemlibra.

Complement. The complement system is a complex enzyme-based defense system depicted in the figure below, developed to protect the body from pathogens, such as viruses and bacteria. Similar to the coagulation system, the complement system employs a triggering mechanism followed by a cascading system of enzymatic proteins (proteases) that, when functioning properly, ultimately leads to the destruction and removal of the pathogen.



* Figure adapted from Mastellos *et al.*, Clinical promise of next-generation complement therapeutics. Nature Reviews. 2019

Complement system disorders. Deficient or excessive activation of the complement system may lead to severe disorders, including micro thrombotic, autoimmune, and severe infectious diseases. Complement system disorders can be caused either by defects in the complement system that prevent an appropriate response to

Table of Contents

threats, or by the lack of complement inhibitor activity, which can cause the complement system to become hyperactive and become self-destructive. Either imbalance can have severe or even fatal consequences in affected individuals.

Complement Factor I Deficiency and CB 4332. CB 4332 is an engineered version of the CFI protease with an extended half-life that was designed for SQ use in patients with CFI deficiency. Even partial CFI deficiency can lead to several diseases:

<i>Atypical Hemolytic Uremic Syndrome (“aHUS”)</i>	aHUS is a severe and life-threatening, ultra-rare disease characterized by chronic uncontrolled complement activation and the formation of blood clots in small blood vessels throughout the body, causing a reduction in platelet count (thrombocytopenia) and life-threatening damage to the kidney, brain, heart and other vital organs. In aHUS, clots in small vessels are common, and the disease is diagnosed based on a combination of hemolytic anemia, thrombocytopenia, and kidney impairment followed by testing for complement protein levels and/or aberrant genes. Disease manifestation can occur at any age and is often caused by a combination of environmental and genetic factors. Not all aHUS patients are CFI deficient, however, and a definitive diagnosis of CFI deficiency requires measurement of CFI antigen and/or activity eventually supplemented by genetic testing.
<i>C3 Glomerulonephritis (“C3G”) and Immune Complex Membranoproliferative Glomerulonephritis (“IC-MPGN”)</i>	Glomerulonephritis is a group of diseases that affects the kidneys. Symptoms of glomerulonephritis are related to a loss of normal kidney function, which includes vital functions such as removing wastes from the body, balancing body fluids, regulating blood pressure, and making the hormones that help make blood platelets and red blood cells. Signs can include blood and excess protein in the urine, edema, gout, infections, high blood pressure, fatigue and reduced alertness, lack of appetite, nausea and vomiting, difficulty sleeping, dry and itchy skin and muscle cramps.
<i>Complete CFI Deficiency (“CFID”)</i>	CFID may present with a variety of disease manifestations, such as recurrent invasive infections with encapsulated bacteria, but patients are also at risk for developing noninfectious diseases such as chronic inflammation of the blood vessels of the brain and/or spinal cord. Clinical presentations include invasive bacterial infections, peritonitis, meningitis, cutaneous IgA vasculitis and bacteremia. The heterogenous clinical presentation likely makes the disease significantly underdiagnosed and patients may experience life threatening emergencies that may have severe long-term impact on the quality of life. No real prophylaxis exists and patients often receive lifelong antibiotic treatment, which may cause a range of additional problems.

Currently, there are no therapeutic options approved to specifically replace the deficient CFI protein with a well-functioning CFI to treat these disorders. While not specifically targeting CFI deficiency, eculizumab and ravulizumab are indicated for use in aHUS. Neither eculizumab nor ravulizumab address the root cause of the CFI deficiency; instead, they are designed to prevent the downstream effects of uncontrolled complement activity. Patients with aberrant CFI may therefore still have uncontrolled complement activation downstream of CFI. This may cause deposition of complement proteins, for example, on red blood cells, and some CFI patients may have a worse prognosis than others even when on non-replacement therapy.

CB 4332 is designed to address this unmet need by providing a therapeutic option that corrects the root problem of these diseases by simple, fast and easy SQ administration. The total US and EU5 market potential in kidney

Table of Contents

disease caused by CFI deficiency such as aHUS, C3G, and IC-MPGN is estimated to be around \$500M with a potential to grow as genetic diagnostics gain more widespread use. Similarly, diagnosis of complete CFI deficiency can be expected to grow in the future. The size of the market for these potential opportunities is estimated to be approximately \$10.0 billion. This would represent a further upside to the market estimate as CFI deficiency may be significantly underdiagnosed at present.

Diseases of the Classical Complement Pathway. In healthy individuals, the classical complement pathway is triggered by antibody-pathogen interactions. Specifically, antibodies bind to pathogens and mark them as targets for destruction by the complement system. This lets the complement system know that an unwanted pathogen is present and needs to be destroyed and cleared.

In disease, however, the antibody mediated targeting affects an individual's own cells and the classical complement system triggers an uncontrolled self-destructive process, which can have dire consequences. This response involves complement proteins C1, C2, and C4, and modulating these factors could potentially treat disorders of the classical complement pathway in a way that leaves the alternative and lectin as well as common pathways intact to carry out their normal physiological functions.

Examples of disorders related to the classical complement pathway for which limited treatment options are available include the following:

<i>Warm Autoimmune Hemolytic Anemia ("wAIHA")</i>	wAIHA is a hemolytic anemia where destruction of red blood cells "tagged" by antibodies may cause fatigue, shortness of breath, dizziness chest pain, decreased alertness, confusion, transient loss of consciousness and deregulation of heart rate and blood pressure. wAIHA is also associated with an increased risk of blood clots. Even after treatment, approximately 70% are at risk of developing recurrent episodes of hemolysis. The majority of people with wAIHA survive, although mortality rates of about 5% have been reported. Children may develop wAIHA, but it is more common among adults.
<i>Cold Agglutinin Disease ("CAD")</i>	Similar to wAIHA, CAD is a hemolytic anemia with similar symptoms. CAD is, however, triggered by cold temperatures. In addition to symptoms mentioned above, patients with CAD may have cold and/or discolored feet or hands. CAD can also cause potentially fatal thrombotic events. Current treatments include blood transfusions, steroids or off-label rituximab often requiring patients to have recurring transfusions which may lead to iron overload. CAD can also be seen in association with some cancers.
<i>Generalized Myasthenia Gravis ("gMG")</i>	Myasthenia gravis is a neuromuscular disease caused by an antibody-mediated autoimmune response in which the complement system inappropriately attacks receptors in muscles that receive nerve impulses. gMG patients suffer profound muscle weakness throughout the body, resulting in slurred speech, impaired swallowing and choking, double vision, upper and lower extremity weakness, disabling fatigue, shortness of breath due to respiratory muscle weakness and episodes of respiratory failure. In 2017, eculizumab was approved for gMG in patients who are anti-acetylcholine receptor antibody-positive. As described elsewhere in this prospectus supplement, eculizumab does not directly modulate the classical pathway hyperreactivity that is causing the disease.
<i>Guillain-Barré Syndrome ("GBS")</i>	GBS is a severe disorder where the complement system triggered by an infection also attacks innocent bystander nerve cells resulting in muscle weakness, inability to climb stairs or walk, double vision or inability to move eyes, severe cramp-like pain, lack of bladder control or bowel function as well as impaired ability to breathe. Although most people recover from GBS, the mortality rate has been reported at about 5%.

Table of Contents

<i>Amyotrophic Lateral Sclerosis (“ALS”)</i>	ALS is a motor neuron disease that can cause symptoms similar to those of gMG. The weakness eventually affects chewing, swallowing, speaking and breathing. People with ALS are also at increased risk for acute inflammation of the lungs, caused by the inhalation of food or stomach contents due to loss of control of the muscles normally preventing this whereas pain is uncommon as is the loss of bladder control and senses.
<i>Multifocal Motor Neuropathy (“MMN”)</i>	MMN is a rare disease characterized by slowly progressive muscle weakness, primarily of the arms and legs due to antibody-initiated complement activation. There is often asymmetric muscle weakness in the hands and lower arms as well as cramping, involuntary contractions or twitching, wrist or foot drop and wasting of affected muscles. Men are more frequently affected than women and men tend to be diagnosed at a younger age.
<i>Systemic Lupus Erythematosus (“SLE”)</i>	SLE is an autoimmune disorder causing widespread inflammation and tissue damage in the affected organs. It can affect the joints, skin, brain, lungs, kidneys, and blood vessels. Accordingly, affected individuals can present with a variety of symptoms including fatigue, skin rashes, fevers, and pain or swelling in the joints. The symptoms may wax and wane and come in “flares” that can be more or less frequent. Other symptoms of SLE can include sun sensitivity, ulcers in the mouth, joint and lung disease, heart and kidney problems, seizures, psychosis, and blood cell and immunological abnormalities.
<i>Lupus Nephritis (“LN”)</i>	LN is a nephritic complication of SLE induced by autoantibody-initiated complement activation in which the symptoms share many similarities with those of other kidney disorders including blood and proteins in the urine, high blood pressure, edema and high levels of creatinine in the blood. Treatment is generally unspecific and may involve immunosuppressants, dialysis, or kidney transplantation.
<i>Schizophrenia</i>	Schizophrenia is a complex disorder. Growing evidence points to imbalances in the classical pathway, such as C4 hyperreactivity, that may be involved in aberrant pruning of nerve cell interactions.

In general, these disorders have large patient populations. For example, it is estimated that across the US/EU5 markets there are: 32,000 patients with ALS; 76,000 with wAIHA; 129,000 with gMG; 13,000 with GBS; 22,000 with CAD; 4,000 with MMN, and 372,000 and 129,000 with SLE and LN, respectively. Taken together as a whole the classical pathway disorders either have no approved therapies or severe unmet needs exists that if addressed by successful drug candidates could significantly improve patient outcomes and become great commercial successes.

Catalyst protease programs in complement. We believe that engineered proteases hold a unique potential to address disorders driven by dysregulated biological processes and are differentiated by circumventing certain limitations of small molecule and antibody based therapeutics. Two examples of biological processes/systems that can be targeted by engineered proteases are the coagulation and complement systems. In both systems one protease molecule can modulate tens, hundreds, thousands, or even more target molecules to either activate or inactivate them. This is because a protease therapeutic does not become consumed in the process of engaging its target. Therefore, smaller amounts of protease-based drug molecules can have profound impact on biological regulatory pathways. In comparison, small molecule drugs normally only inhibit a single target molecule per drug molecule and antibodies inhibit two at best. Proteases do not have this inherent limitation. Moreover, proteases lend themselves well to half-life extension allowing infrequent convenient administration.

We currently have several protease programs in preclinical discovery or early non-clinical development. Common to the programs is that they target diseases caused by deficient regulation of the complement system. One ocular program for dry AMD is partnered with Biogen; the remaining complement programs are focused on systemic complement disorders and are wholly owned by Catalyst.

CB 2782-PEG for dry AMD (Biogen collaboration). CB 2782-PEG is an engineered pegylated C3 degrader that we designed with a best-in-class anti-C3 profile for dry AMD. Dry AMD is an ocular disease leading to vision loss and blindness for which there is currently no approved therapies. Complement hyperreactivity plays an important role in dry AMD. Using the protease CB 2782-PEG to degrade C3 allows for the neutralization of C3 activity. It is expected that maintaining low C3 in the eye can significantly slow disease progression in dry AMD in patients who would otherwise lose their vision over time. The global market potential in dry AMD has been estimated to be \$8.6 billion which could grow to over \$18.0 billion by 2028. In December 2019, we entered into a License and Collaboration Agreement with Biogen for the development and commercialization of CB2782-PEG.

C4b degraders for classical pathway disorders. A key regulation of the classical pathway occurs at the level of C2/C4. Specifically, CFI together with co-factors, cleave and inactivate C4b to appropriately limit the downstream response. However, in diseases of the classical complement pathway, this regulatory step can be overwhelmed by too much upstream activity leading to uncontrolled downstream complement activation, even in people with normal CFI, ultimately resulting in destruction of the patient's own cells. We are engineering specific and potent C4b degraders to counteract this imbalance to alleviate disease in disorders of classical pathway hyperactivity by engineering an existing regulatory mechanism to become more effective and thereby applicable in individuals with normal CFI levels. By taking this approach we leverage existing biological functions and aim to specifically address fundamental deficiencies in the way current and future antibody and small molecule-based therapeutics work. Our engineered C4b degrader program aims to leverage the same SQ delivery and high-yield production process used for CB 4332. Notably, although we have not chosen a disorder for our first clinical trial with a C4b degrader, the concept is designed to work across disorders of the classical pathway irrespective of the patients CFI genotype.

Future programs currently in discovery. We have additional early stage complement targeted discovery programs that have not yet been disclosed. The programs target different proteins from C3b and C4b.

Complement intellectual property. The United States Patent and Trademark Offices issued a patent covering Catalyst's portfolio of engineered proteases that selectively cleave and degrade complement Factor 3 (C3), including the lead candidate CB 2782-PEG, a potential best-in-class treatment for dry AMD currently in development and under a license and collaboration agreement with Biogen. These modified proteases inhibit complement activation and have the potential to treat multiple diseases in which complement activation plays a role. The newly issued patent provides protection until at least 2038. Our portfolio encompasses additional issued IP and pending applications in the complement space across a range of targets and protease scaffolds.

DalcA Clinical Development. DalcA is a next-generation SQ Factor IX product candidate for the prophylactic treatment of individuals with Hemophilia B, which completed a Phase 2b study in 2020.

We completed a 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 study 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 root 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.

In 2020, we completed 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 during which FIX activity levels, clotting parameters, half-life, safety, tolerability and anti-drug antibody formation were monitored.

At the World Federation of Hemophilia Virtual Summit in June 2020, we reported that 28 days of daily SQ dosing of DalcA at 100 IU/kg achieved protective target FIX levels of >12% in all participants, with FIX levels of up to 27% and a half-life of 2.5 to 5.1 days. No bleeds were reported during the 28 days of dosing and the 5 day wash-out, demonstrating effective prophylaxis and the potential for lower or less frequent dosing. Injection volumes were less than 1 mL. One subject withdrew on day 7 after reporting injection site reactions (“ISR”) from the first 3 SQ doses. No neutralizing anti-drug antibodies were detected, and no serious adverse events were reported. A single non-neutralizing anti-drug antibody to DalcA was observed at the end of study time point and had no clinical effect. Some subjects reported mild ISR of pain and/or redness, primarily with the initial injections. No thrombotic events occurred, and blood coagulation markers did not show any prothrombotic signals.

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 and blood loss in a preclinical Hemophilia B mouse model compared with the Padua variant of Factor IX. Fidanacogene elaparvovec (Pfizer/Spark), AMT-061 (uniQure), TAK-748 (Takeda) and FLT180A (Freeline) use the Padua FIX 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 in the upper end of the mild to normal ranges. 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 European Association for Haemophilia and Allied disorders (“EAHAD”) in February 2020 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 reported at the World Federation of Hemophilia Virtual Summit in June 2020 that studies of CB 2679d-GT in Hemophilia B mice have demonstrated a 4-fold reduction in blood loss and an 8-fold reduction in bleeding time when compared with the same dose of the Padua variant of FIX. We also reported that in a non-human primate study evaluating expression and tolerability, CB 2679d-GT in the novel chimeric capsid KP1 was well tolerated with high FIX expression that stabilized to approximately 25% to 50% FIX above baseline levels at the 6-week interim data cutoff. The novel chimeric capsid had differentiated and superior response to anti-capsid neutralizing antibodies compared to that observed for the LK03 comparator during the screening of non-human primates for the study.

Our Strategy

We are building a protease medicines company. Our portfolio of engineered protease therapies is designed for individuals with disorders of the complement and coagulation systems who need new or better treatment options. Our overall strategy builds on our belief that proteases can uniquely be engineered to improve their properties as potential drugs, for example by circumventing limitations of small molecule and antibody-based therapies. We are focused on building a portfolio of closely linked, yet highly differentiated drug candidates that leverages the unique attributes of proteases. Key focus areas for us in the near and longer term include:

Complement Therapeutics:

- Invest in multiple differentiated systemic complement regulation programs with our proprietary protease engineering platform.

Table of Contents

- Initiate clinical trial(s) with CB 4332 including an observational trial and a Phase 1/2 trial.
- Advance C4b-degraders and other novel complement programs into clinical development.

Hemostasis Therapeutics:

- Initiate and complete a registrational Phase 3 trial for the treatment of acute bleeds.
- Expand clinical development of MarzAA in additional indications.
- Complete formulation studies of DalcA.

Leverage the protease engineering platform to develop novel differentiated therapeutics:

- Focus on rare systemic disorders amenable to engagement by proteases and where clear unmet needs exist.
- Engineer drug candidates that have applications across multiple indications.
- Utilize existing processes across candidates and programs to achieve platform benefits.
- Strategically develop candidates with a fast to clinic approach.
- Develop therapeutics with infrequent, convenient SQ administration.

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 a Phase 1 IV 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 \$1.0 million milestone payment based on the dosing of the first patient in a 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 \$17.0 million in commercial milestone payments.

Under the original agreement with ISU, we received and recognized \$2.7 million from ISU through 2018.

CB 2782-PEG. In 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 preclinical and manufacturing activities, and Biogen will be solely responsible for funding the preclinical and manufacturing activities and performing investigational new drug (“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 \$340.0 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 (“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 an FTE-based fee. Pursuant to a subsequent amendment in May 2020, Mosaic received a one-time cash payment of \$0.8 million and is eligible to receive up to \$4.0 million in potential future milestone payments for regulatory and clinical development milestones resulting from the development of CB 2782-PEG and an additional anti-complement product candidate payable in cash or common stock at the Company’s election. As a result, we now own one hundred percent of all future payment streams related to these product candidates.

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 enrolling 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 on demand use in individuals with Factor VII deficiency and Glanzmann thrombasthenia, but not for prophylaxis. It is also approved for treatment of 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.

- HEMA Biologics' SEVENFACT 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 approved in 2020.
- In addition to currently approved products, several other companies including Novo Nordisk, Pfizer, Genzyme and others are developing SQ agents for the treatment of Hemophilia A or B with or without inhibitors or Hemophilia B with inhibitors using a variety of technologies.
- **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.
- **Dry AMD Competition:** While there are no currently approved treatments for dry AMD, several companies are developing cyclic peptide, aptamer, antibody or gene therapy 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.
 - Iveric Bio (formerly Ophthotech) is developing two therapies to treat GA secondary to dry AMD. Iveric Bio completed its Phase 2b clinical of Zimura® (avacincaptad pegol) with positive data in patients with dry AMD.
 - Gemini Therapeutics is developing "GEM103" a recombinant human complement factor H ("FH") for patients with genetically well-defined dry AMD and "GEM104," a recombinant human complement factor I as well as additional molecules in preclinical development for other genetically defined subpopulations of patients with dry AMD.
 - Gyroscope Therapeutics is developing "GT005" a gene therapeutic approach to expressing additional CFI in the patient's eye after subretinal delivery. GT005 is being developed for a genetically well-defined subpopulation of patients with dry AMD.

Systemic Complement Factor I Deficiency Competition: There are currently no approved agents specifically targeting systemic factor I deficiency patients irrespective of the resultant disease phenotype being aHUS, C3G, IC-MPGN, invasive infections or any other. There are no approved therapies for C3G and IC-MPGN. There are, however, less specific treatment options on the market or in clinical development which may be applicable to some disease manifestations of systemic CFI deficiency, for instance aHUS and C3G.

- Alexion Pharmaceuticals (to be acquired by AstraZeneca) markets eculizumab and ravulizumab for use in aHUS irrespective of the patients' CFI status.

- Apellis is conducting clinical development for APL-2 (pegcetacoplan), a pegylated peptide based C3 inhibitor, in IgA Nephropathy (“IgAN”), LN, Membranous Nephropathy (“MN”), C3G, and Dense Deposit Disease irrespective of the patients’ CFI status.
- ChemoCentryx is developing CCX168 (avacopan), a twice daily oral small molecule inhibitor of the complement 5a receptor (“C5aR”) in C3G – currently in phase 2.
- Novartis is conducting clinical development for iptacopan (“LNP023”), a small peptide complement factor B inhibitor. Iptacopan is in development for PNH, as well as C3G and several other rare renal diseases including IgAN, aHUS, and membranous nephropathy. Novartis expect first FDA filings in 2023. Iptacopan has received Rare Pediatric Disease Designation in C3G.
- Omeros is developing OMS721 (“narsoplimab”). Narsoplimab is a human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (“MASP-2”), the effector enzyme of the lectin pathway of the complement system. Clinical activities have been initiated in IgAN, LN, MN, & C3G and a phase 3 clinical program is underway in aHUS.

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.

COVID-19 Business Impact

The current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, potential trial participants, communities and business operations, as well as the U.S. economy and financial markets. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets.

To date, we have instructed our employees to work from home except as needed to ensure continuity of our operations. As we continue to actively advance our clinical programs, we are in close contact with our principal investigators, clinical sites and contractors, including manufacturers, and are assessing the impact of COVID-19 on our current and planned trials, expected timelines and costs on an ongoing basis. We are continuing study start-up activities where possible to allow rapid site activation and enrollment of our registrational Phase 3 trial (MAA-304) at the appropriate time, although we may experience delays. We have experienced some supply chain disruptions as the ongoing COVID-19 pandemic has impacted the ability of some of our suppliers to deliver certain raw materials on a timely basis.

Given the focus of healthcare providers and hospitals on fighting COVID-19, and the reluctance of potential trial participants to visit hospitals or other clinical trial sites, we have experienced delays in the enrollment of patients in our upcoming clinical trials. We will continue to evaluate the impact of the COVID-19 pandemic on our business and will reevaluate the timing of our anticipated clinical milestones as we learn more and the impact of COVID-19 on our industry becomes clearer.

For additional information on the various risks posed by the COVID-19 pandemic, please read the section entitled “Risk Factors” included in this prospectus supplement.

Recent Developments

Certain Preliminary Financial Results as of December 31, 2020

Although we have not finalized our full financial results for the fourth quarter and fiscal year ended December 31, 2020, we expect to report that we had approximately \$81.9 million in cash, cash equivalents and investments as of December 31, 2020.

The information above is based on preliminary unaudited information and management estimates for the year ended December 31, 2020, is not a comprehensive statement of our financial results, and is subject to completion of our financial closing procedures. Our independent registered public accounting firm has not conducted an audit or review of, and does not express an opinion or any other form of assurance with respect to, these preliminary estimates.

Company Information

We commenced operations in 2002 and are a Delaware corporation. On August 20, 2015, we merged with Targacept, Inc. Our corporate headquarters are located at 611 Gateway Blvd., Suite 710, South San Francisco, California 94080. Our telephone number is (650) 871-0761, and our website address is www.catalystbiosciences.com. The information contained on, or that can be accessed through, our website is not part of this prospectus supplement, and you should not consider information on our website to be part of this prospectus supplement.

THE OFFERING

Common stock offered by us	8,700,000 Shares of common stock, par value \$0.001 per share.
Option to purchase additional shares	We have granted the underwriters an option to purchase up to 1,305,000 additional shares of common stock. This option is exercisable, in whole or in part, for a period of 30 days from the date of this prospectus supplement.
Common stock to be outstanding after this offering	30,782,924 shares (or approximately 32,087,924 shares if the underwriters exercise their option to purchase additional shares of common stock in full).
Use of proceeds	We expect the net proceeds from this offering to us, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately \$46.7 million (\$53.7 million if the underwriters exercise their option to purchase additional shares in full). We currently expect to use the net proceeds primarily for general corporate purposes, including research, development and manufacturing activities in our hemophilia and complement programs, specifically for MarzAA (FVIIa), CB 4332 (enhanced complement Factor I) and others, capital expenditures, selling, general and administrative costs, facilities expansion, and to meet working capital needs. We expect from time to time to evaluate the acquisition of businesses, products and technologies for which a portion of the net proceeds may be used, although we currently are not planning or negotiating any such transactions. See "Use of Proceeds" on page S-57 of this prospectus supplement.
Risk factors	Investing in our common stock involves significant risks. See "Risk Factors," beginning on page S-21 as well as the other information included in or incorporated by reference in this prospectus supplement and the accompanying prospectus, for a discussion of risks you should carefully consider before investing in our securities.
Nasdaq Capital Market symbol	"CBIO"

The number of shares of our common stock to be outstanding immediately after this offering as shown above is based on 22,082,924 shares of common stock outstanding as of September 30, 2020, and excludes:

- 2,264,141 shares of common stock issuable upon exercise of options outstanding as of September 30, 2020, with a weighted average exercise price of \$8.841 per share;
- 83,000 shares of common stock issuable upon exercise of options granted after September 30, 2020, with a weighted average exercise price of \$5.946 per share;
- 722 shares of common stock issuable upon exercise of warrants outstanding as of September 30, 2020, with a weighted average exercise price of \$90.26 per share;

Table of Contents

- 1,674,278 shares of common stock reserved and available for future issuance as of September 30, 2020, under our equity incentive plans, consisting of (1) 1,373,834 shares of common stock reserved and available for issuance under our 2018 Omnibus Incentive Plan as of September 30, 2020, and (2) 300,444 shares of common stock reserved for issuance under our 2018 Employee Stock Purchase Plan as of September 30, 2020; and
- 1,275,938 additional shares of common stock reserved and available for future issuance after September 30, 2020 under our 2018 Omnibus Incentive Plan.

Except as otherwise indicated, all information in this prospectus supplement assumes no exercise of outstanding options and warrants and no exercise of the underwriters' option to purchase additional shares of common stock.

RISK FACTORS

An investment in our securities involves a high degree of risk. Prior to making a decision about investing in our securities, you should carefully consider the risk factors described below, together with all of the other information included in this prospectus, including the risks described in our reports and other documents, which are incorporated herein by reference, and may be amended, supplemented or superseded from time to time by other reports we file with the Securities and Exchange Commission (the “SEC”), in the future.

If any of the risks incorporated by reference or set forth below occurs, our business, operations and financial condition could suffer significantly. As a result, you could lose some or all of your investment in our common stock. The risks and uncertainties we have described are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business, operations and financial condition, or cause the value of our common stock to decline.

Summary of Risk Factors

Investing in our securities involves a high degree of risk. Below please find a summary of the principal risks we face. These risks are discussed more fully below.

- We are experiencing operational and other challenges as a result of the COVID-19 global pandemic, which have delayed our enrollment in MAA-304 and MAA-202 and which may delay or halt our development in these or other programs.
- CB 4332, one of our complement product candidates, is in the early stages of development and its commercial viability remains subject to preclinical studies, clinical trials, regulatory approvals and the risks generally inherent in the development of a pharmaceutical product candidate. If we are unable to advance or develop our complement product candidates, our business may be materially harmed.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our regulatory approvals could be delayed or prevented. Competitive products or products that reduce the frequency of bleeding among patients treated with our drugs have reduced the likelihood that patients will enroll in our clinical trials.
- The operations of our third-party manufacturers may be requisitioned by government orders such as under emergency, disaster and civil defense declarations in connection with the COVID-19 pandemic.
- COVID-19 may impact our third-party supply of the raw materials needed for our product candidates, which increases the risk that we will not have sufficient quantities of such product candidates or quantities at an acceptable cost, which could delay, prevent or impair our development efforts.
- We have incurred significant losses since our inception and are expected to continue to incur significant losses for the foreseeable future.
- We will need additional capital. If we are unable to raise sufficient capital, we will be forced to delay, reduce or eliminate product development programs.
- 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.
- We are focused on the clinical development of MarzAA and our complement product candidates. Any adverse events, trial failures or material delays in these programs could materially harm our business.

Table of Contents

- DalcA has caused and MarzAA or our complement product candidates may cause the generation of neutralizing antibodies, which could prevent their further development.
- MarzAA and DalcA are in late-stage clinical trials, and all of our other product candidates are still in preclinical development. If we are unable to obtain regulatory clearance and commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.
- Results from our trials may not be confirmed, and if serious adverse side effects are identified during development of product candidates, we may need to abandon or limit development of some product candidates.
- Fast Track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.
- Our collaboration with Biogen may not result in successful product development or payments to us.
- 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.
- We contract with third parties for the manufacture of our product candidates. 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 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.
- We 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.
- Our employees, principal investigators and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and insider trading.
- 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.
- 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.
- 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.
- 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 products, and our ability to generate revenue will be materially impaired.
- The FDA may disagree with our regulatory plan and we may fail to obtain regulatory approval of our product candidates.

Table of Contents

- Our results of operations may be adversely affected by current and potential future healthcare legislative and regulatory actions.
- If we fail to protect personal information or comply with existing or future data protection regulations, our business, financial condition, results of operations and prospects may be materially 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.
- Even if any of our product candidates receives marketing approval, we may fail to achieve the degree of market acceptance necessary for commercial success.
- Our product candidates are years away from regulatory approval.
- 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 face substantial competition that may result in others discovering, developing or commercializing products before or more successfully than we do.
- If the market opportunities for our product candidates are smaller than expected, our revenues may be adversely affected and our business may suffer.
- 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.
- We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.
- If you purchase shares of common stock sold in this offering you will experience immediate and substantial dilution in your investment.

Risks related to our financial condition and capital requirements

The outbreak of the novel coronavirus disease, COVID-19, could adversely impact our business, including our preclinical studies and clinical trials.

The global coronavirus pandemic has resulted in widespread requirements for individuals to work from their homes, strained medical facilities worldwide and is causing disruptions to certain pharmaceutical manufacturing and product supply chains. We are experiencing operational and other challenges as a result of the COVID-19 global pandemic, which have delayed our enrollment in MAA-304 and MAA-202, and which may delay or halt our development in these or other programs. In particular, as a result of the COVID-19 pandemic, we may experience disruptions that could severely impact our business, preclinical studies, drug manufacturing and clinical trials including:

- additional delays or difficulties in enrolling potential trial participants in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;

Table of Contents

- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- delays in manufacturing of our product candidates as third-party manufacturing capacity is shifted towards the production of COVID-19 vaccines;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA, European Medicines Agency (the “EMA”) or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in preclinical studies due to restricted or limited operations at laboratory facilities;
- suspension or termination of our clinical trials for various reasons, such as a finding that the participants are being exposed to infectious diseases like COVID-19 or the participants involved in our clinical trials have become infected with COVID-19;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- material delays and complications with respect to our research and development programs.

In addition, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. Furthermore, a recession or market correction resulting from the spread of COVID-19 could materially affect our operations and the value of our common stock.

CB 4332, one of our complement product candidates, is in the early stages of development and its commercial viability remains subject to current and future preclinical studies, clinical trials, regulatory approvals and the risks generally inherent in the development of a pharmaceutical product candidate. If we are unable to successfully advance or develop our complement product candidates, our business may be materially harmed.

Failure to successfully advance the development of our complement product candidates, including CB 4332, may have a material adverse effect on us. To date, we have not successfully commercially marketed, distributed or sold any product candidate. The success of our business depends primarily upon our ability to successfully advance the development of our product candidates through preclinical studies and clinical trials, have the product candidates approved for sale by the FDA or regulatory authorities in other countries, and ultimately have the product candidates successfully commercialized by us or a strategic partner. We cannot assure you that the results of our ongoing preclinical studies or future clinical trials will support or justify the continued development of CB 4332, or that we will receive approval from the FDA, or similar regulatory authorities in other countries, to advance the development of CB 4332.

Table of Contents

Our product candidates, including MarzAA, CB 4332 and DalcA, must satisfy rigorous regulatory standards of safety and efficacy before we can advance or complete their clinical development or can be approved for sale. To satisfy these standards, we must engage in expensive and lengthy preclinical studies and clinical trials, develop acceptable manufacturing processes, and obtain regulatory approval of our complement product candidates. Despite these efforts, our complement product candidates, including MarzAA, CB 4332 and DalcA, may not:

- offer therapeutic or other medical benefits over existing drugs or other product candidates in development to treat the same patient population;
- be proven to be safe and effective in current and future preclinical studies or clinical trials;
- have the desired effects;
- be free from undesirable or unexpected effects;
- meet applicable regulatory standards;
- be capable of being formulated and manufactured in commercially suitable quantities and at an acceptable cost; or
- be successfully commercialized by us or by collaborators.

Even if we demonstrate favorable results in preclinical studies and early-stage clinical trials, we cannot assure you that the results of late-stage clinical trials will be favorable enough to support the continued development of our product candidates. A number of companies in the pharmaceutical and biopharmaceutical industries have experienced significant delays, setbacks and failures in all stages of development, including late-stage clinical trials, even after achieving promising results in preclinical testing or early-stage clinical trials. Accordingly, results from completed preclinical studies and early-stage clinical trials of our complement product candidates, including MarzAA, CB 4332 and DalcA, may not be predictive of the results we may obtain in later-stage trials. Furthermore, even if the data collected from preclinical studies and clinical trials involving our complement product candidates, demonstrate a favorable safety and efficacy profile, such results may not be sufficient to support the submission of a new drug application or biologics license application (“BLA”) to obtain regulatory approval from the FDA in the United States or other similar regulatory agencies in other jurisdictions, which is required to market and sell the products.

MarzAA, CB 4332 and DalcA will require significant additional research and development efforts, the commitment of substantial financial resources, and regulatory approvals prior to advancing into clinical development or being commercialized by us or collaborators. We cannot assure you that CB 4332 will successfully progress into clinical development or that CB 4332, MarzAA or DalcA will progress through the drug development process or will result in a commercially viable product. We do not expect CB 4332 or any of our other complement product candidates to be commercialized by us or collaborators for at least several years.

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, which may cause delays in enrollment of clinical trials of MarzAA in individuals with hemophilia A and B with an inhibitor, and there are a limited number of individuals with CFI deficiency for whom CB 4332 can be used in clinical trials. Competitive products or products that reduce the frequency of bleeding among patients treated with our drugs have reduced the likelihood that patients

Table of Contents

will enroll in our clinical trials. Some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates and thus compete with us to enroll patients in their clinical trials. The availability of other approved products and other products in clinical trials may limit the number of patients willing to participate in our clinical trials.

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;
- laboratory testing and turnaround time for samples needed for eligibility assessments;
- 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.

The operations of our third-party manufacturers may be requisitioned, diverted or allocated by U.S. or foreign government orders such as under emergency, disaster and civil defense declarations in connection with the COVID-19 pandemic or otherwise.

Our third-party manufacturers of MarzAA have advised us that they could be required under orders of the U.S. government to allocate manufacturing capacity to the manufacture or distribution of COVID-19 vaccines. If any of our third-party manufacturers become subject to acts or orders of U.S. or foreign government entities to allocate manufacturing capacity to the manufacture or distribution of COVID-19 vaccines or medical supplies needed to treat COVID-19 patients, this could delay or interrupt, perhaps substantially, our supply of clinical trial material for MarzAA which could materially and adversely affect our business. Refer to the risk factor entitled “The outbreak of the novel coronavirus disease, COVID-19, could adversely impact our business, including our preclinical studies and clinical trials.”

The coronavirus disease, COVID-19, may impact our third-party supply of the raw materials and components needed for our product candidates, which increases the risk that we will not have sufficient quantities of such product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development efforts.

If supplies of the raw materials for our product candidates are significantly delayed, or if the third parties that we engage to supply any materials or to manufacture any products for our preclinical tests and clinical trials should cease to continue to do so for any reason, including due to the effects of the COVID-19 pandemic and the actions undertaken by governments and private enterprises to contain COVID-19, we likely would experience delays in advancing these tests and trials while we identify and qualify replacement suppliers or manufacturers and we may be unable to obtain replacement supplies on terms that are favorable to us. In addition, if we are not able to

[Table of Contents](#)

obtain adequate supplies of our product candidates or the substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

Our current and anticipated dependence upon third-party suppliers may adversely affect our ability to develop product candidates and could delay our clinical trials and development programs, and otherwise harm our operations and financial condition and increase our costs and expenses.

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. In addition, our net loss was \$37.3 million for the nine months ended September 30, 2020. As of September 30, 2020, we had an accumulated deficit of \$295.9 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, our complement product candidates and DalcA. 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 and DalcA;
- continue preclinical development and begin clinical development of CB 4332 and our other complement product candidates;
- further develop the manufacturing process for our product candidates;
- attract and retain skilled personnel;
- seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical studies;
- 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.

Table of Contents

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 the section entitled “Collaborations” in this prospectus supplement.

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 \$17.0 million in commercial milestone payment, if the applicable milestones are met. See the section entitled “Collaborations” in this prospectus supplement.

In connection with our collaboration with Mosaic 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 as of 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 clinical trials totaling \$0.5 million and all outstanding amounts were paid during the nine months ended September 30, 2020.

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

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our research and development expenses to increase with our ongoing activities, particularly activities related to the continued clinical development of MarzAA, the preclinical and clinical development of our complement product candidates, and the clinical development of DalcA. We believe that our available cash, cash equivalents and investments will be sufficient to fund our operations for at least the next 12 months. 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 or cease development of some of our product candidates. Even if we raise additional capital, we may elect to focus our efforts on one or more development programs and delay or cease other development programs.

Until we can generate 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

Table of Contents

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 costs and results of preclinical studies or clinical trials of CB 4332 or our other complement product candidates, and expenses related to potential clinical development of such candidates;
- the number and characteristics of product candidates that we pursue;
- the terms and timing of any future collaboration, licensing or other arrangements that we may establish;
- the outcome, timing and cost of regulatory approvals;
- the cost of obtaining, maintaining, defending and enforcing intellectual property rights, including patent rights;
- the effect of competing technological and market developments;
- the cost and timing of completing outsourced manufacturing activities;
- market acceptance of any product candidates for which we may receive regulatory approval;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval; and
- the extent to which we acquire, license or invest in businesses, products or technologies.

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

To the extent that we raise additional capital through the sale of equity or convertible debt securities, stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of common stockholders.

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

Table of Contents

We currently have an effective registration statement on Form S-3 that allows us to offer up to \$140 million of securities in one or more offerings. Any additional sales in the public market of our common stock or other securities under this shelf registration statement could adversely affect prevailing market prices for our common stock.

We have no history of 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 focused on the clinical development of MarzAA and our complement product candidates. Any adverse events, trial failures or material delays in these programs could materially harm our business.

The failure of MarzAA 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, CB 4332 or our other product candidates would significantly harm our business, its prospects and the value of the Company's common stock. There is no guarantee that the results of further clinical trials of MarzAA will be positive or will not generate unanticipated safety concerns. If neutralizing antibodies or other adverse events in patients receiving either MarzAA lead to concerns about patient safety, the long-term efficacy, or commercial viability of MarzAA could be halted. Depending on the availability of additional capital, we may also delay or terminate clinical development of MarzAA.

MarzAA is not expected to be commercially available in the near term, if at all. Further, its commercial success 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, 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 our other product candidates, 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 our other product candidates 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 our other product candidates would be limited.

DalCA has caused and MarzAA or our complement product candidates may cause the generation of neutralizing antibodies, which could prevent their further development.

MarzAA, CB 4332 and DalCA are protein molecules which may cause the generation of antibodies in individuals who receive them. Two patients who received DalCA subcutaneously following intravenous dosing developed

Table of Contents

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 with those products or CB 4332 or our other complement product candidates. 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 late-stage 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 and DalcA have completed Phase 2 clinical trials. 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.

Table of Contents

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

Fast Track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

The FDA grants Fast Track designation to therapies that are considered capable of addressing unmet medical needs and possess the potential to treat serious or life-threatening disease conditions in order to facilitate its development and expedite the review procedure. The FDA has broad discretion in granting Fast Track designation, so even if we believe that a particular product candidate is eligible for such designation, the FDA

Table of Contents

could decide not to grant it. Even though Marzeptacog alfa (activated)—or MarzAA has received Fast Track designation in certain indications, we may not experience a faster development process, review or approval, or receive FDA approval at all, in any of those indications compared to conventional FDA procedures. A Fast Track designation does not change the standards for approval. The FDA may also withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

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 preclinical and manufacturing activities, and Biogen will be solely responsible for funding the preclinical 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

Table of Contents

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 (“GMP”), or good laboratory practices (“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.

Table of Contents

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

We are subject to many manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates and any future products.

To date, our product candidates have been manufactured by third-party manufacturers solely for preclinical studies and relatively small clinical trials. The process of manufacturing MarzAA, DalcA, CB 4332 and our other Complement associated therapeutic product candidates is complex, highly regulated and subject to several risks, including:

- the process of manufacturing biologics is susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error and improper storage conditions. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, the manufacturing facilities may need to be closed for an extended period of time to investigate and eliminate the contamination;
- the manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor and raw material shortages, financial difficulties of our contract manufacturers, including as a result of the evolving effects of the COVID-19 pandemic, natural disasters, power failures, local political unrest and numerous other factors; and
- any adverse developments affecting manufacturing operations or the scale up of manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of our product candidates. We may also have to record inventory write-offs and incur other charges and expenses for product candidates or drug substances that fail to meet specifications, undertake costly remediation efforts or seek costlier manufacturing alternatives.

Specifically, we have entered into various development, manufacturing and clinical supply services agreements with third-party manufacturers for drug substance and drug product manufacturing of MarzAA, DalcA and CB 4332. If any of our third-party manufacturers is not able to provide us with sufficient quantities of (i) MarzAA or DalcA for our clinical trials or (ii) CB 4332 for our preclinical trials on a timely basis, or at all, whether due to production shortages or other supply delays or interruptions resulting from the ongoing COVID-19 pandemic or otherwise, our preclinical trials, clinical trials or regulatory approval, as applicable, may be delayed. Significant portions of our research and development resources are focused on manufacturing. If any of our third-party manufacturers experiences difficulties in scaling production or experiences product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error or improper storage conditions, the potential trials of the affected product candidate would be delayed, perhaps substantially, which could materially and adversely affect our business.

We have minimal process development capabilities and have access only to external manufacturing capabilities. We do not have, and we do not currently plan to acquire or develop, the facilities or capabilities to manufacture bulk drug substance or filled drug product for use in clinical trials or commercialization. Any delay or interruption in the supply of clinical trial material or preclinical trial material could delay the completion of clinical trials or preclinical trials, increase the costs associated with maintaining such trial programs and, depending upon the period of delay, require us to commence new clinical trials or preclinical trials at additional expense or terminate the trials completely.

Table of Contents

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

All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including any contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with GMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a BLA on a timely basis and must adhere to the FDA's 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 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 rely on third parties such as contract research organizations ("CROs"), medical institutions and clinical investigators to enroll qualified patients and conduct, supervise and monitor clinical trials. Our reliance on these

Table of Contents

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, 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

[Table of Contents](#)

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 (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.

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

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

Risks related to our intellectual property

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

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

Table of Contents

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.

Table of Contents

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 also aware of additional patents that have been issued in the United States and Europe that have claims related to Factor VII. We do not believe that MarzAA does or will infringe any valid claims in such patents.

We are aware of a patent family that includes issued patents in the United States, Australia, Israel, Malaysia, New Zealand 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 ("IRB");

Table of Contents

- 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;

Table of Contents

- 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 ("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

Table of Contents

Technology for Economic and Clinical Health Act (“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”)

[Table of Contents](#)

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.

We are subject to evolving privacy and data protection laws, including HIPAA and the EU General Data Protection Regulation (“GDPR”). If we fail to protect personal information or comply with existing or future data protection regulations, our business, financial condition, results of operations and prospects may be materially adversely affected.

Numerous state and federal laws and regulations govern the collection, dissemination, use, privacy, confidentiality, security, availability, integrity, and other processing of personal information. HIPAA establishes a set of national privacy and security standards for the protection of protected health information (as defined in HIPAA) (“PHI”) by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities, and the business associates with whom such covered entities contract for services. HIPAA requires covered entities and business associates, such as us, to develop and maintain policies with respect to the protection of, use and disclosure of electronic PHI, including the adoption of administrative, physical and technical safeguards to protect such information, and certain notification requirements in the event of a data breach.

Table of Contents

By virtue of our clinical trial activities in Europe, we are also subject to European data protection laws, including the GDPR (as implemented in the European Economic Area (the “EEA”) and the United Kingdom). The GDPR which came into effect on May 25, 2018, establishes stringent requirements applicable to the processing of personal data (*i.e.*, data which identifies an individual or from which an individual is identifiable), affords various data protection rights to individuals (e.g., the right to erasure of personal data) and imposes potential penalties for serious breaches of up to 4.0% annual worldwide turnover or €20 million, whichever is greater. Individuals (*e.g.*, study subjects) also have a right to compensation for financial or non-financial losses (*e.g.*, distress). There may be circumstances under which a failure to comply with the GDPR, or the exercise of individual rights under the GDPR, would limit our ability to utilize clinical trial data collected on study subjects. The GDPR imposes additional responsibility and liability in relation to our processing of personal data. This may be onerous and materially adversely affect our business, financial condition, results of operations and prospects. The GDPR also prohibits the international transfer of personal data from the EEA/UK to countries outside of the EEA/United Kingdom unless made to a country deemed to have adequate data privacy laws by the European Commission or a data transfer mechanism has been put in place.

In addition, the interpretation and application of consumer, health-related and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business.

In addition, we are subject to various U.S. state laws which may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply.

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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, an intravenous recombinant Factor VIIa indicated for treatment of bleeding episodes that has been approved for use in treatment of (i) hemophilia A or B individuals with inhibitors to Factor VIII or Factor IX and in individuals with Factor VII deficiency and Glanzmann's thrombasthenia but not for prophylaxis and (ii) peri-operative management in adults with Acquired Hemophilia; HEMA Biologics, which has developed SEVENFACT, 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; Takeda's FEIBA, 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 inhibitors; Roche, which is marketing Hemlibra (emicizumab-kxwh), 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; several companies including Novo Nordisk, Pfizer and Genzyme are developing SQ agents for the treatment of Hemophilia A or B with or without inhibitors or Hemophilia with inhibitors using a variety of technologies. 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

[Table of Contents](#)

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. Although there are no currently approved treatments for dry AMD, several companies are developing cyclic peptide, aptamer, antibody or gene therapy based anti-complement product candidates 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; Iveric Bio (formerly Ophthotech) is developing two therapies to treat GA secondary to dry AMD, iveric Bio completed its Phase 2b clinical of Zimura® (avacincaptad pegol) with positive data in patients with dry AMD; Gemini Therapeutics is developing "GEM103" a recombinant human complement factor H ("FH") for patients with genetically well-defined dry AMD and "GEM104," a recombinant human complement factor I as well as additional molecules in preclinical development for other genetically defined subpopulations of patients with dry AMD and Gyroscope Therapeutics is developing "GT005" a gene therapeutic approach to expressing additional CFI in the patient's eye after subretinal delivery. In addition, there are currently no approved agents specifically targeting systemic factor I deficiency patients irrespective of the resultant disease phenotype being aHUS, C3G, IC-MPGN, invasive infections or any other or any approved therapies for C3G and IC-MPGN. However, there are less specific treatment options on the market or in clinical development which may be applicable to some disease manifestations of systemic CFI deficiency, for instance aHUS and C3G. These treatment options include: eculizumab and ravulizumab marketed by Alexion Pharmaceuticals (to be acquired by AstraZeneca) for use in aHUS irrespective of the patients' CFI status; APL-2 (pegcetacoplan), a pegylated peptide based C3 inhibitor, in IgA Nephropathy ("IgAN"), LN, Membranous Nephropathy ("MN"), C3G, and Dense Deposit Disease which is in clinical development by Apellis; CCX168 (avacopan), a twice daily oral small molecule inhibitor of the complement 5a receptor ("C5aR") in C3G—currently in phase 2 being developed by ChemoCentryx; iptacopan ("LNP023"), a small peptide complement factor B inhibitor which is currently in development by Novartis for PNH, C3G and several other rare renal diseases including IgAN, aHUS, and membranous nephropathy; and Omeros has initiated clinical activities in igAN, LN, MN, & C3G and a phase 3 clinical program in aHUS with OMS721 ("narsoplimab"), a human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 ("MASP-2"), the effector enzyme of the lectin pathway of the complement system.

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.

Table of Contents

Although we believe that MarzAA could be a SQ rescue therapy for hemophilia A (congenital factor VIII deficiency) patients with inhibitors experiencing breakthrough bleeds while on prophylaxis with other agents such as Hemlibra, nevertheless, branded products such as Hemlibra, present a potentially significant competitive risk to the wide-spread use of MarzAA, due to bleeding prophylaxis with Hemlibra requiring less frequent administration while decreasing the risk of breakthrough bleeds. Consequently, MarzAA, if approved, may compete with existing drugs such as Hemlibra, NovoSeven RT, and other therapies, and to the extent it is ultimately used in combination with or as an adjunct to these therapies, MarzAA may not be competitive. The FDA first approved Hemlibra in 2017 for patients with hemophilia A with factor VIII (“FVIII”) inhibitors and in 2018, the FDA approved Hemlibra for prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A with or without FVIII inhibitors. As a result, obtaining market acceptance of, and gaining significant market share for MarzAA may pose challenges.

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.

Table of Contents

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

Table of Contents

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 an effective registration statement on Form S-3 that enables us to sell up to \$140.0 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 2,264,141 shares of common stock at a weighted average exercise price of \$8.84 as of September 30, 2020. 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.

Table of Contents

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.

[Table of Contents](#)

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, as amended (the “Exchange Act”), 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.

Risks related to this offering

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management has broad discretion in the application of the net proceeds from this offering, and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Our management could spend the net proceeds from this offering in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

If you purchase shares of common stock sold in this offering you will experience immediate and substantial dilution in your investment. You will experience further dilution if we issue additional equity securities in the future.

Since the price per share of our common stock being offered is higher than the net tangible book value per share of our common stock, you will suffer dilution with respect to the net tangible book value of the shares of common stock you purchase in this offering. Based on a public offering price of \$5.75 per share and our net tangible book value as of September 30, 2020, if you purchase shares of common stock in this offering, you will suffer immediate dilution of \$1.23 per share with respect to the net tangible book value of the common stock. Furthermore, if outstanding options or warrants are exercised, you could experience further dilution. See “Dilution” for a more detailed discussion of the dilution you will incur if you purchase shares of common stock in this offering.

Future sales of our common stock in the public market could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock and make it more difficult for you to sell your common stock at a time and price that you deem appropriate.

We may raise money through additional public or private offerings of our equity securities or equity-linked securities. Any sales of our equity or equity-linked securities could have a material adverse effect on the market price of our common stock.

In connection with this offering, we and our directors and executive officers have entered into lock-up agreements for a period of 90 days following this offering. The lock-up agreements are subject to various exceptions, and we and our directors and executive officers may be released from the lock-up agreements prior to the expiration of the lock-up period at the sole discretion of the representative. See “Underwriting.” Upon

[Table of Contents](#)

expiration or earlier release of the lock-up agreements, we and our directors and executive officers may sell shares into the market, which could adversely affect the market price of shares of our common stock.

We have registered under the Securities Act of 1933, as amended (the “Securities Act”) shares of common stock that we may issue under our equity compensation plans. In addition, we have a significant number of stock options outstanding, and may also choose to issue additional common stock, or securities convertible into or exchangeable for common stock, in the future in connection with a financing, an acquisition, a litigation settlement, employee arrangements or otherwise. In the event that the outstanding options are exercised, or that we make additional issuances of common stock or other convertible or exchangeable securities, you could experience additional dilution. Furthermore, we cannot assure you that we will be able to issue shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in this offering, and investors purchasing our securities in the future may have rights superior to investors purchasing shares in this offering.

We do not anticipate paying dividends on our common stock in the foreseeable future.

We currently plan to invest all available funds, including the proceeds from this offering and future earnings, if any, in the development and growth of our business. We currently do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, a rise in the market price of our common stock, which is uncertain and unpredictable, will be your sole source of potential gain in the foreseeable future, and you should not rely on an investment in our common stock for dividend income.

CAUTIONARY NOTE REGARDING FORWARD LOOKING INFORMATION

This prospectus supplement, the accompanying prospectus, and documents incorporated by reference herein and therein contain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve a number of risks and uncertainties. We caution readers that any forward-looking statement is not a guarantee of future performance and that actual results could differ materially from those contained in the forward-looking statement. These statements are based on current expectations of future events. Such statements include, but are not limited to, statements about future financial and operating results, plans, objectives, expectations and intentions, costs and expenses, outcome of contingencies, financial condition, results of operations, liquidity, objectives of management, business strategies, financing, the timing, plans and expected results of our current and future clinical trials, the extent to which we will be able to advance development of our product candidates using the proceeds of this offering together with our existing cash resources; our focus on specific product candidates, the progress, outcomes, scope or duration of the development of product candidates or programs, the benefits that may be derived from product candidates or the commercial or market opportunity in any target indication, the progress of our third-party collaborations, including estimated milestones, the advancement of our technologies and our product candidates, approvals and commercialization of product candidates, the impacts of the COVID-19 pandemic and other statements that are not historical facts. You can find many of these statements by looking for words like “believes,” “expects,” “anticipates,” “estimates,” “may,” “might,” “should,” “will,” “could,” “plan,” “intend,” “project,” “seek” or similar expressions in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein and any free writing prospectus. We intend that such forward-looking statements be subject to the safe harbors created thereby.

These forward-looking statements are based on the current beliefs and expectations of our management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results may differ materially from current expectations and projections. Factors that might cause such a difference include those discussed in the Risk Factors sections of our Annual Report on Form 10-K for the year ended December 31, 2019 and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, as well as those discussed in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein and any free writing prospectus. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date made.

All subsequent written or oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We do not undertake any obligation to release publicly any revisions to these forward-looking statements to reflect events or circumstances after the date of this prospectus supplement or to reflect the occurrence of unanticipated events, except as may be required under applicable U.S. securities laws. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

USE OF PROCEEDS

We expect that the net proceeds of this offering, after deducting underwriting discounts and commissions and estimated offering expenses, will be approximately \$46.7 million, or approximately \$53.7 million if the underwriters exercise their over-allotment option in full.

We intend to use the net proceeds from the sale of the shares of common stock under this prospectus supplement for general corporate purposes including research, development and manufacturing activities in our hemophilia and complement programs, specifically MarzAA (FVIIa), CB 4332 (enhanced complement Factor I) and others, capital expenditures, selling, general and administrative costs, facilities expansion, and to meet working capital

[Table of Contents](#)

needs. We expect from time to time to evaluate the acquisition of businesses, products and technologies for which a portion of the net proceeds may be used, although we currently are not planning or negotiating any such transactions.

As of the date of this prospectus supplement, we cannot specify with certainty all of the particular uses of the proceeds from this offering. The amounts and timing of our actual expenditures will depend on numerous factors, including the progress of our clinical trials and other development efforts and other factors described under “Risk factors” in this prospectus supplement and the documents incorporated by reference herein. As a result, our management will have broad discretion over the uses of the net proceeds, if any, we receive in connection with securities offered pursuant to this prospectus supplement. Investors will be relying on the judgment of our management regarding the application of the proceeds, and will not have the opportunity to evaluate the economic, financial or other information on which we base our decisions on how to use the proceeds from this offering. Pending these uses, we intend to invest the net proceeds in short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or guaranteed obligations of the U.S. government.

DIVIDEND POLICY

We have never paid cash dividends on our common stock and we do not anticipate paying cash dividends in the foreseeable future, but intend to retain our capital resources for reinvestment in our business. Any future determination to pay cash dividends on our common stock will be at the discretion of our Board of Directors and will be dependent upon our financial condition, results of operations, capital requirements and other factors as the Board of Directors deems relevant.

DILUTION

If you invest in our common stock, your interest will be diluted immediately to the extent of the difference between the public offering price per share of our common stock and the as adjusted net tangible book value per share of common stock after this offering.

Our net tangible book value as of September 30, 2020 was approximately \$92.5 million, or approximately \$4.19 per share. Net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the number of shares of our common stock outstanding as of September 30, 2020.

After giving effect to our sale of shares of our common stock in this offering at the public offering price of \$5.75 per share, and after deducting the underwriting discount and commissions and the estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2020 would have been approximately \$139.2 million, or \$4.52 per share of common stock. This represents an immediate increase in net tangible book value of \$0.33 per share to existing stockholders and an immediate dilution in net tangible book value of \$1.23 per share to investors participating in this offering. The following table illustrates this dilution on a per share basis:

Public offering price per share of common stock	\$5.75
Net tangible book value per share as of September 30, 2020	\$4.19
Increase in net tangible book value per share attributable to investors in this offering	0.33
As adjusted net tangible book value per share as of September 30, 2020 after giving effect to the offering	4.52
Dilution in net tangible book value per share to new investors	<u>\$1.23</u>

If the underwriters exercise in full their option to purchase 1,305,000 additional shares of common stock at the public offering price of \$5.75 per share, the as adjusted net tangible book value after this offering would be approximately \$4.56 per share, representing an increase in net tangible book value of approximately \$0.37 per share to existing stockholders and immediate dilution in net tangible book value of approximately \$1.19 per share to investors participating in this offering at the public offering price.

The above discussion and table are based on 22,082,924 shares of common stock outstanding as of September 30, 2020, and excludes as of such date:

- 2,264,141 shares of common stock issuable upon exercise of options outstanding as of September 30, 2020, with a weighted average exercise price of \$8.841 per share;
- 83,000 shares of common stock issuable upon exercise of options granted after September 30, 2020, with a weighted average exercise price of \$5.946 per share;
- 722 shares of common stock issuable upon exercise of warrants outstanding as of September 30, 2020, with a weighted average exercise price of \$90.26 per share; and
- 1,674,278 shares of common stock reserved and available for future issuance as of September 30, 2020, under our equity incentive plans, consisting of (1) 1,373,834 shares of common stock reserved and available for issuance under our 2018 Omnibus Incentive Plan as of September 30, 2020, and (2) 1,373,834 shares of common stock reserved for issuance under our 2018 Employee Stock Purchase Plan as of September 30, 2020; and
- 1,275,938 additional shares of common stock reserved and available for future issuance after September 30, 2020 under our 2018 Omnibus Incentive Plan.

To the extent that outstanding options have been or may be exercised or other shares are issued, investors purchasing our common stock in this offering may experience further dilution. In addition, we may choose to issue additional common stock, or securities convertible into or exchangeable for common stock, in the future. The issuance of these securities could result in further dilution for investors purchasing our common stock in this offering.

UNDERWRITING

We have entered into an underwriting agreement, dated as of the date of this prospectus supplement, with respect to the shares being offered. Piper Sandler & Co. (“Piper Sandler”), is acting as the sole lead active bookrunner and as representative of the underwriters. The underwriting agreement provides for the purchase of a specific number of shares of common stock by each of the underwriters. The underwriters’ obligations are several, which means that each underwriter is required to purchase a specified number of shares of common stock, but is not responsible for the commitment of any other underwriter to purchase shares of common stock. Subject to the terms and conditions of the underwriting agreement, each underwriter has severally agreed to purchase the number of shares of common stock set forth opposite its name below:

<u>Underwriters</u>	<u>Number of Shares</u>
Piper Sandler & Co.	6,090,000
Raymond James & Associates, Inc.	2,610,000
Total	8,700,000

The underwriters have agreed to purchase all of the shares of common stock offered by this prospectus supplement (other than those covered by the over-allotment option described below), if any are purchased.

The shares of common stock offered hereby should be ready for delivery on or about January 29, 2021 against payment in immediately available funds.

The underwriters are offering the shares of common stock subject to various conditions (including approval of legal matters by the representatives’ legal counsel and other conditions specified in the underwriting agreement) and may reject all or part of any order. The representatives of the underwriters have advised us that the underwriters propose to offer the common stock directly to the public at the applicable public offering price that appears on the cover page of this prospectus supplement. In addition, the underwriters may offer some of the securities to other securities dealers at such price less a concession of up to \$0.207 per share of common stock. After the shares of common stock are released for sale to the public, the representatives may change the offering price and other selling terms at various times.

We have granted the underwriters the right to purchase up to an aggregate of 1,305,000 additional shares of our common stock. The underwriters may exercise this right, in whole or in part, at any time within 30 days following the date of this prospectus supplement. If the underwriters exercise the option in full, the total underwriting discount payable by us will be \$3,451,725, and the total proceeds to us, before expenses, will be \$54,077,025.

The following table provides information regarding the amount of the discounts and commissions to be paid to the underwriters by us, before expenses:

<u>Underwriters</u>	<u>Per Share</u>		<u>Total</u>	
	<u>Without Option</u>	<u>With Option</u>	<u>Without Option</u>	<u>With Option</u>
Public offering price of common stock	\$ 5.75	\$ 5.75	\$ 50,025,000.00	\$ 57,528,750.00
Underwriting discounts and commissions	\$ 0.345	\$ 0.345	\$ 3,001,500.00	\$ 3,451,725.00
Proceeds before expenses, to us	\$ 5.405	\$ 5.405	\$ 47,023,500.00	\$ 54,077,025.00

We estimate that our total expenses of the offering, excluding underwriting discounts and commissions, will be approximately \$367,000, which includes up to \$150,000 that we have agreed to reimburse the underwriters for the fees and expenses incurred by them in connection with the offering.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act.

Table of Contents

We and our officers and directors have agreed to a 90-day “lock-up” with respect to shares of our common stock and other of our securities that they beneficially own, including securities that are convertible into shares of common stock and securities that are exchangeable or exercisable for shares of common stock. This means that, subject to certain exceptions, for a period of 90 days following the date of this prospectus supplement, we and such persons may not offer, sell, pledge or otherwise dispose of these securities without the prior written consent of Piper Sandler.

Rules of the SEC may limit the ability of the underwriters to bid for or purchase shares before the distribution of the shares is completed. However, the underwriters may engage in the following activities in accordance with the rules:

- Stabilizing transactions — The underwriters may make bids or purchases for the purpose of pegging, fixing or maintaining the price of the shares, so long as stabilizing bids do not exceed a specified maximum.
- Over-allotments and syndicate covering transactions — The underwriters may sell more shares of our common stock in connection with this offering than the number of shares that they have committed to purchase. This over-allotment creates a short position for the underwriters. This short sales position may involve either “covered” short sales or “naked” short sales. Covered short sales are short sales made in an amount not greater than the underwriters’ over-allotment option to purchase additional shares in this offering described above. The underwriters may close out any covered short position either by exercising its over-allotment option or by purchasing shares in the open market. To determine how they will close the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market, as compared to the price at which they may purchase shares through the over-allotment option. Naked short sales are short sales in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that, in the open market after pricing, there may be downward pressure on the price of the shares that could adversely affect investors who purchase shares in this offering.
- Penalty bids — If the representatives purchase shares in the open market in a stabilizing transaction or syndicate covering transaction, they may reclaim a selling concession from the underwriters and selling group members who sold those shares as part of this offering.
- Passive market making — Market makers in the shares who are underwriters or prospective underwriters may make bids for or purchases of shares, subject to limitations, until the time, if ever, at which a stabilizing bid is made.

Similar to other purchase transactions, the underwriters’ purchases to cover the syndicate short sales or to stabilize the market price of our common stock may have the effect of raising or maintaining the market price of our common stock or preventing or mitigating a decline in the market price of our common stock. As a result, the price of the shares of our common stock may be higher than the price that might otherwise exist in the open market. The imposition of a penalty bid might also have an effect on the price of the shares if it discourages resales of the shares.

Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may occur on the Nasdaq Capital Market or otherwise. If such transactions are commenced, they may be discontinued without notice at any time.

Electronic Delivery of Prospectus Supplement: A prospectus supplement in electronic format may be delivered to potential investors by one or more of the underwriters participating in this offering. The prospectus supplement

Table of Contents

in electronic format will be identical to the paper version of such preliminary prospectus supplement. Other than the prospectus supplement in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of this prospectus supplement, the accompanying prospectus or the registration statement of which this prospectus supplement and the accompanying prospectus form a part.

From time to time in the ordinary course of its businesses, one or more of the representatives and certain affiliates have engaged, and may in the future engage, in commercial banking or investment banking transactions with us and our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions. In the ordinary course of its various business activities, they may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve our securities and/or instruments. They may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

NOTICE TO NON-U.S. INVESTORS

Investors are advised to contact their legal, financial or tax advisers to obtain an independent assessment of the financial and tax consequences of an investment in the shares being sold in this offering.

European Economic Area. In relation to each Member State of the European Economic Area which has implemented the Prospectus Regulation (each, a "Relevant Member State") an offer to the public of any shares of our common stock may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any shares of our common stock may be made at any time under the following exemptions under the Prospectus Regulation, if they have been implemented in that Relevant Member State:

- (a) to any legal entity which is a qualified investor as defined in the Prospectus Regulation;
- (b) to fewer than 150, natural or legal persons (other than qualified investors as defined in the Prospectus Regulation), as permitted under the Prospectus Regulation, subject to obtaining the prior consent of the representatives for any such offer; or
- (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation, provided that no such offer of shares of our common stock shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares of our common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of our common stock to be offered so as to enable an investor to decide to purchase any shares of our common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Regulation in that Member State, the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

United Kingdom. Each underwriter has represented and agreed that:

- (a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 (the "FSMA")) received by it in connection with the issue or sale of the shares of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and

Table of Contents

(b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of our common stock in, from or otherwise involving the United Kingdom.

Canada. The common stock may be sold only to purchasers purchasing as principal that are both “accredited investors” as defined in National Instrument 45-106 Prospectus and Registration Exemptions and “permitted clients” as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the common stock must be made in accordance with an exemption from the prospectus requirements and in compliance with the registration requirements of applicable securities laws.

Germany. Each person who is in possession of this prospectus is aware of the fact that no German securities prospectus (wertpapierprospekt) within the meaning of the German Securities Prospectus Act (“Wertpapier-prospektgesetz” or the “Act”) of the Federal Republic of Germany has been or will be published with respect to the shares of our common stock. In particular, each underwriter has represented that it has not engaged and has agreed that it will not engage in a public offering in the Federal Republic of Germany within the meaning of the Act with respect to any of the shares of our common stock otherwise than in accordance with the Act and all other applicable legal and regulatory requirements.

Hong Kong. The common stock may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), or (ii) to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a “prospectus” within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong) and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

Singapore. This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the common stock may not be circulated or distributed, nor may the common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the “SFA”), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to compliance with conditions set forth in the SFA.

Where the common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

Table of Contents

shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the common stock pursuant to an offer made under Section 275 of the SFA except:

- (a) to an institutional investor (for corporations, under Section 274 of the SFA) or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than \$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions specified in Section 275 of the SFA;
- (b) where no consideration is or will be given for the transfer; or
- (c) where the transfer is by operation of law.

Switzerland. The common stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (the "SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the common stock or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, or the common stock have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of common stock will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of common stock has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("CISA"). Accordingly, no public distribution, offering or advertising, as defined in CISA, its implementing ordinances and notices, and no distribution to any non-qualified investor, as defined in CISA, its implementing ordinances and notices, shall be undertaken in or from Switzerland, and the investor protection afforded to acquirers of interests in collective investment schemes under CISA does not extend to acquirers of common stock.

United Arab Emirates. This offering has not been approved or licensed by the Central Bank of the United Arab Emirates (the "UAE"), Securities and Commodities Authority of the UAE and/or any other relevant licensing authority in the UAE including any licensing authority incorporated under the laws and regulations of any of the free zones established and operating in the territory of the UAE, in particular the Dubai Financial Services Authority ("DFSA"), a regulatory authority of the Dubai International Financial Centre ("DIFC"). The offering does not constitute a public offer of securities in the UAE, DIFC and/or any other free zone in accordance with the Commercial Companies Law, Federal Law No 8 of 1984 (as amended), DFSA Offered Securities Rules and NASDAQ Dubai Listing Rules, accordingly, or otherwise. The common stock may not be offered to the public in the UAE and/or any of the free zones.

The common stock may be offered and issued only to a limited number of investors in the UAE or any of its free zones who qualify as sophisticated investors under the relevant laws and regulations of the UAE or the free zone concerned.

France. This prospectus (including any amendment, supplement or replacement thereto) is not being distributed in the context of a public offering in France within the meaning of Article L. 411-1 of the French Monetary and Financial Code (Code monétaire et financier).

This prospectus has not been and will not be submitted to the French Autorité des marchés financiers (the "AMF") for approval in France and accordingly may not and will not be distributed to the public in France.

Table of Contents

Pursuant to Article 211-3 of the AMF General Regulation, French residents are hereby informed that:

1. the transaction does not require a prospectus to be submitted for approval to the AMF;
2. persons or entities referred to in Point 2°, Section II of Article L.411-2 of the Monetary and Financial Code may take part in the transaction solely for their own account, as provided in Articles D. 411-1, D. 734-1, D. 744-1, D. 754-1 and D. 764-1 of the Monetary and Financial Code; and
3. the financial instruments thus acquired cannot be distributed directly or indirectly to the public otherwise than in accordance with Articles L. 411-1, L. 411-2, L. 412-1 and L. 621-8 to L. 621-8-3 of the Monetary and Financial Code.

This prospectus is not to be further distributed or reproduced (in whole or in part) in France by the recipients of this prospectus. This prospectus has been distributed on the understanding that such recipients will only participate in the issue or sale of our common stock for their own account and undertake not to transfer, directly or indirectly, our common stock to the public in France, other than in compliance with all applicable laws and regulations and in particular with Articles L. 411-1 and L. 411-2 of the French Monetary and Financial Code.

LEGAL MATTERS

The validity of the securities being offered by this prospectus will be passed upon by Orrick, Herrington & Sutcliffe LLP, New York, New York. The underwriters are being represented in connection with this offering by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., New York, New York.

EXPERTS

The consolidated balance sheets of Catalyst Biosciences, Inc. 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, have been audited by EisnerAmper LLP, independent registered public accounting firm, as stated in their reports which are incorporated herein by reference, which reports (i) express an unqualified opinion on financial statements which report includes an explanatory paragraph that refers to a change in the method of accounting for leases, and (ii) express an unqualified opinion on the effectiveness of internal control over financial reporting as of December 31, 2019. Such financial statements have been incorporated herein by reference in reliance on the reports of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-3 under the Securities Act with respect to the securities offered hereby. This prospectus supplement, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits filed therewith. For further information about us and the securities offered hereby, reference is made to the accompanying prospectus and registration statement of which it is a part and the exhibits filed therewith. Statements contained in this prospectus supplement regarding the contents of any contract or any other document that is filed as an exhibit to the accompanying prospectus and the registration statement of which it is a part are not necessarily complete, and in each instance we refer you to the copy of such contract or other document filed as an exhibit to the registration statement or the exhibits to the reports or other documents incorporated by reference in this prospectus for a copy of such contract or other document.

Table of Contents

We are subject to the informational requirements of the Exchange Act and are required to file annual, quarterly and other reports, proxy statements and other information with the SEC. The SEC maintains an Internet site (<http://www.sec.gov>) that contains reports, proxy and information statements, and various other information about us. You may also inspect the documents described herein at our principal executive offices, 611 Gateway Blvd., Suite 710, South San Francisco, California 94080, during normal business hours.

Information about us is also available at our website at www.catalystbiosciences.com. However, the information on our website is not a part of this prospectus supplement and is not incorporated by reference into this prospectus supplement.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to “incorporate by reference” the information we file with the SEC, which means we can disclose important information to you by referring you to those documents. The information we incorporate by reference is an important part of this prospectus, and certain information that we will later file with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below as well as any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus until we sell all of the securities under this prospectus, except that we do not incorporate any document or portion of a document that is “furnished” to the SEC, but not deemed “filed.” The following documents filed with the SEC are incorporated by reference in this prospectus:

- our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on [February 20, 2020](#);
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2020, June 30, 2020 and September 30, 2020 filed with the SEC on [May 11, 2020](#), [August 6, 2020](#) and [November 5, 2020](#), respectively;
- our Current Reports on Form 8-K filed with the SEC on [January 17, 2020](#), [January 29, 2020](#), [February 7, 2020 \(Item 8.01\)](#), [February 14, 2020](#), [March 20, 2020](#), [June 16, 2020](#), [June 17, 2020](#), [June 19, 2020](#), [December 2, 2020](#), [January 26, 2021](#) and [January 27, 2021](#); and
- the description of our common stock in our Registration Statement on Form 8-A (Commission File No. 000-51173), filed with the SEC on [April 6, 2006](#), including any subsequent amendment or any report filed for the purpose of updating such description.

We will furnish without charge to you, on written or oral request, a copy of any or all of such documents that has been incorporated herein by reference (other than exhibits to such documents unless such exhibits are specifically incorporated by reference into the documents that this prospectus incorporates). Written or oral requests for copies should be directed Catalyst Biosciences, Inc., Attn: Investor Relations, 611 Gateway Blvd., Suite 710, South San Francisco, California 94080, telephone number (650) 871-0761. See the section of this prospectus supplement entitled “Where You Can Find More Information” for information concerning how to read and obtain copies of materials that we file with the SEC.

Any statement contained in this prospectus supplement, or in a document all or a portion of which is incorporated by reference, shall be modified or superseded for purposes of this prospectus supplement to the extent that a statement contained in this prospectus supplement or any document incorporated by reference modifies or supersedes such statement. Any such statement so modified or superseded shall not, except as so modified or superseded, constitute a part of this prospectus.

PROSPECTUS

\$200,000,000



**Common Stock
Preferred Stock
Debt Securities
Warrants
Units**

From time to time, we may offer and sell, in one or more offerings, in amounts, at prices and on terms determined at the time of any such offering, common stock, preferred stock, debt securities, warrants, either individually or in units, with a total value of up to \$200,000,000. We refer to our common stock, preferred stock, debt securities, warrants and units in this prospectus as “securities.”

Our common stock trades on The Nasdaq Capital Market under the symbol “CBIO.” On December 20, 2018, the last reported sale price of the common stock on The Nasdaq Capital Market was \$7.10 per share.

This prospectus provides you with a general description of the securities we may offer. Each time we offer securities using this prospectus, we will provide the specific terms of the securities and the offering in one or more supplements to this prospectus. We may also authorize one or more free writing prospectuses to be provided to you in connection with these offerings. The prospectus supplement and any related free writing prospectus will also describe the specific manner in which we will offer the securities and may also supplement, update or amend information contained in this prospectus. You should read this prospectus, any accompanying prospectus supplement and any related free writing prospectus carefully before you purchase any of our securities.

We may offer the securities in amounts, at prices and on terms determined at the time of offering. We may sell the securities directly to you, through agents designated from time to time or to or through underwriters or dealers, on a continuous or delayed basis. If we use agents, underwriters or dealers to sell the securities, we will name them and describe their compensation in a prospectus supplement. You can find additional information about our plan of distribution for the securities under the heading “Plan of Distribution” in this prospectus. We will also describe the plan of distribution for any particular offering of these securities in the prospectus supplement. This prospectus may not be used to offer and sell securities unless accompanied by a prospectus supplement.

INVESTING IN OUR SECURITIES INVOLVES A HIGH DEGREE OF RISK. YOU SHOULD CAREFULLY READ AND CONSIDER THE RISKS AND UNCERTAINTIES DESCRIBED IN THIS PROSPECTUS, ANY ACCOMPANYING PROSPECTUS SUPPLEMENT AND ANY RELATED FREE WRITING PROSPECTUS AND IN THE DOCUMENTS INCORPORATED BY REFERENCE INTO THIS PROSPECTUS, ANY ACCOMPANYING PROSPECTUS SUPPLEMENT AND ANY RELATED FREE WRITING PROSPECTUS. SEE “[RISK FACTORS](#)” BEGINNING ON PAGE 5.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is February 14, 2019

TABLE OF CONTENTS

<u>Caption</u>	<u>Page</u>
ABOUT THIS PROSPECTUS	1
OUR COMPANY	2
CAUTIONARY NOTE REGARDING FORWARD-LOOKING INFORMATION	3
RISK FACTORS	5
USE OF PROCEEDS	5
DESCRIPTION OF CAPITAL STOCK	6
ADDITIONAL INFORMATION CONCERNING OUR CAPITAL STOCK	11
DESCRIPTION OF DEBT SECURITIES	14
DESCRIPTION OF WARRANTS	21
DESCRIPTION OF UNITS	23
PLAN OF DISTRIBUTION	25
LEGAL MATTERS	27
EXPERTS	27
WHERE YOU CAN FIND MORE INFORMATION	28

You should rely only on the information contained or incorporated by reference in this prospectus, in any accompanying prospectus supplement or in any related free writing prospectus filed by us with the U.S. Securities and Exchange Commission (the “SEC”). We have not authorized any other person to provide you with different information. If anyone provides you with additional, different or inconsistent information, you should not rely on it. You should not assume that the information appearing in this prospectus, any applicable prospectus supplement, any related free writing prospectus or any documents incorporated by reference herein or therein is accurate as of any date other than the dates of those documents. Our business, financial condition, results of operations and prospects may have changed since those dates. Any information contained on or accessible through our Internet site is not incorporated herein and does not constitute part of this prospectus.

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the U.S. Securities and Exchange Commission, or the SEC, using a “shelf” registration process. Under this shelf registration process, we may, from time to time, issue, offer and sell to the public any part of the securities described in this prospectus, together or separately, in one or more offerings, for a maximum aggregate offering price not to exceed \$200,000,000.

This prospectus provides you with a general description of the securities we may offer. Each time we sell any securities under this prospectus, we will provide a prospectus supplement containing more specific information about the terms of that offering, including the specific amounts, prices and terms of the securities offered. Any such prospectus supplement may include a discussion of risks or other special considerations applicable to us or the securities offered thereby. Any such prospectus supplement may also add, update or change information in this prospectus or in documents incorporated by reference in this prospectus. To the extent that any statement that we make in a prospectus supplement is inconsistent with statements made in this prospectus or in documents incorporated by reference in this prospectus, the statements made or incorporated by reference in this prospectus will be deemed modified or superseded by those made in the prospectus supplement.

This prospectus and any applicable prospectus supplement contain and incorporate by reference market data, industry statistics and other data that have been obtained or compiled from information made available by third parties. These data, to the extent they contain estimates or projections, involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates or projections. Industry publications and other reports we have obtained from independent parties generally state that the data contained in these publications or other reports have been obtained in good faith or from sources considered to be reliable, but they do not guarantee the accuracy or completeness of such data. We urge you to carefully read this prospectus, any applicable prospectus supplement and any related free writing prospectus, any documents that we incorporate by reference in this prospectus, any applicable prospectus supplement and any related free writing prospectus, and the additional information described below under “Where You Can Find More Information” before making an investment decision.

This document may only be used where it is legal to sell these securities. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

THIS PROSPECTUS MAY NOT BE USED TO OFFER AND SELL SECURITIES UNLESS IT IS ACCOMPANIED BY A PROSPECTUS SUPPLEMENT.

For purposes of this prospectus, references to the terms “Catalyst,” the “Company,” “we,” “us” and “our” refer to Catalyst Biosciences, Inc., a Delaware corporation, unless the context otherwise requires.

The registration statement containing this prospectus, including exhibits to the registration statement, provides additional information about us and the securities offered under this prospectus. The registration statement can be read at the SEC’s website or at the SEC offices mentioned under the heading “Where You Can Find More Information.”

OUR COMPANY

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

Additional details of our development or clinical programs and related strategic agreements are contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2018, June 30, 2018 and September 30, 2018.

We commenced operations in 2002 and are a Delaware corporation. Our corporate headquarters are located at South San Francisco, California 94080. Our telephone number is (650) 871-0761, and our website address is www.catalystbiosciences.com. The information on or accessible through our website does not constitute part of this prospectus or any accompanying prospectus supplement and should not be relied upon in connection with making any investment in our securities. Further, our reference to the URL for the website is intended to be an inactive textual reference only. We make our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to these reports available free of charge on our website as soon as reasonably practicable after we file these reports with the SEC. Our Code of Ethics can be found on our website.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING INFORMATION

This prospectus and any accompanying prospectus supplement, as well as the documents we incorporate by reference herein or therein, contains forward-looking statements within the meaning of Section 27A of the Securities Act 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 in this prospectus regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans, intentions and objectives of management are forward-looking statements. We may, in some cases, use words such as “believe,” “anticipate,” “should,” “could,” “intend,” “plan,” “may,” “will,” “seek,” “estimate,” “predict,” “project,” “potentially,” “continue,” “expect” or the negative of these terms or similar expressions, although not all forward-looking statements contain these identifying words. These 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. These forward-looking statements are subject to a number of risks and uncertainties, including those risks described under “Risk Factors” and in other sections in this prospectus and in our current and periodic reports, and other filings, filed from time to time with the SEC that are incorporated by reference into this prospectus, that could cause actual results to differ materially from those anticipated in the forward-looking statements. See “Where You Can Find More Information” below and for information about how to obtain copies of those documents.

Forward-looking statements included or incorporated by reference in this prospectus include, for example, statements about:

- the strategies, prospects, plans, expectations or objectives of management for future operations;
- our focus on specific product candidates;
- the progress, scope or duration of the development of product candidates or programs, clinical trial plans, timelines and potential results;
- 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 and collaborations;
- the responsibilities of our collaborators, including the responsibility to make cost reimbursement, milestone, royalty and other payments to us, and our expectations regarding our collaborators’ plans with respect to our products;
- our responsibilities to our collaborators, including our responsibilities to conduct research and development, clinical trials and manufacture products;
- the results and timing of clinical trials and the possible commencement of future clinical trials;
- conditions for obtaining regulatory approval of our product candidates;
- submission and timing of applications for regulatory approval;
- the impact of the U.S. Food and Drug Administration (FDA) and other government regulations on our business;

[Table of Contents](#)

- 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;
- 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 contemplated by such forward-looking statements. All such forward-looking statements are made only as of the date of the document in which they are contained, based on our management's beliefs and assumptions and information available to us as of the date of that document, and we caution you not to place undue reliance on forward-looking statements in light of the risks and uncertainties associated with them. We undertake no obligation, and disclaim any duty, to update or revise any forward-looking statements in light of future developments. You should also carefully consider other information set forth in reports or other documents that we file with the SEC.

RISK FACTORS

Our business is subject to certain risks and uncertainties. Before you invest in our securities, in addition to the other information, documents or reports incorporated by reference in this prospectus and any prospectus supplement or other offering materials, you should carefully consider the risk factors in this section, the section entitled “Risk Factors” in any prospectus supplement as well as our most recent Annual Report on Form 10-K, and in our Quarterly Reports on Form 10-Q filed subsequent to the Annual Report on Form 10-K, which are incorporated by reference into this prospectus and any prospectus supplement in their entirety, as the same may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future. Each of the risks described in these sections and documents could materially and adversely affect our business, financial condition, results of operations and prospects, and could result in a partial or complete loss of your investment.

USE OF PROCEEDS

Unless otherwise indicated in a prospectus supplement, the net proceeds from the sale of securities offered by this prospectus will be used for general corporate purposes, which may include clinical trials, research and development activities, capital expenditures, selling, general and administrative costs, facilities expansion, and to meet working capital needs. We expect from time to time to evaluate the acquisition of businesses, products and technologies for which a portion of the net proceeds may be used, although we currently are not planning or negotiating any such transactions. Pending such uses, we may invest the net proceeds in investment grade interest-bearing securities.

The amounts actually expended for each purpose may vary significantly depending upon numerous factors, including the amount and timing of the proceeds from this offering and progress with the commercial development of our products as well as our clinical development programs. Expenditures will also depend upon the establishment of collaborative arrangements with other companies, the availability of additional financing and other factors. Investors will be relying on the judgment of our management regarding the application of the proceeds of any sale of securities.

DESCRIPTION OF CAPITAL STOCK

The following description of our common stock and preferred stock, together with the additional information we include in any applicable prospectus supplements, summarizes the material terms and provisions of the common stock and preferred stock that we may offer under this prospectus. It may not contain all the information that is important to you. For the complete terms of our common stock and preferred stock, please refer to our Fourth Amended and Restated Certificate of Incorporation, as amended (the “restated certificate of incorporation”) and our amended and restated bylaws, which are incorporated by reference into the registration statement which includes this prospectus. The Delaware General Corporation Law (“DGCL”) may also affect the terms of these securities. While the terms we have summarized below will apply generally to any future common stock and preferred stock that we may offer, we will describe the particular terms of these securities in more detail in the applicable prospectus supplement. If we so indicate in a prospectus supplement, the terms of any security we offer under that prospectus supplement may differ from the terms we describe below.

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 20, 2018, 11,947,738 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.

[Table of Contents](#)

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.

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 20, 2018, the Company 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.

The preferred stock will have the terms described below unless otherwise provided in the prospectus supplement relating to a particular series of the preferred stock. You should read the prospectus supplement relating to the particular series of the preferred stock being offered for specific terms, including:

- the designation and stated value per share of the preferred stock and the number of shares offered;
- the amount of liquidation preference per share;
- the price at which the preferred stock will be issued;
- the dividend rate, or method of calculation of any dividend, the dates on which dividends will be payable, whether dividends will be cumulative or noncumulative and, if cumulative, the dates from which dividends will accumulate;
- any redemption or sinking fund provisions;
- if other than the currency of the United States, the currency or currencies, including composite currencies, in which the preferred stock is denominated and/or in which payments will or may be payable;
- any conversion provisions; and
- any other rights, preferences, privileges, qualifications, limitations and restrictions on the preferred stock.

The preferred stock will, when issued, be duly authorized, fully paid and nonassessable. Unless otherwise specified in the prospectus supplement, each series of the preferred stock will rank equally as to dividends and liquidation rights in all respects with any other series of preferred stock. The rights of holders of shares of each series of preferred stock will be subordinate to those of our general creditors.

Rank. Unless otherwise specified in the prospectus supplement, the preferred stock will, with respect to dividend rights and rights upon our liquidation, dissolution or winding up of our affairs, rank:

- senior to all classes or series of our common stock and to all equity securities ranking junior to such preferred stock with respect to dividend rights or rights upon our liquidation, dissolution or winding up of our affairs;

Table of Contents

- on a parity with all equity securities issued by us, the terms of which specifically provide that such equity securities rank on a parity with the preferred stock with respect to dividend rights or rights upon our liquidation, dissolution or winding up of our affairs; and
- junior to all equity securities issued by us, the terms of which specifically provide that such equity securities rank senior to the preferred stock with respect to dividend rights or rights upon our liquidation, dissolution or winding up of our affairs.

The term “equity securities” does not include convertible debt securities.

Dividends. Holders of the preferred stock of each series will be entitled to receive, when, as and if declared by our board of directors, cash dividends at such rates and on such dates described in the prospectus supplement. Different series of preferred stock may be entitled to dividends at different rates or based on different methods of calculation. The dividend rate may be fixed or variable or both. Dividends will be payable to the holders of record as they appear on our stock books on record dates fixed by our board of directors, as specified in the applicable prospectus supplement.

Dividends on any series of the preferred stock may be cumulative or noncumulative, as described in the applicable prospectus supplement. If our board of directors does not declare a dividend payable on a dividend payment date on any series of noncumulative preferred stock, then the holders of that noncumulative preferred stock will have no right to receive a dividend for that dividend payment date, and we will have no obligation to pay the dividend accrued for that period, whether or not dividends on that series are declared payable on any future dividend payment dates. Dividends on any series of cumulative preferred stock will accrue from the date we initially issue shares of such series or such other date specified in the applicable prospectus supplement.

Liquidation Preference. Upon any voluntary or involuntary liquidation, dissolution or winding up of our affairs, before we make any distribution or payment to the holders of any common stock or any other class or series of our capital stock ranking junior to the preferred stock in the distribution of assets upon any liquidation, dissolution or winding up of our affairs, the holders of each series of preferred stock shall be entitled to receive out of assets legally available for distribution to stockholders, liquidating distributions in the amount of the liquidation preference per share set forth in the applicable prospectus supplement, plus any accrued and unpaid dividends thereon. Such dividends will not include any accumulation in respect of unpaid noncumulative dividends for prior dividend periods. Unless otherwise specified in the prospectus supplement, after payment of the full amount of their liquidating distributions, the holders of preferred stock will have no right or claim to any of our remaining assets. Upon any such voluntary or involuntary liquidation, dissolution or winding up, if our available assets are insufficient to pay the amount of the liquidating distributions on all outstanding preferred stock and the corresponding amounts payable on all other classes or series of our capital stock ranking on parity with the preferred stock and all other such classes or series of shares of capital stock ranking on parity with the preferred stock in the distribution of assets, then the holders of the preferred stock and all other such classes or series of capital stock will share ratably in any such distribution of assets in proportion to the full liquidating distributions to which they would otherwise be entitled.

Redemption. If so provided in the applicable prospectus supplement, the preferred stock will be subject to mandatory redemption or redemption at our option, as a whole or in part, in each case upon the terms, at the times and at the redemption prices set forth in such prospectus supplement.

Voting Rights. Holders of preferred stock will have voting rights as required by law or as indicated in the applicable prospectus supplement.

Conversion Rights. The terms and conditions, if any, upon which any series of preferred stock is convertible into common stock will be set forth in the applicable prospectus supplement relating thereto. Such terms will include the number of shares of common stock into which the shares of preferred stock are convertible, the conversion

[Table of Contents](#)

price, rate or manner of calculation thereof, the conversion period, provisions as to whether conversion will be at our option or at the option of the holders of the preferred stock, the events requiring an adjustment of the conversion price and provisions affecting conversion in the event of the redemption.

Transfer Agent and Registrar. Any transfer agent and registrar for the preferred stock will be set forth in the applicable prospectus supplement.

Series A Convertible Preferred Stock

As of December 20, 2018, the Company had no shares of preferred stock issued and outstanding.

Liquidation Preference. In the event of a liquidation, the holders of Series A Convertible Preferred Stock will be entitled to participate on an as-converted-to-common-stock basis with holders of the common stock in any distribution of assets of the Company to the holders of the common stock.

Dividends. The Series A Certificate of Designation provides, among other things, that we shall not pay any dividends on shares of common stock (other than dividends in the form of common stock) unless and until such time as we pay dividends on each share of Series A Convertible Preferred Stock on an as-converted basis. Other than as set forth in the previous sentence, the Series A Certificate of Designation provides that no other dividends shall be paid on shares of Series A Convertible Preferred Stock and that we shall pay no dividends (other than dividends in the form of common stock) on shares of common stock unless we simultaneously comply with the previous sentence. The Series A Certificate of Designation does not provide for any restriction on the repurchase of Series A Convertible Preferred Stock by us while there is any arrearage in the payment of dividends on the Series A Convertible Preferred Stock. There are no sinking fund provisions applicable to the Series A Convertible Preferred Stock.

Voting Rights. With certain exceptions, as described in the Series A Certificate of Designation, the Series A Convertible Preferred Stock has no voting rights. However, as long as any shares of Series A Convertible Preferred Stock remain outstanding, the Series A Certificate of Designation provides that we shall not, without the affirmative vote of holders of a majority of the then-outstanding shares of Series A Convertible Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series A Convertible Preferred Stock or alter or amend the Series A Certificate of Designation, (b) increase the number of authorized shares of Series A Convertible Preferred Stock or (c) effect a stock split or reverse stock split of the Series A Convertible Preferred Stock or any like event.

Conversion. Each share of Series A Convertible Preferred Stock is convertible at any time at the holder's option into a number of shares of Common Stock equal to \$1,000.00 per share divided by the Conversion Price. The "Conversion Price" is initially \$5.00, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions as specified in the Certificate of Designation. Notwithstanding the foregoing, the Series A Certificate of Designation provides further that we shall not effect any conversion of the Series A Convertible Preferred Stock, with certain exceptions, to the extent that, after giving effect to an attempted conversion, the holder of Series A Convertible Preferred Stock (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of Common Stock in excess of 4.99% (or, at the election of the purchaser, 9.99%) of the shares of our common stock then outstanding after giving effect to such exercise (the "Preferred Stock Beneficial Ownership Limitation").

Call Right. Additionally, subject to certain exceptions, at any time prior to the three year anniversary of the issuance of the Series A Convertible Preferred Stock, subject to the Preferred Stock Beneficial Ownership Limitation, we will have the right to cause each holder of the Series A Convertible Preferred Stock to convert all or part of such holder's Series A Convertible Preferred Stock in the event that (i) the volume weighted average price of our common stock for 30 consecutive trading days (the "Measurement Period") exceeds 300% of the

[Table of Contents](#)

conversion price of the Series A Convertible Preferred Stock issued (subject to adjustment for forward and reverse stock splits, recapitalizations, stock dividends and similar transactions), (ii) the average daily trading volume for such Measurement Period exceeds \$500,000 per trading day and (iii) the holder is not in possession of any information that constitutes or might constitute, material non-public information which was provided by the Company and subject to the Preferred Beneficial Ownership Limitation. Our right to cause each holder of the Series A Convertible Preferred Stock to convert all or part of such holder's Series A Convertible Preferred Stock shall be exercised ratably among the holders of the then outstanding Series A Convertible Preferred Stock.

Listing. We have not applied for listing of the Series A Convertible Preferred Stock on any securities exchange or other trading system.

Transfer Agent. The transfer agent for our Series A Convertible Preferred Stock is American Stock Transfer & Trust Company, LLC.

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.

ADDITIONAL INFORMATION CONCERNING OUR CAPITAL STOCK

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 Catalyst 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 amended and restated 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. The amended and restated 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 amended and restated 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;

Table of Contents

- 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

[Table of Contents](#)

plan or other enterprise, against the expenses, liabilities or other matters referred to in or covered by Section 145 of the DGCL. Our amended and restated 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 have 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.

DESCRIPTION OF DEBT SECURITIES

The following description, together with the additional information we include in any applicable prospectus supplements, summarizes the material terms and provisions of the debt securities that we may offer under this prospectus. While the terms we have summarized below will apply generally to any future debt securities we may offer under this prospectus, we will describe the particular terms of any debt securities that we may offer in more detail in the applicable prospectus supplement. The terms of any debt securities we offer under a prospectus supplement may differ from the terms we describe below.

The following summary description, together with the additional information we may include in any applicable prospectus supplements does not purport to be complete and is subject to, and qualified in its entirety by reference to, the form of indenture filed as an exhibit to the registration statement of which this prospectus is part, as it may be supplemented, amended or modified from time to time, as well as the notes and supplemental agreements relating to each series of debt securities that will be incorporated by reference as exhibits to the registration statement that includes this prospectus or as exhibits to a current report on Form 8-K if we offer debt securities.

We will issue senior debt securities under one or more senior indentures that we will enter into with a trustee named in the relevant senior indenture. We will issue subordinated debt securities under one or more subordinated indentures that we will enter into with a trustee named in the relevant subordinated indenture. We have filed a form of indenture as an exhibit to the registration statement of which this prospectus is a part. We use the terms “indenture” and “indentures” in this prospectus to refer to both the senior indenture and the subordinated indenture.

The indentures will be qualified under the Trust Indenture Act of 1939, as amended. We use the term “debenture trustee” to refer to either the trustee under the senior indenture or the trustee under the subordinated indenture, as applicable.

The following summaries of material provisions of the senior debt securities, the subordinated debt securities and the indentures are subject to, and qualified in their entirety by reference to, all the provisions of the indenture applicable to a particular series of debt securities. We urge you to read the applicable prospectus supplements related to the debt securities that we sell under this prospectus, as well as the indenture that would contain the terms of the debt securities. Except as we may otherwise indicate, the terms of the senior indenture and the subordinated indenture would be identical.

General

We will describe in each prospectus supplement the following terms relating to a series of debt securities:

- the title;
- the principal amount being offered, and if a series, the total amount authorized and the total amount outstanding;
- any limit on the amount that may be issued;
- whether or not we will issue the series of debt securities in global form, the terms and who the depository will be;
- the maturity date;
- whether and under what circumstances, if any, we will pay additional amounts on any debt securities held by a person who is not a U.S. person for tax purposes, and whether we can redeem the debt securities if we have to pay such additional amounts;

Table of Contents

- the annual interest rate, which may be fixed or variable, or the method for determining the rate and the date interest will begin to accrue, the dates interest will be payable and the regular record dates for interest payment dates or the method for determining such dates;
- whether or not the debt securities will be secured or unsecured, and the terms of any secured debt;
- the terms of the subordination of any series of subordinated debt;
- the place where payments will be payable;
- restrictions on transfer, sale or other assignment, if any;
- our right, if any, to defer payment of interest and the maximum length of any such deferral period;
- the date, if any, after which, and the price at which, we may, at our option, redeem the series of debt securities pursuant to any optional or provisional redemption provisions and the terms of those redemptions provisions;
- the date, if any, on which, and the price at which we are obligated, pursuant to any mandatory sinking fund or analogous fund provisions or otherwise, to redeem, or at the holder's option to purchase, the series of debt securities and the currency or currency unit in which the debt securities are payable;
- whether the indenture will restrict our ability and/or the ability of our subsidiaries to:
 - incur additional indebtedness;
 - issue additional securities;
 - create liens;
 - pay dividends and make distributions in respect of our capital stock and the capital stock of our subsidiaries;
 - redeem capital stock;
 - place restrictions on our subsidiaries' ability to pay dividends, make distributions or transfer assets;
 - make investments or other restricted payments;
 - sell or otherwise dispose of assets;
 - enter into sale-leaseback transactions;
 - engage in transactions with stockholders and affiliates;
 - issue or sell stock of our subsidiaries; or
 - effect a consolidation or merger;
- whether the indenture will require us to maintain any interest coverage, fixed charge, cash flow-based, asset-based or other financial ratios;
- a discussion of any material or special U.S. federal income tax considerations applicable to the debt securities;
- information describing any book-entry features;
- provisions for a sinking fund purchase or other analogous fund, if any;
- whether the debt securities are to be offered at a price such that they will be deemed to be offered at an "original issue discount" as defined in paragraph (a) of Section 1273 of the Internal Revenue Code;
- the denominations in which we will issue the series of debt securities, if other than denominations of \$1,000 and any integral multiple thereof; and

[Table of Contents](#)

- any other specific terms, preferences, rights or limitations of, or restrictions on, the debt securities, including any additional events of default or covenants provided with respect to the debt securities, and any terms that may be required by us or advisable under applicable laws or regulations.

Conversion or Exchange Rights

We will set forth in the prospectus supplement the terms on which a series of debt securities may be convertible into or exchangeable for our common stock or our other securities. We will include provisions as to whether conversion or exchange is mandatory, at the option of the holder or at our option. We may include provisions pursuant to which the number of shares of our common stock or our other securities that the holders of the series of debt securities receive would be subject to adjustment.

Consolidation, Merger or Sale

Any successor to or acquiror of the indentures must assume all of our obligations under the indentures or the debt securities, as appropriate. If the debt securities are convertible for our other securities or securities of other entities, the person with whom we consolidate or merge or to whom we sell all of our property must make provisions for the conversion of the debt securities into securities that the holders of the debt securities would have received if they had converted the debt securities before the consolidation, merger or sale.

Events of Default Under the Indenture

Unless otherwise provided in any applicable prospectus supplement, documents incorporated by reference or free writing prospectus, the following will be events of default under the indenture with respect to each series of debt securities issued thereunder:

- (a) if we fail to pay interest when due and payable and our failure continues for 30 days, or within such other time period as may be specified in the applicable indenture, and the time for payment has not been extended or deferred;
- (b) if we fail to pay the principal, premium or sinking fund payment, if any, when due and payable and the time for payment has not been extended or delayed;
- (c) if specified events of bankruptcy, insolvency or reorganization occur; and
- (d) if we fail to observe or perform any other covenant contained in the debt securities or the indentures, other than a covenant specifically relating to another series of debt securities, and our failure continues for 60 days, or within such other time period as may be specified in the applicable indenture, after we receive notice from the debenture trustee or holders of at least a majority in principal amount of the outstanding debt securities of an affected series, or such other percentage as may be specified in the applicable indenture, in aggregate principal amount of the outstanding debt securities of the applicable series.

If an event of default with respect to debt securities of any series occurs and is continuing, other than an event of default specified in the last bullet point above, the debenture trustee or the holders of at least 25%, or such other percentage as may be specified in the applicable indenture, in aggregate principal amount of the outstanding debt securities of that series, by notice to us in writing, and to the debenture trustee if notice is given by such holders, may declare the unpaid principal of, premium, if any, and accrued interest, if any, due and payable immediately. If an event of default specified in the last bullet point above occurs with respect to us, the principal amount of and accrued interest, if any, of each issue of debt securities then outstanding shall be due and payable without any notice or other action on the part of the debenture trustee or any holder.

The holders of a majority in principal amount of the outstanding debt securities of an affected series may waive any default or event of default with respect to the series and its consequences, except defaults or events of default regarding payment of principal, premium, if any, or interest, unless we have cured the default or event of default in accordance with the indenture. Any waiver shall cure the default or event of default.

[Table of Contents](#)

Subject to the terms of the indentures, if an event of default under an indenture shall occur and be continuing, the debenture trustee will be under no obligation to exercise any of its rights or powers under such indenture at the request or direction of any of the holders of the applicable series of debt securities, unless such holders have offered the debenture trustee reasonable indemnity. The holders of a majority in principal amount of the outstanding debt securities of any series will have the right to direct the time, method and place of conducting any proceeding for any remedy available to the debenture trustee, or exercising any trust or power conferred on the debenture trustee, with respect to the debt securities of that series, provided that:

- the direction so given by the holder is not in conflict with any law or the applicable indenture; and
- subject to its duties under the Trust Indenture Act of 1939, the debenture trustee need not take any action that might involve it in personal liability or might be unduly prejudicial to the holders not involved in the proceeding.

A holder of the debt securities of any series will only have the right to institute a proceeding under the indentures or to appoint a receiver or trustee, or to seek other remedies if:

- the holder has given written notice to the debenture trustee of a continuing event of default with respect to that series;
- the holders of at least 25% (or, in the case of a default of the type described under subsection (d), above, a majority in principal amount of the outstanding debt securities of an affected series), or such other percentage as may be specified in the applicable indenture, in aggregate principal amount of the outstanding debt securities of that series have made written request, and such holders have offered reasonable indemnity to the debenture trustee to institute the proceeding as trustee; and
- the debenture trustee does not institute the proceeding, and does not receive from the holders of a majority in aggregate principal amount of the outstanding debt securities of that series other conflicting directions within 60 days, or within such other time period as may be specified in the applicable indenture, after the notice, request and offer of indemnity.

These limitations do not apply to a suit instituted by a holder of debt securities if we default in the payment of the principal, premium, if any, or interest on, the debt securities.

We will periodically file statements with the debenture trustee regarding our compliance with specified covenants in the indentures.

Modification of Indenture; Waiver

We and the debenture trustee may change an indenture without the consent of any holders with respect to specific matters:

- to evidence the succession of another corporation to us and the assumption by any such successor of our covenants in such indenture and in the debt securities issued thereunder;
- to add to our covenants or to surrender any right or power conferred on us pursuant to the indenture;
- to establish the form and terms of debt securities issued thereunder;
- to evidence and provide for a successor trustee under such indenture with respect to one or more series of debt securities issued thereunder or to provide for or facilitate the administration of the trusts under such indenture by more than one trustee;
- to cure any ambiguity, to correct or supplement any provision in the indenture that may be defective or inconsistent with any other provision of the indenture or to make any other provisions with respect to matters or questions arising under such indenture; provided that no such action adversely affects the interests of the holders of any series of debt securities issued thereunder in any material respect;

Table of Contents

- to add to, delete from or revise the conditions, limitations and restrictions on the authorized amount, terms or purposes of issue, authentication and delivery of securities under the indenture;
- to add any additional events of default with respect to all or any series of debt securities;
- to supplement any of the provisions of the indenture as may be necessary to permit or facilitate the defeasance and discharge of any series of debt securities, provided that such action does not adversely affect the interests of any holder of an outstanding debt security of such series or any other security in any material respect;
- to make provisions with respect to the conversion or exchange rights of holders of debt securities of any series;
- to pledge to the trustee as security for the debt securities of any series any property or assets;
- to add guarantees in respect of the debt securities of one or more series;
- to change or eliminate any of the provisions of the indenture, provided that any such change or elimination becomes effective only when there is no security of any series outstanding created prior to the execution of such supplemental indenture which is entitled to the benefit of such provision;
- to provide for certificated securities in addition to or in place of global securities;
- to qualify such indenture under the Trust Indenture Act of 1939, as amended;
- with respect to the debt securities of any series, to conform the text of the indenture or the debt securities of such series to any provision of the description thereof in our offering memorandum or prospectus relating to the initial offering of such debt securities, to the extent that such provision, in our good faith judgment, was intended to be a verbatim recitation of a provision of the indenture or such securities; or
- to make any other change that does not adversely affect the rights of holders of any series of debt securities issued thereunder in any material respect.

In addition, under the indentures, the rights of holders of a series of debt securities may be changed by us and the debenture trustee with the written consent of the holders of at least a majority in aggregate principal amount of the outstanding debt securities of each series that is affected. However, we and the debenture trustee may only make the following changes with the consent of each holder of any outstanding debt securities affected:

- extending the fixed maturity of the series of debt securities; or
- reducing the principal amount, reducing the rate of or extending the time of payment of interest, or reducing any premium payable upon the redemption of any debt securities; or
- reducing the percentage of debt securities, the holders of which are required to consent to any amendment, supplement, modification or waiver; or
- make any change that adversely affects the right to convert or exchange any security into or for common stock or other securities, cash or other property in accordance with the terms of the applicable debt security.

Each indenture provides that we can elect to be discharged from our obligations with respect to one or more series of debt securities, except for specified obligations, including obligations to:

- register the transfer or exchange of debt securities of the series;
- replace stolen, lost or mutilated debt securities of the series;
- maintain paying agencies;
- hold monies for payment in trust;

[Table of Contents](#)

- recover excess money held by the debenture trustee;
- compensate and indemnify the debenture trustee; and
- appoint any successor trustee.

In order to exercise our rights to be discharged, we must deposit with the debenture trustee money or government obligations sufficient to pay all the principal of, any premium, if any, and interest on, the debt securities of the series on the dates payments are due.

Form, Exchange and Transfer

Each debt security will be represented by either one or more global securities registered in the name of The Depository Trust Company, as depository, or a nominee (which we refer to, in the case of any debt security represented by a global debt security, as a “book-entry debt security”), or a certificate issued in definitive registered form (which we refer to, in the case of any debt security represented by a certificated security, as a “certificated debt security”) as set forth in the applicable prospectus supplement. Except as set forth in the applicable prospectus supplement, book-entry debt securities will not be issuable in certificated form.

You may transfer or exchange certificated debt securities at any office we maintain for this purpose in accordance with the terms of the indenture. No service charge will be made for any registration of transfer or exchange of certificated debt securities, but we may require payment of a sum sufficient to cover all taxes, assessments or other governmental charges that may be imposed in connection with a transfer or exchange.

You may effect the transfer of certificated debt securities and the right to receive the principal of, and any premium and interest on, certificated debt securities only by surrendering the certificate representing those certificated debt securities and either execution by us, and authentication and delivery by the debenture trustee, of the certificate to the new holder or execution by us, and authentication and delivery by the debenture trustee, of a new certificate to the new holder.

If we elect to redeem the debt securities of any series, we will not be required to:

- issue, register the transfer of, or exchange any debt securities of that series during a period beginning at the opening of business 15 days, or within such other time period as may be specified in the applicable indenture, before the day of mailing of a notice of redemption of any debt securities that may be selected for redemption and ending at the close of business on the day of the mailing; or
- register the transfer of or exchange any debt securities so selected for redemption, in whole or in part, except the unredeemed portion of any debt securities we are redeeming in part.

Repurchases on the Open Market

We, or an affiliate of ours, may at any time or from time to time repurchase any debt security in the open market or otherwise. Such debt securities may, at our option (or our affiliate’s option), be held, resold or surrendered to the trustee for cancellation.

Discharge of Debt Securities

When all outstanding debt securities of any series will become due and payable within one year of their stated maturity and we have deposited with the debenture trustee cash sufficient to pay and discharge all outstanding debt securities of such series on the date of their stated maturity, then we may discharge our obligations under the relevant indenture with respect to such debt securities while they remain outstanding.

Information Concerning the Debenture Trustee

The debenture trustee, other than during the occurrence and continuance of an event of default under an indenture, undertakes to perform only those duties as are specifically set forth in the applicable indenture. Upon an event of default under an indenture, the debenture trustee must use the same degree of care as a prudent person would exercise or use in the conduct of his or her own affairs. Subject to this provision, the debenture trustee is under no obligation to exercise any of the powers given him or her by the indentures at the request of any holder of debt securities unless he or she is offered reasonable security and indemnity against the costs, expenses and liabilities that he or she might incur.

Payment and Paying Agents

Unless we otherwise indicate in the applicable prospectus supplement, we will make payment of the interest on any debt securities on any interest payment date to the person in whose name the debt securities, or one or more predecessor securities, are registered at the close of business on the regular record date for the interest.

We will pay principal of and any premium and interest on the debt securities of a particular series at the office of the paying agents designated by us, except that unless we otherwise indicate in the applicable prospectus supplement, we will make interest payments by check that we will mail to the holder or by wire transfer to certain holders. Unless we otherwise indicate in a prospectus supplement, we will designate the corporate trust office of the debenture trustee in the City of New York as our sole paying agent for payments with respect to debt securities of each series. We will name in the applicable prospectus supplement any other paying agents that we initially designate for the debt securities of a particular series. We will maintain a paying agent in each place of payment for the debt securities of a particular series.

All money we pay to a paying agent or the debenture trustee for the payment of the principal of or any premium or interest on any debt securities that remains unclaimed at the end of two years after such principal, premium or interest has become due and payable will be repaid to us, and the holder of the debt security thereafter may look only to us for payment thereof.

Governing Law

The indentures and the debt securities will be governed by and construed in accordance with the laws of the State of New York, except to the extent that the Trust Indenture Act of 1939 is applicable.

Subordination of Subordinated Debt Securities

The subordinated debt securities will be unsecured and will be subordinate and junior in priority of payment to certain of our other indebtedness to the extent described in a prospectus supplement. The subordinated indenture does not limit the amount of subordinated debt securities that we may issue. It also does not limit us from issuing any other secured or unsecured debt.

Outstanding Debt Securities

As of December 20, 2018, the Company had no outstanding debt securities.

DESCRIPTION OF WARRANTS

The following description, together with the additional information we may include in any applicable prospectus supplements, summarizes the material terms and provisions of the warrants that we may offer under this prospectus and the related warrant agreements and warrant certificates. While the terms summarized below will apply generally to any warrants that we may offer, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement. The terms of any warrants offered under that prospectus supplement may differ from the terms described below.

The following summary description, together with the additional information we may include in any applicable prospectus supplements does not purport to be complete and is subject to, and qualified in its entirety by reference to, the form of warrant agreement and form of warrant certificate relating to each series of warrants that will be incorporated by reference as an exhibit to the registration statement that includes this prospectus or as an exhibit to a current report on Form 8-K if we offer warrants.

General

We will describe in the applicable prospectus supplement the terms of the series of warrants, including:

- the offering price and aggregate number of warrants offered;
- the currency for which the warrants may be purchased;
- if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;
- if applicable, the date on and after which the warrants and the related securities will be separately transferable;
- in the case of warrants to purchase common stock, the number of shares of common stock purchasable upon the exercise of one warrant and the price at which these shares may be purchased upon such exercise;
- the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreements and the warrants;
- the terms of any rights to redeem or call the warrants;
- any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;
- the dates on which the right to exercise the warrants will commence and expire;
- the manner in which the warrant agreements and warrants may be modified;
- federal income tax consequences of holding or exercising the warrants;
- the terms of the securities issuable upon exercise of the warrants; and
- any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

Before exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including the right to receive dividends, if any, or, payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any.

Exercise of Warrants

Each warrant will entitle the holder to purchase the securities that we specify in the applicable prospectus supplement at the exercise price that we describe in the applicable prospectus supplement. Unless we otherwise

[Table of Contents](#)

specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants at any time up to 5:00 P.M. Eastern Time on the expiration date that we set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Holders of the warrants may exercise the warrants by delivering the warrant certificate representing the warrants to be exercised together with specified information, and paying the required amount to the warrant agent in immediately available funds, as provided in the applicable prospectus supplement. We will set forth on the reverse side of the warrant certificate and in the applicable prospectus supplement the information that the holder of the warrant will be required to deliver to the warrant agent.

Upon receipt of the required payment and the warrant certificate properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement, we will issue and deliver the securities purchasable upon such exercise. If fewer than all of the warrants represented by the warrant certificate are exercised, then we will issue a new warrant certificate for the remaining amount of warrants. If we so indicate in the applicable prospectus supplement, holders of the warrants may surrender securities as all or part of the exercise price for warrants.

Enforceability of Rights by Holders of Warrants

Any warrant agent will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants.

Form, Exchange, and Transfer

We may issue the warrants in registered form or bearer form. Warrants issued in registered form, i.e., book-entry form, will be represented by a global security registered in the name of a depository, which will be the holder of all the warrants represented by the global security. Those investors who own beneficial interests in a global warrant will do so through participants in the depository's system, and the rights of these indirect owners will be governed solely by the applicable procedures of the depository and its participants. In addition, we may issue warrants in non-global form, i.e., bearer form. If any warrants are issued in non-global form, warrant certificates may be exchanged for new warrant certificates of different denominations, and holders may exchange, transfer, or exercise their warrants at the warrant agent's office or any other office indicated in the applicable prospectus supplement or other offering material.

Outstanding Warrants

As of December 20, 2018, we have outstanding warrants to purchase common stock as follows: (i) at any time until the 5-year anniversary of the original date of issuance in 2014, warrants to purchase an aggregate of 2,313 shares of our common stock at an exercise price of \$499.05 per share, (ii) at any time until the 5-year anniversary of the original date of issuance in 2015, as applicable, warrants to purchase an aggregate of 7,772 shares of our common stock at an exercise price of \$49.91 per share and warrants to purchase an aggregate of 24 shares of our common stock at an exercise price of \$499.05 per share, and (iii) at any time until the 7-year anniversary of the original date of issuance in 2012, warrants to purchase an aggregate of 85 shares of our common stock at an exercise price of \$392.70 per share. Effective November 13, 2018, Healthcare Ventures VIII, L.P. agreed to cancel outstanding warrants representing the right to purchase up to an aggregate 1,845 shares of the Company's common stock (as adjusted for the 15:1 reverse stock split effected February 10, 2017).

DESCRIPTION OF UNITS

The following description, together with the additional information we may include in any applicable prospectus supplements, summarizes the material terms and provisions of the units that we may offer under this prospectus. While the terms we have summarized below will apply generally to any units that we may offer under this prospectus, we will describe the particular terms of any series of units in more detail in the applicable prospectus supplement. The terms of any units offered under a prospectus supplement may differ from the terms described below.

The following summary description, together with the additional information we may include in any applicable prospectus supplements does not purport to be complete and is subject to, and qualified in its entirety by reference to, the form of unit agreement and form of unit certificate relating to each series of units that will be incorporated by reference as an exhibit to the registration statement that includes this prospectus or as an exhibit to a current report on Form 8-K if we offer units.

General

We may issue units comprised of common stock, preferred stock, debt securities, debt obligations of third parties, including U.S. treasury securities, warrants or any combination thereof. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date.

We will describe in the applicable prospectus supplement the terms of the series of units, including:

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any provisions of the governing unit agreement that differ from those described below; and
- any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units.

The provisions described in this section, as well as those described under “Description of Capital Stock,” “Description of Debt Securities” and “Description of Warrants” will apply to each unit and to any common stock, preferred stock, debt security or warrants included in each unit, respectively.

Issuance in Series

We may issue units in such amounts and in such numerous distinct series as we determine.

Enforceability of Rights by Holders of Units

Any unit agent will act solely as our agent under the applicable unit agreement and will not assume any obligation or relationship of agency or trust with any holder of any unit. A single bank or trust company may act as unit agent for more than one series of units. A unit agent will have no duty or responsibility in case of any default by us under the applicable unit agreement or unit, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a unit may, without the consent of the related unit agent or the holder of any other unit, enforce by appropriate legal action its rights as holder under any security included in the unit.

[Table of Contents](#)

Title

We, any unit agents and any of their agents may treat the registered holder of any unit certificate as an absolute owner of the units evidenced by that certificate for any purpose and as the person entitled to exercise the rights attaching to the units so requested, despite any notice to the contrary. See “Legal Ownership of Securities” below.

Outstanding Units

We have no outstanding units.

PLAN OF DISTRIBUTION

We may sell the securities being offered by this prospectus separately or together through any of the following methods:

- to or through one or more underwriters or dealers in a public offering and sale by them;
- directly to investors;
- through agents;
- through block trades in which the broker or dealer engaged to handle the block trade will attempt to sell the securities as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- through any combination of these methods of sale; or
- in any manner, as provided in the applicable prospectus supplement.

We may distribute securities from time to time in one or more transactions:

- at a fixed price or prices, which may be changed;
- at market prices prevailing at the times of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

We will describe the method of distribution of the securities in the applicable prospectus supplement. We may also determine the price or other terms of the securities offered under this prospectus by use of an electronic auction. We will describe how any auction will determine the price or any other terms, how potential investors may participate in the auction and the nature of the obligations of the underwriter, dealer or agent in the applicable prospectus supplement.

Unless otherwise specified in the applicable prospectus supplement, each class or series of securities will be a new issue with no established trading market, other than our common stock, which is traded on The Nasdaq Capital Market. We may elect to list any other class or series of securities on any exchange, but we are not obligated to do so. It is possible that one or more underwriters may make a market in a class or series of securities, but the underwriters will not be obligated to do so and may discontinue any market making at any time without notice. We cannot give any assurance as to the liquidity of the trading market for any of the securities.

Underwriters, dealers or agents may receive compensation in the form of discounts, concessions or commissions from us or our purchasers (as their agents in connection with the sale of the securities). In addition, underwriters may sell the securities to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for whom they act as agent. These underwriters, dealers or agents may be considered to be underwriters under the Securities Act. As a result, discounts, commissions, or profits on resale received by the underwriters, dealers or agents may be treated as underwriting discounts and commissions. The prospectus supplement will identify any such underwriter, dealer or agent, and describe any compensation received by them from us. Only underwriters named in the prospectus supplement are underwriters of the securities offered by the prospectus supplement. Any initial public offering price and any discounts or concessions allowed or reallocated or paid to dealers may be changed from time to time.

We may sell the securities directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of securities and we will describe any commissions we will pay the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, our agent will act on a best-efforts basis for the period of its appointment.

[Table of Contents](#)

We may authorize agents or underwriters to solicit offers by certain types of institutional investors to purchase securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in the prospectus supplement.

Underwriters, dealers and agents may be entitled to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, or to contribution with respect to payments made by the underwriters, dealers or agents, under agreements between us and the underwriters, dealers and agents.

Any person participating in the distribution of common stock registered under the registration statement that includes this prospectus will be subject to applicable provisions of the Exchange Act, and the applicable SEC rules and regulations, including, among others, Regulation M, which may limit the timing of purchases and sales of any of our common stock by any such person. Furthermore, Regulation M may restrict the ability of any person engaged in the distribution of our common stock to engage in market-making activities with respect to our common stock. These restrictions may affect the marketability of our common stock and the ability of any person or entity to engage in market-making activities with respect to our common stock.

We may grant underwriters who participate in the distribution of the securities an option to purchase additional securities to cover overallocments, if any, in connection with the distribution. Any underwriter may engage in overallocation, stabilizing transactions, short-covering transactions and penalty bids in accordance with Regulation M that stabilize, maintain or otherwise affect the price of the offered securities. Overallocation involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Short covering transactions involve purchases of the common stock in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the common stock originally sold by the dealer is purchased in a covering transaction to cover short positions. Those activities may cause the price of the common stock to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time. If any such activities will occur, they will be described in the applicable prospectus supplement.

Underwriters or agents and their associates may be customers of, engage in transactions with or perform services for us in the ordinary course of business and any such relationships will be described in the applicable prospectus supplement.

To the extent required, this prospectus may be amended or supplemented from time to time to describe a specific plan of distribution.

LEGAL MATTERS

The validity of the securities being offered by this prospectus will be passed upon by Morrison & Foerster LLP of Palo Alto, California. Additional legal matters may be passed upon for us or any underwriters, dealers or agents, by counsel that we will name in an applicable prospectus supplement.

EXPERTS

The consolidated balance sheets of Catalyst Biosciences, Inc. as of December 31, 2017 and 2016, and the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity and cash flows for each of the years then ended, have been audited by EisnerAmper LLP, independent registered public accounting firm, as stated in their report which is incorporated herein by reference. Such financial statements have been incorporated herein by reference in reliance on the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission, or the SEC. You may read and copy these reports, proxy statements and other information at the SEC's public reference rooms at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference rooms. Our SEC filings are also available at the SEC's website at www.sec.gov and our website at www.catalystbiosciences.com. We have not incorporated by reference into this prospectus the information contained on our website and you should not consider it to be part of this prospectus. In addition, you can read and copy our SEC filings at the office of the National Association of Securities Dealers, Inc. at 1735 K Street, Washington, D.C. 20006.

We have filed a registration statement on Form S-3 with the SEC relating to the securities covered by this prospectus. This prospectus is a part of the registration statement and does not contain all of the information in the registration statement. You may review a copy of the registration statement at the SEC's public reference room in Washington, D.C., as well as through the SEC's Internet site at www.sec.gov.

The SEC allows us to "incorporate by reference" the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. In addition, information we file with the SEC in the future will automatically update and supersede information contained in this prospectus and any accompanying prospectus supplement.

This prospectus incorporates by reference the documents set forth below that we have previously filed with the SEC:

- our Annual Report on [Form 10-K](#) for the fiscal year ended December 31, 2017 filed with the SEC on March 19, 2018;
- our Quarterly Reports on Form 10-Q for the quarterly periods ended [March 31, 2018](#), [June 30, 2018](#) and [September 30, 2018](#) filed with the SEC on May 3, 2018, August 2, 2018 and November 1, 2018, respectively; and
- our Current Reports on Form 8-K filed with the SEC on [April 13, 2018](#), [June 14, 2018](#), [June 18, 2018](#), [July 18, 2018](#), [August 15, 2018](#), [August 31, 2018](#) and [December 18, 2018](#).

All filings filed by us pursuant to the Exchange Act after the date of the initial filing of the registration statement of which this prospectus is a part and prior to effectiveness of the registration statement shall be deemed to be incorporated by reference into this prospectus.

We also incorporate by reference into this prospectus additional documents that we may file with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, excluding, in each case, information deemed furnished and not filed until we sell all of the securities we are offering. Any statements contained in a previously filed document incorporated by reference into this prospectus is deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus, or in a subsequently filed document also incorporated by reference herein, modifies or supersedes that statement.

[Table of Contents](#)

We will provide to you at no cost a copy of any and all of the information incorporated by reference into the registration statement of which this prospectus is a part. You may make a request for copies of this information in writing or by telephone. Requests should be directed to:

Catalyst Biosciences, Inc.
611 Gateway Blvd. Suite 710
South San Francisco, CA 94080
Attn: Fletcher Payne, Chief Financial Officer
(650) 871-0761

8,700,000 SHARES



Catalyst Biosciences, Inc.

Common Stock

PROSPECTUS SUPPLEMENT

Sole Lead Active Bookrunner

Piper Sandler

Bookrunner

Raymond James

January 26, 2021