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

FORM 8-K/A
(Amendment No. 1)

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 17, 2020

COMPASS THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	000-55939	EIN 82-4876496
(State of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

245 First Street
3rd Floor
Cambridge, Massachusetts 02142
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (617) 500-8099

Olivia Ventures, Inc.
2255 Glades Road
Suite 324A
Boca Raton, Florida 33431
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Exchange Act: none.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

EXPLANATORY NOTE

June 23, 2020, Compass Therapeutics, Inc. (the "Company") filed a Current Report on Form 8-K (the "Original Report") with the Securities and Exchange Commission (the "SEC") disclosing the consummation, on June 17, 2020, of the merger between the Company's wholly-owned subsidiary, Compass Acquisition LLC, a Delaware limited liability company, with and into Compass Therapeutics LLC, a privately held Delaware limited liability company ("Compass Therapeutics"). As a result of the merger, the Company acquired the business of Compass Therapeutics and will continue the existing business operations of Compass Therapeutics as a public reporting company under the name Compass Therapeutics, Inc.

As used in this Report, unless otherwise stated or the context clearly indicates otherwise, the terms the "Company", "we", "us" and "our" refer to Compass Therapeutics, Inc. after giving effect to the merger described above.

The Company is filing this Current Report on Form 8-K/A (the "Amended Report") to amend and restate the following sections in the Original Report: "Description of Business", "Risk Factors", "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Principal Stockholders". This Amended Report should be read in conjunction with the Original Report and with our filings with the SEC subsequent to the Original Form 8-K. The Amended Report speaks as of the filing date of the Original Report, and we have not updated the disclosures contained therein or herein to reflect any events which occurred at a date subsequent to the filing of the Original Report. Defined terms not otherwise defined herein shall have the meaning ascribed to such terms in the Original Report, save that all references to the "Report" shall now refer to the Original Report, as amended by this Amended Report.

As used in this Amended Report, unless otherwise stated or the context clearly indicates otherwise, the terms the "Company", "we", "us" and "our" refer to Compass Therapeutics, Inc. after giving effect to the merger described above.

This Amended Report contains summaries of the material terms of various agreements executed in connection with the transactions described herein. The summaries of these agreements are subject to, and are qualified in their entirety by, reference to these agreements, which were filed as exhibits to the Original Report and are incorporated herein by reference.

Item 2.01. Completion of Acquisition or Disposition of Assets

DESCRIPTION OF BUSINESS

Overview

We are a clinical-stage biopharmaceutical company developing proprietary antibody therapeutics intended to engage the immune system to treat both solid tumors and hematological malignancies. Our immuno-oncology product candidates include a clinical-stage monoclonal antibody and a portfolio of bispecific antibodies. These product candidates are designed to address three critical components required for an effective immune response to cancer: induction of a potent innate immune response; activation of the adaptive immune system; and alleviation of immunosuppressive mechanisms used by tumors to evade immune surveillance and activation. We plan to advance our product candidates through clinical development either as standalone therapies or in combination with existing therapies as long as their continued development is supported by clinical and nonclinical data.

Our lead product candidate, CTX-471, is a monoclonal antibody agonist of CD137, a key co-stimulatory receptor on immune cells. In preclinical studies, we observed that CTX-471 led to complete eradication of large tumors in mice when dosed as a monotherapy. In treated mice, dosing with CTX-471 was associated with extensive reprogramming of the tumor microenvironment, resulting in increased survival and long-term immune protection. Long after therapy had been completed, after more than eight half-lives of the antibody, treated mice exhibited immune memory that prevented reestablishment of the same tumor. Based on these and other preclinical results, in July 2019 we initiated a Phase 1 dose-escalating trial evaluating CTX-471 as a monotherapy in oncology patients who were previously treated with PD-1 or PD-L1 immune checkpoint inhibitors and subsequently relapsed or progressed after a period of stable disease. The design of this trial includes a dose escalation period, which is currently ongoing, to be followed by a dose expansion cohort. We reported topline data from the dose escalation stage of the Phase 1 trial as discussed below in "—Phase 1 clinical trial of CTX-471" and plan to initiate a dose expansion stage shortly thereafter.

If our Phase 1 of CTX-471 as monotherapy is successful, we plan to initiate a second Phase 1 trial of CTX-471 in combination with trastuzumab, marketed as Herceptin® by Genentech, in selected human epidermal growth factor receptor 2, or Her2 positive tumors and with cetuximab, marketed as Erbitux® by Eli Lilly, in epidermal growth factor receptor, or EGFR positive tumors.

In addition to CTX-471, we are also developing a portfolio of bispecific antibody product candidates, which are currently in preclinical development. These programs all derive from our in-house antibody discovery and development platforms.

Our approach is based on the observation that traditional methods of antibody discovery are slow, inefficient, and are limited by lack of diversity of antigenic sites, or epitopes, that are recognized using these methods. We believe these limitations impair drug developers' ability to identify the best product candidates. We have created several technological solutions that are designed to address the key challenges in antibody development with the goal of incorporating our solutions into bispecific product candidates. First, we developed and acquired several complementary platforms that enable us to generate antibodies with a high level of epitope diversity and excellent physical and biochemical properties. Second, we have developed sophisticated technologies to screen our antibody sets in functional biological assays designed to prioritize antibodies with desirable biological activities. Third, we have developed proprietary technology StitchMabs^{TM} that allow us to rapidly evaluate the potential of the antibodies we discover in a bispecific antibody format.

We have also developed a proprietary transgenic mouse that produces antibodies with the differentiated property that they all share a human common light chain. We imposed this restriction at the earliest stage of our bispecific antibody discovery process in anticipation of the need to simplify the manufacturing of our bispecific product candidates. Sharing a common light chain enables our bispecific antibodies to be manufactured using a well-established process that has been successfully used by the biopharmaceutical industry to produce monoclonal antibodies at commercial scale, thereby avoiding the complexities associated with the manufacture of bispecific products that lack this property. We found that imposing this restriction on the construction of the antibody pool did not hinder our ability to obtain highly potent and selective antibodies.

Our second product candidate, CTX-8371, is a bispecific antibody that simultaneously targets both PD-1 and PD-L1, the targets of well-known and widely used checkpoint inhibitor antibodies. Single inhibitors of PD-1 and PD-L1 include some of the highest-revenue-generating therapeutics in history and have been approved for the treatment of a wide range of tumors. There is no marketed therapy that combines inhibition of both PD-1 and PD-L1 in the same molecule and, in CTX-8371, we are working on developing one. We discovered CTX-8371 using our StitchMabs™ technology when we screened for the best antibody to pair with our proprietary PD-1 blocker. Additional studies demonstrated that CTX-8371 works via a novel mechanism of action not shared by PD-1 or PD-L1 blockers. We have shown in animal models that CTX-8371 was associated with greater antitumor activity than a PD-1 inhibitor, a PD-L1 inhibitor or a combination of the two. We plan to begin IND-enabling studies with CTX-8371 in the third quarter of 2020.

We have also leveraged our proprietary platform technologies to identify and evaluate a novel class of bispecific product candidates that serve as antigen-specific innate cell engagers. These product candidates contain an antibody binding domain that functions as an agonist of NKp30, an activating receptor expressed on natural killer, or NK cells and on gamma delta T-cells or γδ T-cells. We have shown that pairing the NKp30 binding domain together with antibodies that target tumor-antigen binding domains led to the generation of bispecific product candidates that can selectively stimulate NK cells to kill corresponding tumor cells. We are generating *in vivo* data on a number of NKp30 bispecific product candidates so that we can prioritize and advance the most promising of these candidates into clinical development.

CTX-8573 is our first bispecific product candidate in this novel NKp30 innate cell engager class. CTX-8573 is designed to activate NK cells, and direct them against cells expressing B cell maturation antigen, or BCMA, an antigen that is significantly over-expressed in multiple myeloma and on antibody producing plasma cells. CTX-8573 has exhibited between 80% -100% specific cytotoxic activity toward cells expressing high, intermediate and low levels of BCMA in cell-based assays. When we tested other cell engagers that do not bind to the NKp30 receptor in these same cell-based assays, these agents demonstrated up to 100% specific cytotoxic activity against cells expressing high BCMA levels, but its activity drops significantly (~ 30%) when tested against cells expressing low levels of BCMA. The ability of CTX-8573 to induce selective cell killing of cells expressing low BCMA levels suggests that CTX-8573 can be used to selectively deplete antibody-producing plasma cells, and could therefore represent a novel treatment for severe autoimmune diseases mediated by pathogenic antibodies such as myasthenia gravis, immune thrombocytopenia and pemphigus vulgaris. We plan to begin IND-enabling studies with CTX-8573 in the first half of 2021.

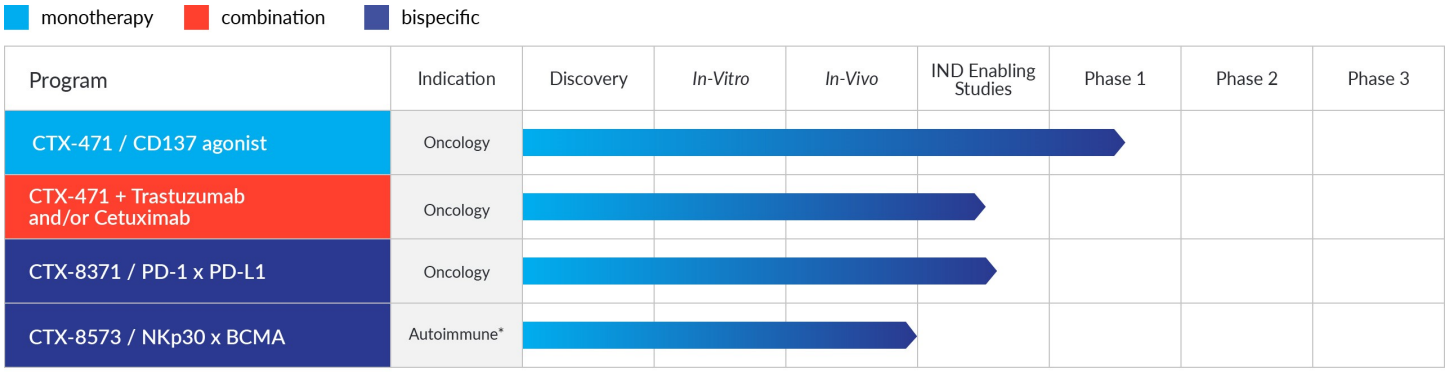
Our management team has a successful record of building and growing biotechnology companies. Our Chief Executive Officer and co-founder, Thomas J. Schuetz, M.D., Ph.D. has over 20 years of experience in oncology, biopharmaceutical drug development and life science venture investing. Prior to co-founding Compass Therapeutics, Dr. Schuetz was a venture partner with Orbimed Advisors where he participated in Orbimed's investments in Enobia Pharma (sold to Alexion), Relypsa (sold to Galenica), Arteaus Therapeutics (sold to Eli Lilly), and Audentes (sold to Astellas) and served on the board of each of these companies. Dr. Schuetz was also the chief medical officer of Therion Biologic Corporation and was vice president of clinical affairs at Transkaryotic Therapies, a company acquired by Shire.

Our Chief Operating Officer, Vered Bisker-Leib, Ph.D., MBA, has over 18 years of experience in strategy, business development, finance and operations of biotechnology and pharmaceutical companies. Prior to joining Compass Therapeutics, she served as an entrepreneur-in-residence with Atlas Venture. Previously, Dr. Bisker-Leib was chief business officer of Cydan, a biotech accelerator, where she co-founded IMARA, Inc. (NASDAQ: IMRA) and other biotech companies focused on therapies addressing rare diseases and served as an executive director and global head of business development for the cardiovascular and metabolic franchises of Bristol-Myers Squibb.

Our syndicate of investors is led by OrbiMed, F-Prime Capital, Cowen Healthcare Investments, Biomatics Capital, Borealis Ventures, Peter Thiel, Biomed Ventures and Alexandria Venture Investments, LLC.

Pipeline

The figure below details our pipeline of product candidates, including our lead product candidate CTX-471, and our key pre-clinical programs: CTX-8371 and CTX-8573.



Strategy

Our goal is to expand and extend the role of the immune system in fighting cancer with antibody-based therapies. We believe our approach can be applied both to solid tumors as well as to hematologic malignancies. Our strategy to achieve this goal includes:

- **Advance our lead product candidate, CTX-471 through clinical development to evaluate its therapeutic potential alone and in combination with other therapies.** We seek to translate the antitumor activity of CTX-471 observed in preclinical testing into meaningful clinical results in patients with immunogenic tumors, such as non-small cell lung cancer, or NSCLC and melanoma. Our ongoing Phase 1 clinical trial is being conducted in patients who relapse after prior checkpoint therapies.

- **Advance CTX-8371 into clinical development as a next generation checkpoint inhibitor.** Our bispecific inhibitor that targets PD-1 and PD-L1 has demonstrated higher antitumor activity in preclinical experiments than single PD-1, a PD-L1, or combinations of PD-1 and PD-L1 inhibitors. We plan to initiate IND-enabling studies with CTX-8371 in the third quarter of 2020 with the goal of commencing clinical testing in 2021.

- **Advance CTX-8573 into clinical development in antibody-mediated autoimmune diseases**. CTX-8573 is a product candidate that stimulates cell killing by directly activating NK cells to selectively destroy BCMA-expressing cells. We plan to begin IND-enabling studies with CTX-8573 in the first half of 2021 and advance it to clinical development as a therapy for antibody-mediated autoimmune diseases such as myasthenia gravis, immune thrombocytopenia and pemphigus vulgaris.

- **Expand the potential of our NKp30 innate cell engagers**. Through our innate cell-engager bispecific platform, we are generating a broad portfolio of bispecific product candidates that pair various tumor antigen binding domains to our NKp30 binding domain. We believe that the ability to activate NK cells in a selective and directed way against various cancers will allow us to identify bispecifics with differentiated cytotoxic activity. We are currently screening several innate cell engagers in animal models to prioritize those with the greatest promise for future clinical development.

- **Leverage our proprietary platforms to generate novel bispecific product candidates.** Our platform technologies, including our antibody generation process, our common light chain approach and StitchMabs™, are focused on the discovery and development of bispecific products. We continue to use these technologies to generate a broad portfolio of early-stage bispecific assets that we then evaluate in preclinical experiments with the intent of advancing the most promising candidates into clinical development.

- **Seek strategic partnerships for select product candidates**. Our technology platform is designed to generate a broad pipeline of product candidates with high potential for clinical application. We intend to assess on a case-by-case basis the opportunities for accelerating the preclinical and clinical development of these candidates in a capital-efficient manner, including selectively pursuing strategic partnerships with leading biopharmaceutical companies with domain-specific expertise in clinical development to maximize the value of our pipeline.

Our approach

We are focused exclusively on modulation of the immune system through the development of novel antibody therapeutics. Antibodies are structurally distinct Y-shaped proteins formed through the pairing of two long proteins, called heavy chains, and two short proteins, called light chains. Each heavy and light chain pair forms a binding site where the antibody specifically binds its target, which is also known as an antigen.

The immune system is capable of not only fighting foreign invaders, but also of recognizing and eliminating a human body's own cells that have become pathogenic after transformation, such as in cancer. There are two broad classes of antibodies used in cancer therapy. The majority of antibodies directly target the tumor or its surroundings. The more recent class consists of antibodies that modulate the immune system leading to immune-mediated killing of tumors. These antibody drugs mainly exert this effect via single modulation of the immune system. We believe that modulation of more than one function of the immune system simultaneously has the potential to improve the therapeutic benefit and utility of immuno-oncology therapies.

Antibodies can be generated in many ways, and multiple companies claim to possess proprietary antibody discovery platforms, each with specific advantages. Our antibody platform was designed with a broad set of capabilities and resources that we can leverage with the goal of generating a portfolio of highly distinct bispecific products.

Our approach to bispecific antibody discovery encompasses four principles:

- antibody diversity is required to generate a representative sample of possible therapies;
- functional screening is critical to identifying optimal solutions;
- a combinatorial approach enables parallel assessment of many potential bispecific antibodies; and
- decisions made at the start of the discovery process have a major impact on successful clinical and commercial-scale manufacturing.

Antibody diversity

We obtain our initial pools of antibodies from multiple internally-developed platforms, including our custom phage display library and our transgenic mouse line. We constructed our phage display library based on the peripheral B cell diversity of 70 healthy human donors. This system allows us to generate large and highly diverse sets of antibodies that are fully human; target multiple epitopes on a target of interest; and possess excellent physical and biochemical properties. We describe these antibodies as having good 'drug-like' properties. To generate additional antibody candidates, we can also immunize a proprietary line of humanized transgenic mice with antigens of interest to isolate a diverse set of fully human antibodies that share a common human light chain, but distinct native mouse heavy chains. We estimate that the pool of antibodies from these two platforms represents over 10^{10} unique sequences.

We express libraries of antibodies against any particular target using our Human Display technology which streamlines the expression of functional antibodies such that each cell expresses only one antibody clone. We then further screen our diverse sets of antibodies expressed with our Human Display technology to fine-tune for specificity. Sequence changes can be readily introduced to further optimize leads from our screens.

Our ability to generate viable antibody candidates, with good drug-like properties and high manufacturability potential in a high-throughput manner has enabled us to rapidly assemble a portfolio of proprietary antibodies to over 40 key innate and adaptive immune targets and tumor antigens. This portfolio of antibodies is designed to provide us with a set of well-characterized antibodies that can be incorporated into our combinatorial bispecific antibody screening platform.

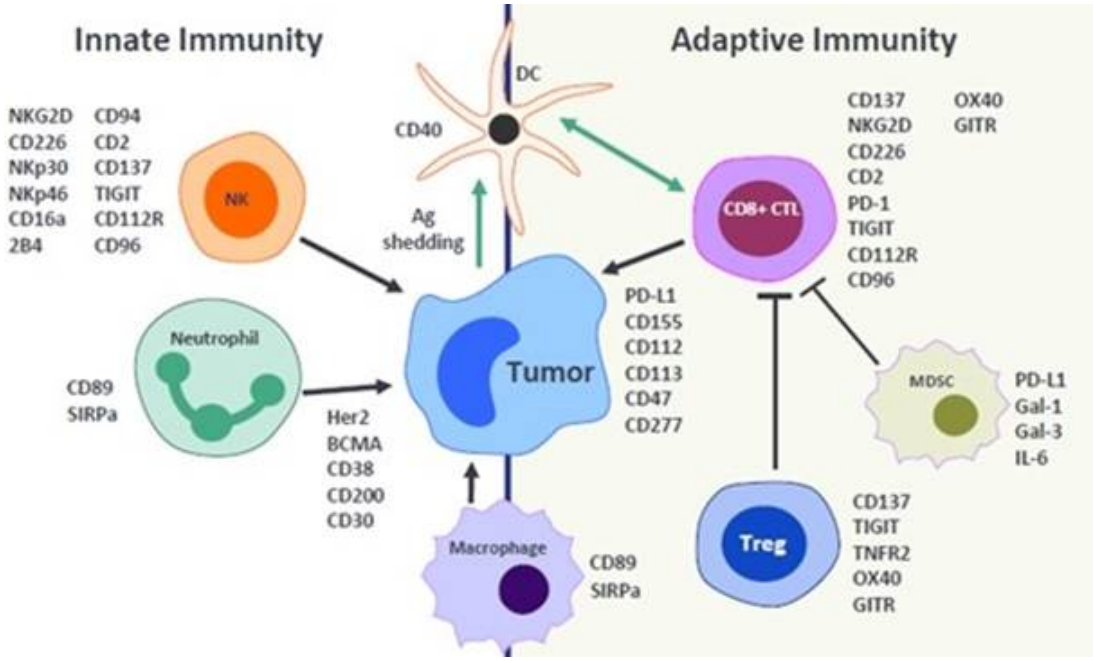


Figure 1. We have discovered proprietary antibodies that modulate two key components of the immune system: innate immunity and adaptive immunity. These antibodies bind to different cells of the immune system, and enhance its activities. In addition, we have discovered proprietary antibodies to selected antigens on tumor cells, including antibodies to well-known antigens, such as Her2 and BCMA. We intend to advance antibodies to tumor antigens only as components of combination regimen or multi-specifics.

Functional screening

A critical part of our antibody discovery process is our ability to produce sufficient quantities of purified antibodies to assess their biological activities both in cells and, in some cases, animal models. Our human display technology allows us to efficiently express full-length antibodies on cell surface, thereby facilitating the high throughput screening of our antibodies across multiple functional screens. While we do assess standard biochemical parameters such as binding affinity and specificity as part of the initial screening of our candidate sets, we note that activity in a complex biological system cannot be predicted based on physical and biochemical parameters alone. We have shown with CTX-471, for example, that activity in a complex biological system cannot necessarily be predicted on strictly biochemical parameters.

Combinatorial approach

A natural antibody recognizes a single target antigen and is therefore monospecific. Because a natural antibody features two identical binding sites, it is considered bivalent for that target. Although natural antibodies recognize a single target antigen, it is possible to engineer antibodies so that their two binding sites bind two different targets. The construction of a bispecific antibody typically requires a significant investment in cloning, construct optimization, protein expression, and protein purification before the therapeutic potential of any particular bispecific antibody can be assessed. In practice, these requirements mean that the diversity of antigen pairs targeted by bispecific antibodies is limited, and development is oftentimes prioritized for antigen pairs suggested by existing scientific literature.

Our proprietary StitchMabs^{TM} technology is a novel screening approach which we developed to assess the potential of any pair of antigen-binding sites in a bispecific antibody format. This combinatorial antibody-linking technology stably and irreversibly attaches a second pair of antigen-binding domains to a standard antibody during a 15-minute incubation at room temperature. The resulting stitched antibody acts structurally and functionally like a bispecific antibody.

StitchMabs^{TM} allows us to assess our large library of antigen-binding domains in combinatorial fashion. Once we have generated and purified large numbers of bispecific candidates, we then assess the potential of these candidates in functional assays and determine whether these bispecifics have additive, reductive or synergistic activity. Screening of these bispecific molecules in functional assays has led us to discover novel product candidates with unexpected synergistic activity in cellular and animal model, including CTX-8371 and CTX-8573.

Our common light chain platform greatly simplifies manufacturing

The embedded common light chain feature in our antibodies greatly simplifies the manufacture of our bispecific product candidates. Most antigen-binding domains of antibodies are composed of a heavy chain and a light chain that have been optimized together to recognize a specific antigen. If these two chains are expressed independently, as is the case with most antibody manufacturing processes, they are often reassembled in various ways, leading to heterogenous mixture of the desired product along with peptide segments corresponding to two heavy chains and two light chains. Separation of the desired product from the mixture is a technically challenging and expensive process.

We address this challenge by including only common light chain compatible antibodies as part of our antibody discovery process for potential incorporation into bispecifics. The variability in the antigen-binding domain of our antibodies in the heavy chain is sufficient to generate a diverse, potent, selective, and functionally active set of antibodies. We further simplified the manufacturing of our bispecific antibodies by assembling a single heavy chain construct that encodes both antigen-binding domains. As a result, the manufacturing of our bispecifics closely resembles that of standard monoclonal antibodies, which include – one heavy chain and one light chain. Our focus on common light chain antibodies simplifies the process of converting our StitchMabs^{TM} screening candidate bispecifics into bispecific antibody product candidates.

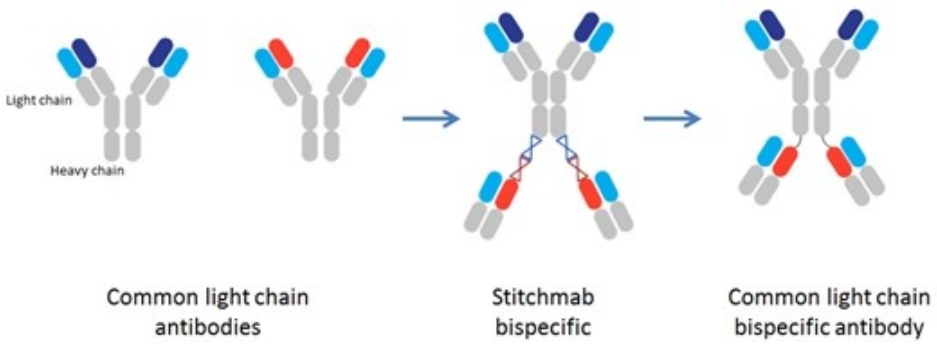


Figure 2. A common light chain simplifies the production of bispecific antibodies

CTX-471, a monoclonal antibody targeting CD137

CTX-471, our monoclonal antibody product candidate, is an agonist of CD137, a key co-stimulatory receptor on immune cells. Binding of CTX-471 to CD137 leads to ligand-stimulated activation of T-cells and NK cells. In tumor models, treatment with CTX-471 as a monotherapy led to recruitment and activation of immune cells in the tumor microenvironment. In the treated mice, dosing with CTX-471 led to extensive reprogramming of the tumor microenvironment, including increased recruitment of immune cells, reversion of exhausted cytotoxic CD8+ T-cells, reductions in immunosuppressive regulatory T-cells, and reductions in immunosuppressive tumor-associated macrophages. Long after the completion of the treatment with CTX-471, a period described as eight half-lives of the antibody, treated mice exhibited immune memory that prevented reestablishment of the same tumor.

In July 2019 we initiated a Phase 1 trial evaluating CTX-471 as a monotherapy in cancer patients who were previously treated with a PD-1 or PD-L1 immune checkpoint inhibitor and subsequently relapsed or progressed after a prior response or stable disease. The design of this trial includes a dose escalation period, which is currently ongoing, to be followed by a dose expansion cohort. We reported topline data from the dose escalation stage of the Phase 1 trial as discussed below in "—Phase 1 clinical trial of CTX-471" and plan to initiate a dose expansion stage in the near.

Overview of non-small cell lung cancer

An estimated 1.8 million people die of lung cancer each year, making lung cancer the leading cause of cancer-related death. Lung cancer accounts for approximately 18% of all cancer deaths globally. There are an estimated 228,000 newly diagnosed cases of lung cancer and 143,000 deaths in the United States annually. Non-small cell lung cancer, or NSCLC, accounts for approximately 80% - 85% of lung cancer cases. The treatment paradigm for NSCLC has significantly changed over the past few years. Previously patients were primarily treated with radiation therapy or combinations of cytotoxic drugs. Recent advancements have led to the development of targeted therapies based on blockade of alteration in mutated genes, such as the epidermal growth factor receptor, or EGFR, anaplastic lymphoma kinase gene, or ALK, ROS1 or BRAF. Up to two thirds of advanced or metastatic NSCLC patients who are ineligible for or resistant to treatment with targeted therapies have tumors that express PD-L1 and are candidates for checkpoint inhibitor therapies, which lead to significant improvements in progression free survival and overall survival compared to standard chemotherapy. Despite the availability of these therapies, the prognosis in NSCLC remains poor, with an overall five-year survival for all patients diagnosed with NSCLC of 19%. In the KEYNOTE-042 trial in treatment naïve metastatic NSCLC patients, conducted by Merck from Dec 2014 to March 2017, treatment with pembrolizumab as monotherapy led to partial responses in 27% of patients and complete responses in 0.5%. The duration of response in the majority of the patients was less than one year. We believe there remains significant unmet medical need in this patient population that could be addressed with novel antibody therapeutics.

Role of CD137 in immunology

CD137, also known as 4-1BB and TNFRSF9, is an inducible co-stimulatory receptor expressed on T-cells and NK cells. Activation of CD137 triggers a signaling cascade that results in upregulation of antiapoptotic molecules, cytokine secretion and enhanced cell killing function. On NK cells, CD137 signaling can increase antibody-dependent cell-mediated cytotoxicity, or ADCC.

When antigen-presenting cells, such as dendritic cells, express CD137L or 4-1BBL, the natural ligand for CD137, they induce increases in the levels of CD137 on T-cells. Tumors with a high tumor mutation burden are enriched in these antigen-presenting cells and such tumors represent promising opportunities to improve on standard of care checkpoint inhibitors by adding antibody therapies directed against CD137.

Historically, across preclinical cancer models, agonist antibodies targeting CD137 have been immunotherapeutic agents that showed great promise. In the clinic, however, these agents have been hampered, in part by dose-limiting toxicities, as seen with urelumab, and, in part by weak agonist activity, as seen with utomilumab .

Our solution, CTX-471

CTX-471 is a fully human, IgG4 monoclonal antibody that is an agonist of the CD137 receptor. We selected CTX-471 from among a panel of CD137 antibodies based on multiple preclinical parameters. The CD137 antigenic site recognized by CTX-471 does not block the binding of CD137 ligand and is differentiated from the site recognized by CD137 antibodies from competitors. We designed and made the antibody using different backbones and chose to use a human IgG4 backbone for CTX-471 to enable engagement of Fc receptors $Fc_{\gamma}RI$ and $Fc_{\gamma}RIIb$ to facilitate CD137 cross-linking while avoiding binding to $FC_{\gamma}RIIIa$ and depletion of immune effector cells through ADCC.

Identification through functional screening

We evaluated a panel of anti-CD137 antibodies as potential candidates for CTX-471 and used a series of *in vitro* and *in vivo* functional assays to screen for the best candidate. One of the most stringent assays was antitumor activity in a CT26 mouse colon carcinoma model in which tumors were allowed to grow to 500 mm^3 before CTX-471 candidates were administered. Tumors of this size are generally considered futile to treat and are highly resistant to monotherapy with other immuno-oncology therapies such as checkpoint inhibitors.

Figure 3. Preclinical antitumor activity evaluation of CTX-471 was conducted in mice with 500 mm^3 CT26 tumors

We observed that multiple CTX-471 candidates exhibited activity treatments in this model, leading to the complete eradication of these large tumors when dosed as monotherapy. Certain antibody candidates exhibited greater activity than others and there was not a strict correlation between potency for the CD137 antigen and antitumor activity. We selected the antibody candidate that became CTX-471 based on a combination of *in vivo* and *in vitro* properties. We also tested antibodies that target PD-1, PD-L1, CTLA-4 and OX-40 in the CT26 model alongside CTX-471 and observed that these antibodies failed to generate similar responses in this model.

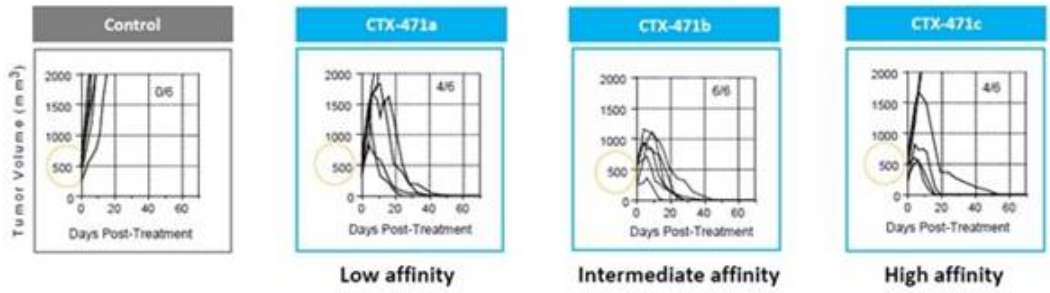


Figure 4. CTX-471a, CTX-471b and CTX-471c are three CD137 agonistic antibodies with low, intermediate and high affinity to CD137 respectively. Four groups of CT-26 syngeneic mice models were dosed with control antibody, CTX-471a, CTX-471b and CTX-471c. Treatment initiated when tumors reached 500 mm3. CTX-471b exhibited the most activity, eradicating tumors in 6/6 mice, followed by CTX-471a and CTX-471c, which eradicated tumors in 4/6 mice each, and none in the control group.

Immunoregulatory role

Treatment of mice with CTX-471 stimulated long-term immunological memory. In order to assess the long-term immunological memory, we tested tens of mice cured of their initial tumors by CTX-471 monotherapy to a re-challenge with the same tumor. Upon a re-challenge, these mice have all demonstrated resistance to establishment of new tumors. To investigate whether this observed effect may be explained by residual CTX-471, we have conducted some of these re-challenge experiments 88 days after dosing, or greater than eight half-lives of CTX-471. We believe that, in mice previously cured of CT-26 tumors by CTX-471, the inability to establish CT-26 tumors is consistent with the ability of CTX-471 to induce long-term immune memory capable of rejecting the reintroduced tumor cells.

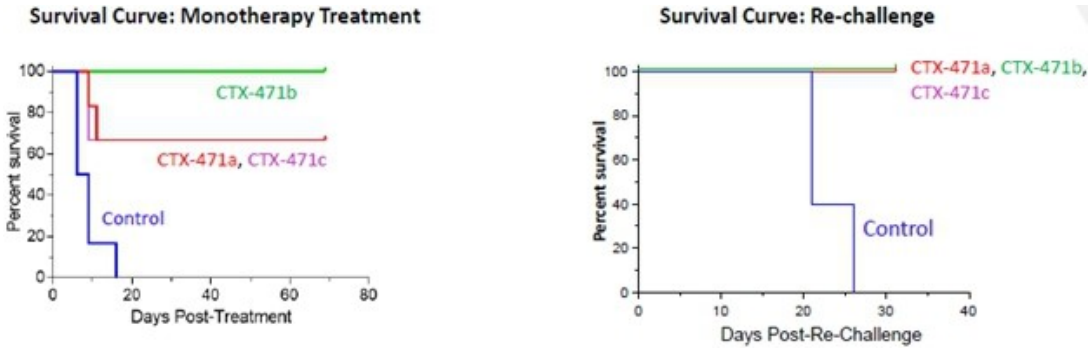


Figure 5. All mice cured by CTX-471 treatment have been resistant to re-challenge with the same tumor

Immune cell depletion experiments showed that the activity of CTX-471 required the presence of CD4+ T-cells, CD8+ T-cells, and NK cells, indicating a coordinated involvement of both innate and adaptive immune cells. Encouragingly, treatment of tumors in mice with CTX-471 led to a marked reprogramming of the immune component of the tumor microenvironment. CTX-471-treated mice had over three times more tumor infiltrating immune cells than control mice. Of the CD8+ T-cells in these tumors, there was a reduction of exhausted T-cells, determined by the reduction of CD8+ T-cells that express both PD-1 and TIGIT, from 43% to 8%. Similarly, treatment with CTX-471 led to a sharp decline in immunosuppressive regulatory T-cells, or Tregs, from 31% to 7%. We also observed that tumors treated with CTX-471 had an approximate two-fold reduction in the number of immunosuppressive tumor-associated macrophages.

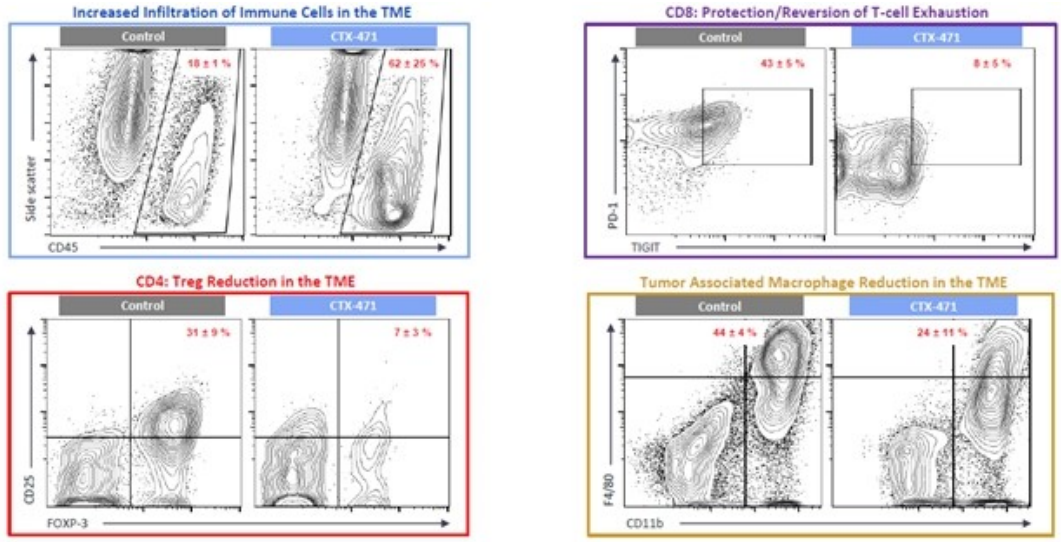


Figure 6. CTX-471 altered the immune composition in the tumor microenvironment

We believe that the ability of CTX-471 to transform the tumor microenvironment by the combined action of immune cell recruitment, alleviation of T-cell exhaustion, suppression of Tregs, and reduction of tumor suppressing macrophages is what drives CTX-471's antitumor activity in mouse models. We believe that CTX-471 has the potential to affect the same aspects of the immune system in cancer patients in the clinic, which could lead to improved patient outcomes.

In addition to testing CTX-471 in the CT-26 syngeneic mouse model described above, we have also tested CTX-471 as a monotherapy in multiple other syngeneic tumor models of different histologies and have observed potent activity, including various levels of tumor eradication. CTX-471 have demonstrated activity and led to tumor eradication in the A20 model of lymphoma, the MC38 model of colon carcinoma, and in the EMT6 model of breast cancer. We believe that this broad biological activity across multiple tumor models of different histologies suggests that CTX-471 might benefit patients with different tumor types.

Combination activity

T-cell-dependent antitumor activity also led to an antitumor response in an adoptive transfer tumor model in mice expressing CT26 cells that were engineered to express human Her2. Her2, also known as human epidermal growth factor receptor 2 and receptor tyrosine protein kinase erbB-2, is overexpressed or amplified in certain aggressive types of breast cancer. Antibodies directed against Her2, such as trastuzumab, marketed as Herceptin® by Genentech, have been approved for the treatment of Her2 expressing breast cancer. Dosing Herceptin was associated with modest activity in this model, slightly reducing the rate of tumor growth. Monotherapy with CTX-471 led to complete responses in three of eight mice. The combination of trastuzumab and CTX-471 led to the complete eradication of tumors in all eight mice and 100% survival at the termination of the experiment at day 64. Depletion of immune effector cells in this model eliminated this activity, highlighting the essential role of T-cells in driving CTX-471 antitumor response.

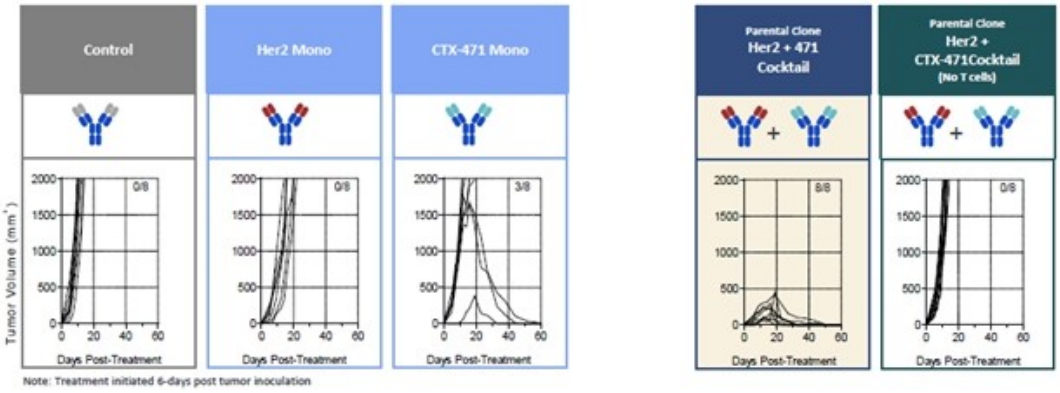


Figure 7. Treatment with a combination of CTX-471 with trastuzumab led to complete eradication of CT26 tumors expressing Her2

Phase 1 clinical trial of CTX-471

We are currently conducting a Phase 1 clinical trial of CTX-471 in adult patients who have achieved three months of stable disease or better after treatment with PD-1/PD-L1 checkpoint therapy and who have subsequently progressed. We selected this population of patients for this trial because multiple clinical trials and meta-analyses have shown that not all patients respond to checkpoint inhibitor therapy due to many possible reasons. By focusing on those that did previously respond to checkpoint inhibitor therapy, we believe that this trial design enriches for patients who have tumors that are capable of being recognized and killed by their immune systems. We believe that disease progression after the initial checkpoint inhibitor response is likely due to an increase in immunosuppressive activity that CTX-471 has the potential to overcome.

This Phase 1 trial is an open-label multiple ascending dose, dose-escalation trial. The Phase 1 trial has two parts: Part 1 is the dose escalation portion and Part 2 is the dose expansion portion of the study. After a period of 28 days to allow checkpoint inhibitors and other drugs to be eliminated from the body, each patient receives CTX-471 by intravenous infusion every two weeks as monotherapy. Disease progression is measured by CT scans every eight weeks. We collect blood samples to assess standard safety biomarkers as well as cytokines and potential pharmacodynamic biomarkers. Baseline tumor biopsies are also collected for retrospective analyses.

The primary objective of the ascending dose portion of the trial is to assess the safety and tolerability of CTX-471 monotherapy in six cohorts at various doses. Following the determination of the safety and tolerability of CTX-471 at various doses, we plan to initiate the dose expansion stage to evaluate CTX-471 in a larger cohort of patients. The goal of the dose expansion cohort is to determine an optimized dose for future Phase 2 clinical trials. Secondary endpoints include measures of overall response rate and progression-free survival, among others. We reported topline data from the dose escalation stage of the Phase 1 trial as discussed below in “—Phase 1 clinical trial of CTX-471” and plan to initiate a dose expansion stage in the near future.

Dosing strategy

In contrast to dosing strategies for other immuno-oncology antibodies, such as checkpoint inhibitors where the goal is often to deliver a dose that is capable of fully inhibiting the receptor at all times, our dose selection for this trial is aimed at binding to only a fraction of the available CD137 receptors. Dosing of an agonist antibody, such as CTX-471, at levels capable of binding to the majority of receptors can lead to inappropriate cell activation and downregulation of the receptor and overall weaker activity.

Agonist antibodies typically trigger their activity through independent binding of each of their two antigen-binding domains to individual receptors on a cell surface. This binding to both receptors at once forces the receptors into close physical proximity. This grouping of receptors that drives receptor activation, especially when the ratio of antibody molecules to receptor molecules is relatively low. As the ratio of antibody to receptor increases, the level of receptor activation increases up to a point above which activation may decrease due to down-regulation of the receptors. This results in a bell-shaped activation curve in which maximal activation occurs at intermediate antibody concentrations.

We observed evidence of the importance of lower receptor occupancy while screening candidate antibodies against CD137. The antibodies with the greatest tumor-killing activity were the ones with intermediate potency. Very high-potency antibodies had weaker antitumor activity.

Consistent with the finding of lower activity at high antibody to receptor levels, we observed that the antitumor activity of CTX-471 appeared to peak at doses between 50 ug and 100 ug in the mouse CT26 tumor model. At the higher dose of 200 ug, the number of complete responses, four out of eight mice, was less than that observed at 100 ug, seven out of eight mice, suggesting that the optimal receptor occupancy had been exceeded. This is also consistent with our observation that intermediate affinity antibodies exhibited greater antitumor activity compared to high affinity antibodies.

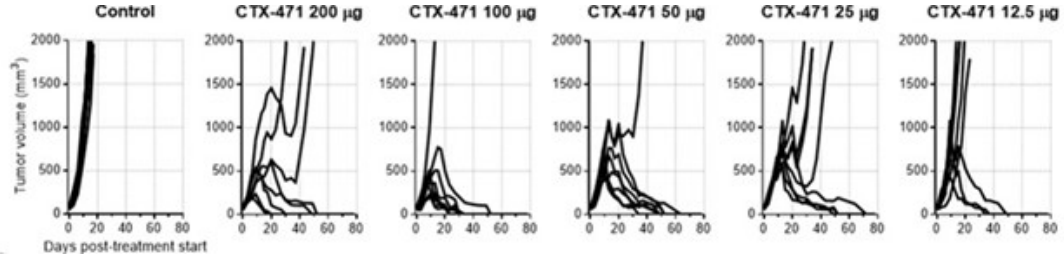


Figure 8. Antitumor activity of CTX-471 is optimized at intermediate dose and decreased at the highest dose level

Our findings are consistent with those reported for an agonist antibody against OX40, another immune target in oncology. Thus, for many agonist antibodies, it is likely that both intermediate affinities and intermediate doses will deliver optimal activity.

Phase 1 clinical trial data as of May 24, 2020

We are conducting a Phase 1 trial of CTX-471 in patients with metastatic or locally advanced solid tumors whose tumors have progressed while receiving an approved PD-1 or PD-L1 inhibitor after a period of stable disease. The Phase 1 study has two parts. Part 1 of this trial is a dose escalation and Part 2 of the trial is dose expansion. The goal of the Part 1 of the study is to evaluate the safety and tolerability of CTX-471 and to determine the recommended dose for Part 2 of our Phase 1 study. The goal of the Part 2 dose expansion of the study is to obtain certain efficacy data for CTX-471.

Our selection of doses in Part 1 of the trial was informed by multispecies pharmacokinetics and by the intent to select doses capable of maintaining receptor occupancy between 20% and 80% in tumors.

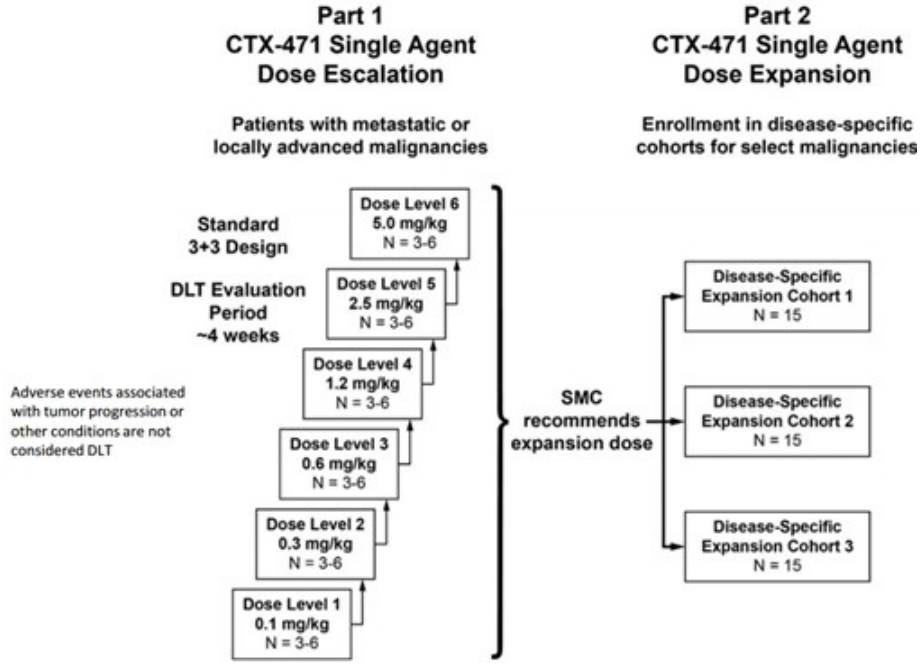


Figure 9. Design of the multiple ascending dose escalation Phase 1 trial of CTX-471

As of May 24, 2020, 19 patients have received at least one dose of CTX-471 in dosing cohorts 1 through 4. The number of patients in cohort 4 was expanded to six due to a dose-limiting toxicity.

Cohort	Cohort 1 0.1 mg/kg	Cohort 2 0.3 mg/kg	Cohort 3 0.6 mg/kg	Cohort 4 1.2 mg/kg	Total
Enrolled	3	3	6	7	19

Figure 10. The number of patients dosed with CTX-471 as of May 24th, 2020

CTX-471 has been observed to be generally well-tolerated. There have been six serious adverse events reported with two of those adverse events considered treatment-related. The treatment related serious adverse events are one hypoxia event that resolved quickly and one immune thrombocytic purpura event that also resolved. There have been two events of thrombocytopenia that were dose-limiting toxicities in Cohort 4 at 1.2 mg/Kg. Based on these results, 0.6 mg/kg was determined to be the maximum tolerated dose. We have expanded the number of patients receiving this dose to collect additional safety data.

While the goal of Part 1 of our study is to evaluate the safety of CTX-471, we have also collected data from these patients to evaluate the pharmacokinetics of CTX-471, the potential development of anti-drug antibodies of CTX-471, and to obtain certain efficacy data, based on the objective response rate, or ORR, as per Response Evaluation Criteria in Solid Tumors, RECIST. Accordingly, patients who have enrolled in Part 1 of our Phase 1 study have been evaluated every eight weeks by imaging techniques, such as MRI or CT, until disease progression or withdrawal from the study, in order to collect such data.

Of the nineteen patients who have been enrolled in the study, 11 patients have reached the first tumor evaluation visit at Week 9. Six of those 11 patients who have reached the first tumor evaluation had stable disease (55%). Two of those patients have been on CTX-471 for over 8 months, one with NSCLC and one with melanoma. The patient with melanoma has been on CTX-471 for more than 10 months and has had greater than a 24% decline in the total size of his measured metastatic tumors. Three of the four patients to reach Week 17 had stable disease, and of the 19 patients enrolled in the study, 8 patients are continuing to receive therapy with CTX-471 in the Phase 1 study. None of the patients enrolled in the Part 1 of the study had a complete response or a partial response by RECIST.

We have preliminary pharmacokinetic data from the study and these data have confirmed our receptor occupancy modeling. Based on this modeling and the correlation of the observed pharmacokinetics with our predictions, we estimate that a dose of 0.3 mg/kg would lead to a peak receptor occupancy of approximately 50% and a dose of 0.6 mg/kg would lead to a peak receptor occupancy of approximately 70%.

In the second half of 2020 we plan to enroll patients in Part 2, the dose expansion stage of this Phase 1 trial. The dose expansion stage will inform the Phase 2 recommended dose.

If our Phase 1 of CTX-471 as monotherapy is successful, we also plan to initiate a second Phase 1 trial of CTX-471 in combination with trastuzumab, marketed as Herceptin® by Genentech, in Her2 positive tumors, and with cetuximab, marketed as Erbitux® by Eli Lilly, in EGFR positive tumors.

Potential market opportunity for CTX-471

In preclinical studies, CTX-471 was associated with antitumor activity as a monotherapy in multiple syngeneic tumor models, including colon carcinoma, lymphoma, and breast cancer. This broad biological activity suggests that CTX-471 may have benefit as a therapy for patients with different tumor types.

We seek to maximize the potential value of each of our product candidates, if any, across all indications in which it may demonstrate promising clinical results and receives marketing approval. While we have not selected a specific target indication for CTX-471, as an example for the potential size of the market opportunity for CTX-471 in one of those potential target indications, we have modeled the positioning of CTX-471 as a second line therapy for advanced/metastatic NSCLC.

In the United States, there are 282,000 lung cancer patients each year, of those 80-85% have NSCLC. Patients with stage 0-2 NSCLC are treated with surgery or a combination of surgery and chemotherapy, which are generally effective. However, some patients will progress to the later stages of the disease, and other patients already have locally advanced or metastatic disease at the time of diagnosis. These are approximately 90,000 patients with advanced/ metastatic NSCLC per year who are in great need of pharmacological treatment.

In the 1st line setting, the majority of the advanced/metastatic NSCLC patients without defined point mutations are treated by either PD-1 blocker alone or PD-1 blocker combination with chemotherapy, depending on PD-1 expression levels. Patients who do not respond to the 1st line settings have very limited therapeutic options, mostly comprising chemotherapy combinations, with or without checkpoint blockers. We estimate that there are approximately 36,000 patients in this category who will progress after 1st line treatment to 2nd line setting as seen in the schema below.

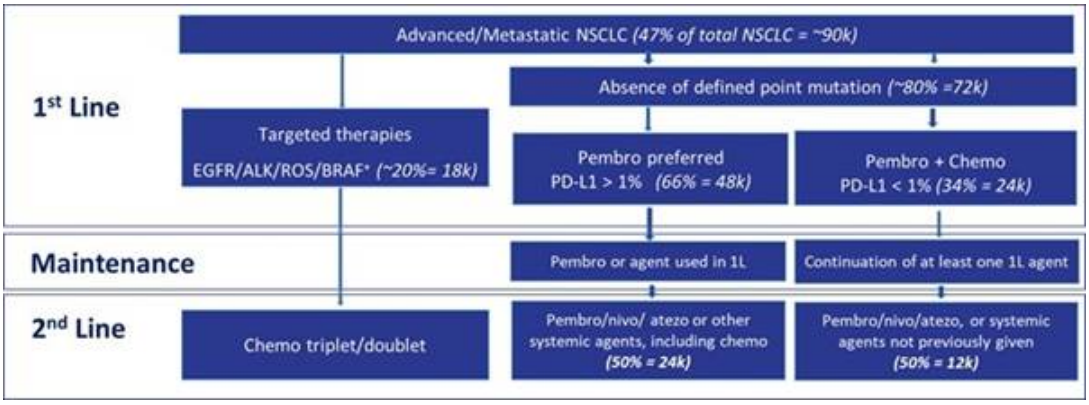


Figure 10. Estimate of the number of treatment-eligible advanced/metastatic NSCLC patients based on NCCN guidelines and other Compass analysis.

CTX-8371, a PD-1 x PD-L1 bispecific antibody

CTX-8371 is a bispecific antibody that binds to both PD-1 and PD-L1. CTX-8371 outperforms PD-1, PD-L1, and combinations of the two to activate T-cells in *in vitro* assays. In mouse xenografts, treatment with CTX-8371 led to significantly greater tumor growth control and longer survival than the combination of a PD-1 and PD-L1 inhibitor. We expect to initiate IND-enabling studies on CTX-8371 in the third quarter of 2020.

Figure 11. CTX-8371 is a PD-1 x PD-L1 bispecific antibody

Overview of PD-1 and PD-L1 checkpoint inhibitors

PD-L1 is a surface protein that is overexpressed by over 35% of certain types of cancer, such as melanoma, hepatocellular carcinoma, colorectal cancer, and NSCLC. Binding of PD-L1 to its receptor, PD-1, on immune T-cells leads to suppression of cytotoxic CD8+ T-cells preventing immune attack of the tumor. Multiple inhibitors of PD-1 and PD-L1 have been approved as therapies for a broad range of tumors including: melanoma, NSCLC, small cell lung cancer, or SCLC, head and neck squamous cell cancer, or HNSCC, renal cell carcinoma, or RCC, bladder cancer; gastric cancer, cervical cancer; and other cancers with microsatellite instability or mismatch repair deficiency. While PD-1/PD-L1 checkpoint therapies have resulted in remarkable clinical efficacy across multiple cancer types, their efficacy, even in tumors with high immunogenicity, is limited to approximately 20% of patients. Nevertheless, sales of checkpoint therapies in 2019 were estimated to be total $22 billion. There is no marketed therapy that combines inhibition of both PD-1 and PD-L1 in the same molecule.

Discovery and preclinical activity of CTX-8371

The desire to improve the efficacy of PD-1/PD-L1 inhibitors has sparked multiple attempts to create bispecific antibodies in which one antigen binding site targets PD-1 or PD-L1 and the other targets immuno-oncology receptors such as LAG-3 or TIM-3. In contrast to those bispecific efforts described by others that have focused on a single pair of antigen-binding domains at a time, we have applied our StitchMabs^{TM} technology to broadly screen for pairs of bispecific antigen-binding domains with the highest potential to generate antitumor activity. Our efforts were enabled not only by the StitchMabs^{TM} technology, but also by our investment in generating a broad portfolio of selective antibodies to 40 potential immune targets across the innate and adaptive immune system.

We designed our combinatorial screen such that one antigen-binding domain was directed against PD-1, and the other selected from our library of candidate antibodies. We screened these StitchMabs™ bispecific constructs in T-cell activation assays in the presence of PD-L1 expressing cells. Our unbiased screening led us to an antibody that pairs a PD-1 binding domain and a PD-L1 binding domain. This novel bispecific antibody contributed to T-cell activation that outperformed the activation observed in response to treatment with PD-1-only antibodies. We designated CTX-8371 as the bispecific antibody we constructed using our common light chain antibodies having a PD-1 and PD-L1 antigen binding domains.

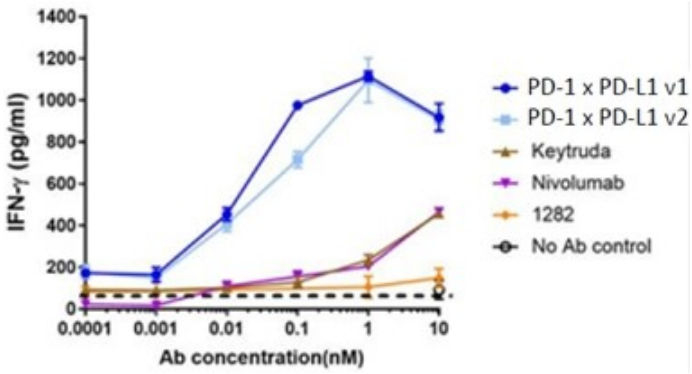


Figure 12. A PD-1 x PD-L1 bispecific antibody outperformed PD-1 antibodies in a T-cell activation assay

The observation that the combination of a PD-1 and PD-L1 antibody into a bispecific antibody would be hundreds to thousands fold more potent than in a T-cell activation assay than a PD-1 antibody alone was unexpected. A simple model would suggest that inhibiting either PD-1 or PD-L1 should have approximately equal effects in this assay and there would be no advantage to inhibiting both. Further investigation into the mechanism of CTX-8371 found that it led to T-cell activation through four mechanisms:

- preventing PD-L1 to PD-1 binding, thus relieving the immunosuppressive PD-1 signal;
- bridging the connection between the PD-L1 expressing tumor cell and the PD-1 expressing T-cell, potentially facilitating T-cell engagement;
- triggering the shedding of the extracellular domain of PD-1 receptors from the surface of T-cells resulting in a reduction in the levels of PD-1 on T-cells; and
- increasing the pool of free CD80 on tumor cells making it available to bind and activate the CD28 T-cell co-stimulatory receptor.

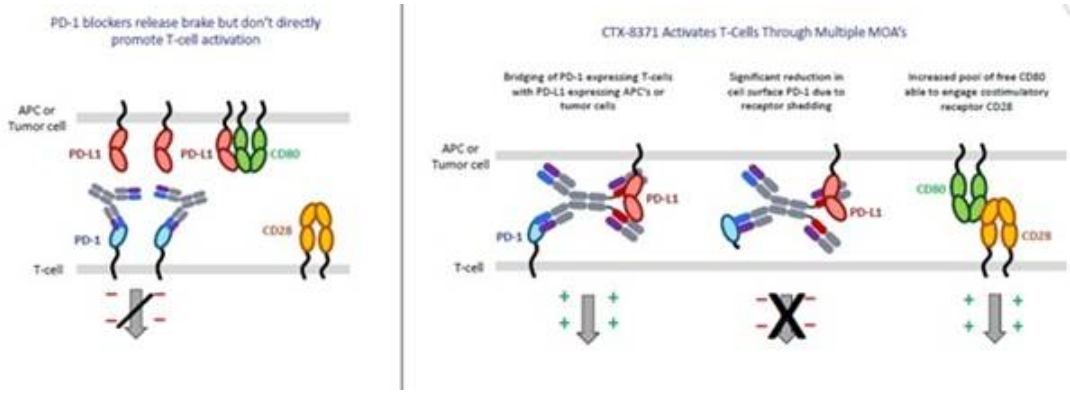


Figure 13. Differentiated mechanism of action of CTX-8371 drives enhanced T-cell activation

We also found that the greater activity of CTX-8371 in our T-cell activation assay compared to PD-1 inhibition also extended to PD-L1 inhibition. Furthermore, CTX-8371 was associated with significantly more antitumor acivity in a murine B16F10 melanoma model than was monotherapy with either a PD-1 inhibitor or a PD-L1 inhibitor or combination of both. Tumor growth in monotherapy-treated mice and in the combination PD-1 and PD-L1-treated mice was slowed to approximately half that observed with tumors in untreated mice. In contrast, tumor growth was essentially stopped by the CTX-8371 bispecific antibody. Treatment with CTX-8371 resulted in improved overall survival in this model and cured three of eight mice, such that their tumors were completely eradicated.

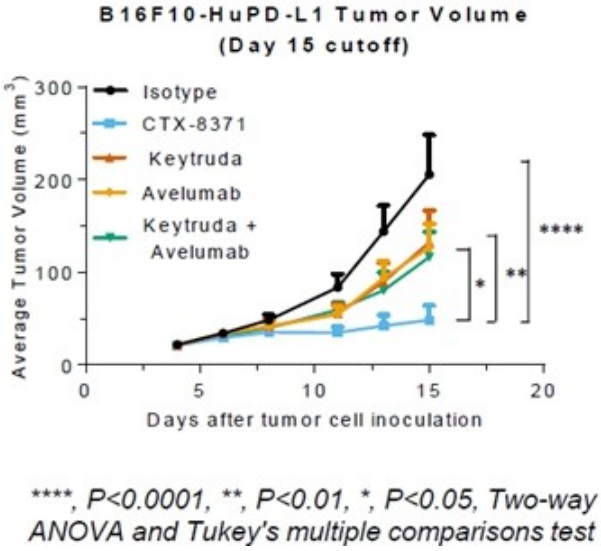


Figure 14. Tumor growth inhibition was improved when treating mice with CTX-8371 compared to treating them with monoclonal antibodies that inhibited either PD-1, PD-L1, or the combination of PD-1 and PD-L1

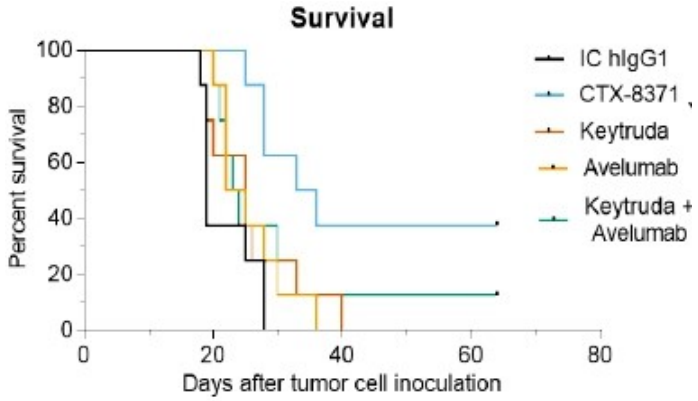


Figure 15. Dosing with CTX-8371 led to improved overall survival in a B16F10 melanoma model compared to either PD-1- or PD-L1- checkpoint inhibitors or to the combination of both

CTX-8371 also reduced tumor growth in the syngeneic MB49 bladder cancer model and in the syngeneic EMT-6 breast cancer models which are known to be non-responsive to checkpoint blocker treatments.

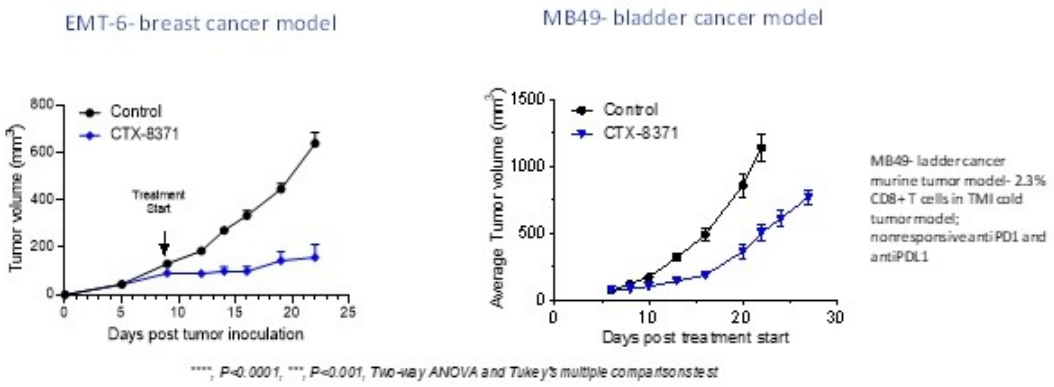


Figure 16. Dosing with CTX-8371 led to tumor growth inhibition in the syngeneic EMT-6 breast cancer model and in the syngeneic MB49 bladder cancer model

We plan to initiate IND-enabling studies with CTX-8371 in the third quarter of 2020 with the goal of initiating its clinical testing in the second half of 2021 following submission of an IND.

Our innate cell engager platform

In addition to our work developing promising inhibitors of the adaptive immune system such as CTX-8371, we have also focused on discovering bispecific activators of the innate immune system. Specifically, we hypothesized that a bispecific antibody with one antigen-binding domain that recognized a tumor antigen and another binding domain that bound to and activated NK cells would lead to highly effective NK cell-dependent killing of tumor cells.

Using our StitchMabs^{TM} technology, we generated a panel of bispecific candidates by combining a BCMA binding domain with common light chain antibodies that targeted a series of antigens expressed on NK cells. Functional screen led us to the identification of NKp30 binding domain as the anchor for an innate engager bispecific construct. NKp30, also known as natural cytotoxicity factor 3 and CD337, is a stimulatory receptor on NK cells and on a subset of T-cells called gamma delta T-cells or γδT-cells. Stimulation of NKp30 leads to activation of NK cell and γδ T-cells.

When dosing *in vivo* models with bispecifics created using this NKp30 binding domain and various tumor antigen-specific binding domains, we observed that this treatment led to antitumor activity. These bispecifics are able to bypass the normal mechanism of antibody-directed NK cell activation and killing by eliminating the requirement for antibodies to bind to CD16a, also known as the FcγRIIIa receptor, on NK cells, thereby, these bispecifics activate NK-cells independently of CD16a binding. This is important because it allows these cell engagers to avoid the gradual loss of activity associated with the shedding of CD16a by proteases, a resistance mechanism known to be used by tumors. By directly linking tumor cells to NK cells with or without CD16a engagement, bispecifics created using NKp30 function as antigen-specific activators of the innate immune system.

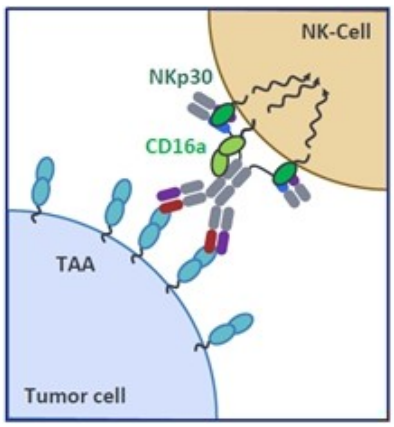


Figure 17. Proposed mechanism of NKp30 bispecific directed tumor cell killing

CTX-8573, a NKp30 x BCMA bispecific antibody

CTX-8573 is the first bispecific product candidate from our NKp30 innate cell engager platform which we have decided to advance. CTX-8573 is a bispecific antibody designed to activate NK cells and direct the killing of cells expressing BCMA. CTX-8573 functions by activating NK cells while bridging the connection between BCMA-expressing cells and NK cells, triggering cell lysis. We intend to begin IND-enabling studies of CTX-8573 in the first half of 2021.

Figure 18. CTX-8573, a BCMA + NKp30 bispecific antibody

CTX-8573 led to efficient NK cell killing of H929 multiple myeloma cells with a potency that was approximately twenty-fold better than that of a parental BCMA monoclonal antibody. We also tested the importance of CD16a-dependent binding to the potency of cell killing activity through the generation of variants of CTX-8573 with differences in glycosylation. It is known that binding of antibodies to CD16a is highly sensitive to specific glycosylation modifications on antibodies. Antibodies lacking all glycosylation, or aglycosylated antibodies, are least efficient at activating NK cells through CD16a binding. In contrast, antibodies that lack only the core fucose sugar residues, or afucosylated antibodies, are the most efficient. We observed a similar trend in potencies when these glycosylation modifications were tested with our NKp30 x BCMA bispecifics. CTX-8573, the afucosylated bispecific, had the highest cell killing potency. These results suggest that although CD16a binding is not essential for these bispecifics to activate NK cell-dependent cell killing, binding to CD16a can enhance it. Similar patterns in cell killing potency were observed with other BCMA-expressing tumor cells while neither CTX-8573 nor a BCMA monoclonal antibody led to killing of cells not expressing BCMA.

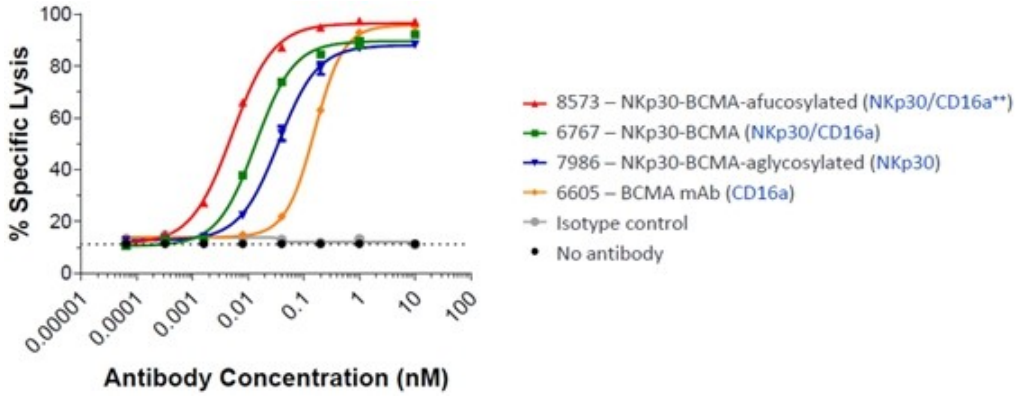


Figure 19. CTX-8573 killed H929 tumor cells with a potency approximately twenty-fold higher than that of a BCMA antibody

The activity against H929 cells seen *in vitro* also extended to *in vivo* experiments in a humanized mouse model of disseminated multiple myeloma with H929 cells. Mice lacking NK cells and those treated with an isotype control antibody all died before day 45. Treatment with CTX-8573, the afucosylated NKp30 x BCMA bispecific, led to long-term survival with all mice surviving beyond day 130.

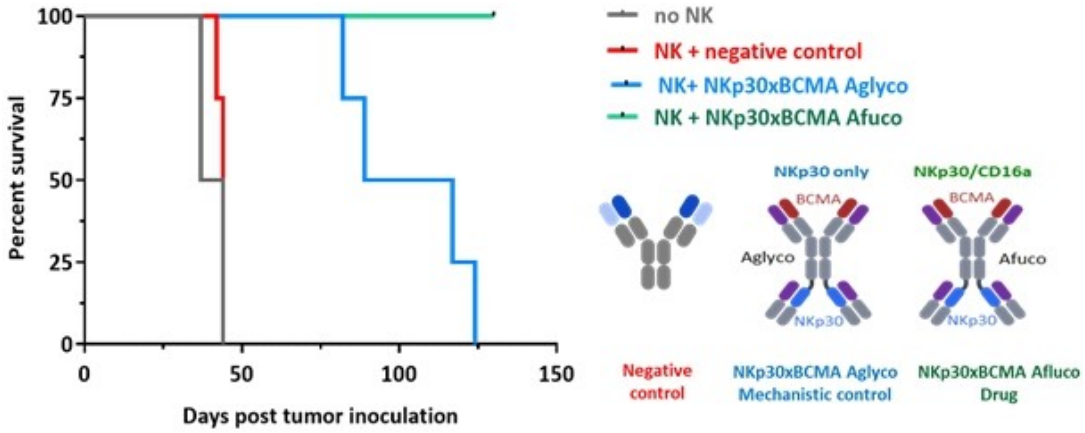


Figure 20. Treatment with CTX-8573 led to long-term survival in a H929 tumor model

We intend to initiate IND-enabling studies with CTX-8573 in the first half of 2021. We are also applying the knowledge gained from CTX-8573 to the development of other NKp30 bispecific antibodies where the BCMA antigen binding domain is replaced with antigen-binding domains against other tumor antigens.

Potential benefit of CTX-8573 in autoimmune diseases

Although the preclinical data with CTX-8573 in multiple myeloma is compelling, there are a number of other BCMA-directed therapies in development for multiple myeloma including CAR-T cells, bispecifics, and antibody drug conjugates that are already in intermediate or late clinical development stages. Most of these approaches show promise when BCMA levels are high, as is the case for multiple melanoma patients, but they fall short of delivering benefit when BCMA levels are low. Additionally, most of these approaches are associated with certain toxicities such as cytokine release storm or broad cytotoxicity, rendering them acceptable therapies for oncology but limit its use outside of oncology in a chronic setting. We believe that CTX-8573 is differentiated from other BCMA product candidates by its ability to deplete not only high but also intermediate and low expressing BCMA plasma cells, and by its selectivity, which we believe may result in a more favorable tolerability profile. These differentiated characteristics make it suitable to serve as a therapeutic agent for a set of severe autoimmune disease indications where pathogenic cells may have lower levels of BCMA and a safety profile is instrumental.

A number of autoimmune diseases are caused by antibody-mediated immune attack on healthy tissues. These diseases include, among others, myasthenia gravis, immune thrombocytopenia and pemphigus vulgaris. A common thread between these diseases is the high level of autoimmune antibodies that are secreted by plasma cells. Current therapeutic approaches for these diseases are focused on removal of these antibodies either physically by techniques such plasmapheresis or by therapies designed to accelerate the destruction of circulating antibodies. We believe that eliminating the plasma cells, which are the source of these antibodies, may be a more effective therapeutic approach.

Plasma cells can be generally divided into two distinct categories: short-lived plasma cells with a lifespan of three to five days and long-lived memory plasma cells able to secrete antibodies for months, years or a lifetime. We believe CTX-8573 has the potential to lead to the destruction of both types of plasma cells resulting in rapid reductions in the number of cells actively secreting antibodies and removal of long-term memory plasma cells which has the potential to result in disease-modifying therapeutic benefit.

Plasma cells produce two types of antibodies, IgM and IgG. IgM antibodies are produced during the initial antibody response to novel antigens. Later, plasma cells secrete IgG antibodies, which are more highly refined for specific antigens. In a humanized mouse model containing human BCMA-expressing plasma cells, treatment with CTX-8573 led to a significant reduction in the serum levels of human IgM.

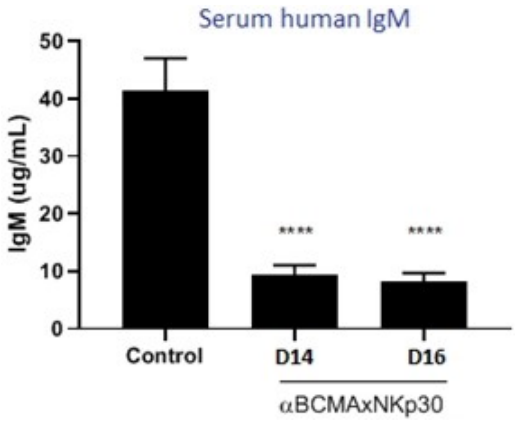


Figure 21. CTX-8573 leads to significant reductions in serum levels of human IgM

In contrast to other cell engagers that demonstrate limited activity against cells expressing low antigen levels, CTX-8573 maintains good level of specific cell killing activity even when antigen levels drop below 5,000 copies per cell.

The ability of CTX-8573 to induce selective killing of cells expressing low BCMA levels can extend its utility to selectively deplete antibody-producing plasma cells. The selective depletion of antibody-producing cells, not only in the periphery but also in the bone marrow, has been a long sought-after goal of novel therapies developed for severe autoimmune diseases mediated by pathogenic antibodies.

We believe that anti-BCMA antibodies lack the potency to lead to the destruction of sufficient numbers of plasma cells, especially those expressing lower levels of BCMA. Conversely, more potent products such as BCMA-antibody drug conjugates, CAR-T cells and BCMA x CD3 BiTE molecules, may have the necessary potency, but that potency is associated with toxicities which may be acceptable in oncology, but not in individuals with autoimmune disease. We believe the ability of CTX-8573 to direct NK cell-dependent destruction of plasma cells gives our BCMA product candidate the proper balance between cell killing activity and limited toxicity.

Broad potential of our innate cell-engager platform

We have created a series of early-stage product bispecific candidates that couple tumor antigen-binding domains to our NKp30 innate cell targeting domain. These candidates include:

- **NKp30 x CD20 bispecifics.** We have shown in animal models that CD20 x NKp30 bispecifics lead to rapid and sustained reductions in the levels of both circulating B cells and B cells in the spleen.

- **NKp30 x Her2 bispecifics.** Through our antibody diversity platform, we have created and fully characterized approximately 50 Her2 binding domains with a wide range of epitope diversity. Each of the bispecific constructs created with these domains has cell lysis activity that compares favorably against trastuzumab, a Her2 specific antibody marketed as Herceptin® by Genentech against breast cancer cells expressing high levels of Her2. However, unlike trastuzumab, our NKp30 bispecifics maintain this high potency against breast and colon tumor cells expressing lower levels of Her2.

License Agreement

We are successor to an amended and restated collaboration agreement with Adimab, LLC, or Adimab, dated February 11, 2015, as amended. This agreement relates to our collaboration with Adimab for certain antibodies for development and commercialization as biopharmaceutical products, including our lead product candidate, CTX-471. We were granted an exclusive option to license antibodies under the agreement, which we exercised with respect to CTX-471, through which we gained an exclusive license to certain Adimab patents and know-how related to CTX-471. We are required to use commercially reasonable efforts to develop, seek marketing authorization for, launch and commercialize the licensed antibody. We are required to make payments upon achievement of development milestones that, as of December 31, 2019, amounted to $3.5 million, of which we have already made $1.5 million milestone payments and we have additional potential payments due in the amount of $2.0 million. In addition, we are required to pay royalties at rates ranging in the single digits as a percentage of future net sales within a specified term from the first commercial sale.

The agreement will expire on a country by country basis on the expiration of the last royalty term for a product in the particular country, which commences from the first commercial sale of such product in such country until the twelve-year anniversary of such sale, in which case the license for any licensed antibody will automatically convert to be perpetual, irrevocable, non-exclusive and fully-paid in such country. The agreement may also be terminated by the parties for uncured material breach by the other party, and we may also terminate the agreement upon three months prior written notice to Adimab.

Intellectual Property

Overview

We strive to protect the proprietary technology, inventions, and know-how to enhance improvements that are important to the development of our business, including seeking, maintaining, and defending patent rights. We also rely on trade secrets and know-how relating to our proprietary technology platform, on continuing technological innovation and on in-licensing opportunities to develop, strengthen and maintain the strength of our position in the field of antibody therapeutics that may be important for the development of our business. We additionally may rely on regulatory protection afforded through data exclusivity, market exclusivity and patent term extensions where available.

Our success depends in part on our ability to: obtain and maintain patent and other protections for commercially important technology, inventions and know-how related to our business; defend and enforce our patents; preserve the confidentiality of our trade secrets; and operate without infringing the valid enforceable patents and intellectual property rights of third parties.

Our ability to stop third parties from making, using, selling, offering to sell, or importing our products depends in large part on the extent to which we have rights under valid and enforceable licenses, patents, or trade secrets that cover these activities. In some cases, these rights may need to be enforced by third party licensors. With respect to company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be useful in protecting our commercial products and methods of manufacturing the same. For more information, please see “Risk Factors—Risks Related to Our Intellectual Property.”

We seek to protect our proprietary position by, among other things, filing patent applications in the United States and internationally in certain jurisdictions where it is available. For example, we file U.S. and selected foreign patent applications related to our proprietary technology, inventions, and improvements that are important to the development of our business. We also intend to seek patent protection, or rely upon trade secret rights, to protect other technologies that may be used to discover and validate targets and that may be used to identify and develop novel products or improvements thereof. We seek protection, in part, through confidentiality and proprietary information agreements.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional application which matures into a granted patent. A U.S. patent also may be accorded a patent term adjustment, or PTA, under certain circumstances to compensate for delays in obtaining the patent caused by the U.S. Patent and Trademark Office. In some instances, such a PTA may result in a U.S. patent term extending beyond 20 years from the earliest date of filing a non-provisional patent application. In addition, in the U.S., the term of a U.S. patent that covers an FDA approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any of our issued patents in any jurisdiction where these are available; however, there is no guarantee that the applicable authorities, including the FDA in the U.S., will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

Patent Protection

For all patent applications, we determine strategy for claim scope on a case-by-case basis, taking into account advice of counsel and our business model and needs. We file patents containing claims for protection of all useful applications of our proprietary technologies and any products, as well as all new applications and/or uses we discover for existing technologies and products, based on our assessment of their strategic value. We continuously reassess the number and type of patent applications, as well as pending and issued patent claims to ensure that maximum coverage and value are obtained for our processes and compositions, given existing patent office rules and regulations. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs.

Our patent estate includes patent applications with claims relating to our product candidates, methods of use and manufacturing processes, and claims for potential future products and developments. We have 91 patent applications pending in the United States and foreign jurisdictions relating to CTX-471, CTX-8371, CTX-8573 and other discovery and research programs. We have five patents which have issued in the United States related to our CTX-471 program.

We own six pending patent families with five issued U.S. patents, five U.S. Utility or provisional patent applications, two Patent Cooperation Treaty, or PCT, patent applications and 25 patent applications in foreign jurisdictions, including Argentina, Australia, Brazil, Canada, Chile, China, Colombia, Eurasian Patent Office, Egypt, Europe, Israel, India, Japan, Korea, Mexico, Malaysia, New Zealand, Peru, Singapore, Thailand, Taiwan, and South Africa related to our CD137 agonist antibody therapeutic platform including, but not limited to, our CTX-471 therapeutic candidate. Patents that grant from these patent families are generally expected to start to expire in 2038, subject to possible patent term extension.

We own two pending patent families with two U.S. Utility or provisional patent applications, one PCT patent application, and two patent applications in foreign jurisdictions, including Argentina and Taiwan related to our PD-1/PD-L1 bispecific antibody therapeutic platform including, but not limited to, our CTX-8371 therapeutic candidate. Patents that grant from these patent families are generally expected to start to expire in 2039, subject to possible patent term extension.

We own 11 pending patent families with 13 U.S. Utility or provisional patent applications, one PCT patent application and one patent application in a foreign jurisdiction, including Taiwan related to our NKp30 bispecific antibody therapeutic platform including, but not limited to, our CTX-8573 therapeutic candidate. Patents that grant from these patent families are generally expected to start to expire in 2039, subject to possible patent term extension.

We own, or have an ownership interest in, 12 pending patent families with four U.S. Utility or provisional patent applications, four PCT patent applications, and 17 patent applications in foreign jurisdictions including Australia, Canada, China, Europe, Hong Kong, and Japan related to our discovery and research programs. Patents that grant from these patent families are generally expected to start to expire in 2036, subject to possible patent term extension.

We own eight pending patent families with six U.S. Utility or provisional patent applications, two PCT patent applications, and three patent applications in foreign jurisdictions including China, Europe, and Japan related to our antibody and display programs including, but not limited to, common light chains mammalian display platforms and StitchMabs™. Patents that grant from these patent families are generally expected to start to expire in 2039, subject to possible patent term extension.

Trademark Protection

We have filed for and obtained trademark protection in the U.S., China, Europe and Japan for the COMPASS THERAPEUTICS word mark for goods and services.

We have filed for and obtained protection in China for the Compass Therapeutics logo in China for goods and services.

We have filed for trademark protection of the StitchMabs word mark in the U.S. for goods and services.

Trade Secret Protection

Finally, we may rely, in some circumstances, on trade secrets to protect our technology. 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. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For further information, please see "*Risk Factors—Risks Related to Our Intellectual Property*."

Competition

The biotechnology and pharmaceutical industries, and the immuno-oncology subsector, are characterized by rapid evolution of technologies, fierce competition and strong defense of intellectual property. We believe that our programs, including CTX-471, CTX-8371, CTX-8573 and our platform technologies, including our StitchMabs platform and our NKp30 platform, programs, technology, knowledge, experience and scientific resources provide us with competitive advantages, but we also face competition from pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others. Our competitors include larger and better funded biopharmaceutical, biotechnology and therapeutics companies, including companies focused on cancer immunotherapies, such as AbbVie, Amgen, Inc., AstraZeneca plc, Bristol-Myers Squibb Company, or BMS, Eli Lilly, Genentech, Inc., GlaxoSmithKline PLC, Johnson & Johnson, Merck & Co., Inc., Merck KGaA, Novartis AG, Pfizer Inc., Roche Holding Ltd and Sanofi S.A. Moreover, we may also compete with smaller or earlier-stage companies, universities and other research institutions that have developed, are developing or may be developing current and future cancer therapeutics.

Product candidates that we successfully develop will compete with a range of therapies that are currently approved and any new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products. Currently marketed oncology drugs and therapeutics range from traditional cancer therapies, including chemotherapy, to antibody-drug conjugates, such as Genentech Inc.'s Kadcyla, to immune checkpoint inhibitors targeting CTLA-4, such as BMS' Yervoy, and PD-1/PD-L1, such as BMS' Opdivo, Merck & Co.'s Keytruda and Genentech's Tecentriq, to T cell-engager immunotherapies, such as Amgen's Blincyto. In addition to these marketed therapies, numerous compounds are in clinical development for the potential treatment of cancer. In addition, we are exploring CTX-8573 for the treatment of severe autoimmune indications, for which there are several approved and marketed products that CTX-8573 may compete with, if approved, including Alexion's Soliris and Roche's Rituxan.

If we are successful in advancing one or more of our product candidates toward registrational studies and filing a BLA or BLAs, and if we are successful at obtaining approvals from the FDA or any other regulatory agency to market one or more of our product candidates, then the availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. Our competitors, who may be successful at obtaining marketing approval from the FDA or other regulatory approval for their products prior to us obtaining marketing approval for our product candidates, could result in our competitors launching their products sooner and establishing a strong market position before we are even able to enter the market.

Sales and Marketing

We hold worldwide rights to all of our product candidates, which provide us the optionality to grow our internal pipeline independently or partner selected rights to our product candidates in different geographies throughout the world. Subject to receiving marketing approval, we intend to maximize the value of our product candidates by either independently planning to pursue the ultimate commercialization of our products in one or more major geographies by building an internal sales and marketing organization, or by seeking collaborations with third parties with commercialization infrastructure.

At the appropriate time in the future, and if one or more of our product candidates continues to advance successfully in development and enter registrational studies, we plan to build a marketing and sales management organization to create and implement marketing strategies for any product candidates that we would potentially market through our own sales organization and to oversee and support our sales force. The responsibilities of such marketing organization would include developing educational initiatives with respect to approved products and establishing relationships with researchers and practitioners in relevant fields of medicine.

Manufacturing

We do not currently own or operate manufacturing facilities for the production of clinical quantities of our product candidates. We have relied on, and intend to continue to rely on, qualified third-party contract manufacturers to produce our product candidates, including clinical supplies to support our clinical trials. At the appropriate time in the product development process, we will determine whether to establish manufacturing facilities or continue to rely on third parties to manufacture clinical quantities of any products that we may successfully develop. We expect that commercial quantities of any compound and materials for our product candidates, if approved, will be manufactured in facilities and by processes that comply with FDA and other regulations, which may differ from our current clinical supply manufacturers.

Government Regulation

Government authorities in the United States, including federal, state, and local authorities, and in other countries, extensively regulate, among other things, the manufacturing, research and clinical development, marketing, labeling and packaging, storage, distribution, post-approval monitoring and reporting, advertising and promotion, and export and import of biological products, such as those we are developing. In addition, some government authorities regulate the pricing of such products. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

Review and Approval for Licensing Biologics in the United States

In the United States, the FDA regulates biological products under the Federal Food, Drug, and Cosmetic Act, or FDCA, and the Public Health Service Act, or PHSA, and their implementing regulations. FDA approval is required before any biological product can be marketed in the United States. Biological products are also subject to other federal, state, and local statutes and regulations. If we fail to comply with applicable FDA or other requirements at any time during the product development process, clinical testing, the approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any FDA enforcement action could have a material adverse effect on us.

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

- completion of extensive nonclinical laboratory tests and nonclinical animal studies, all performed in accordance with the Good Laboratory Practices, or GLP, regulations;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin and must be updated annually;
- approval by an independent institutional review board, or IRB, or ethics committee representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practices, or GCPs, to establish the safety and efficacy of the product candidate for each proposed indication;
- preparation of and submission to the FDA of a biologics license application, or BLA, after completion of all pivotal clinical trials;
- review of the product application by an FDA advisory committee, where appropriate and if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities where the proposed product is produced to assess compliance with current Good Manufacturing Practices, or cGMP;
- satisfactory completion of any FDA audits of the clinical study sites to assure compliance with GCPs, and the integrity of clinical data in support of the BLA; and
- FDA review and approval of a BLA for a biological product candidate that is safe, pure, and potent prior to any commercial marketing or sale of the product in the United States.

The nonclinical and clinical testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

An IND is a request for authorization from the FDA to administer an investigational biological product to humans in clinical trials. The central focus of an IND submission is on the general investigational plan, the protocol(s) for human trials and the safety of study participants. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical trials. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical trials can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence. The FDA may impose a clinical hold at any time during clinical trials and may impose a partial clinical hold that would limit trials, for example, to certain doses or for a certain length of time.

Clinical Trials

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the inclusion and exclusion criteria, the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical trial site's IRB, before the trials may be initiated and the IRB must monitor the trial until completed. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

The clinical investigation of a biological product is generally divided into three or four phases. Although the phases are usually conducted sequentially, they may overlap or be combined.

Phase 1. The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational product in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness.

Phase 2. The investigational product is administered to a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse side effects and safety risks, and preliminarily evaluate efficacy.

Phase 3. The investigational product is administered to an expanded patient population, generally at geographically dispersed clinical trial sites to generate enough data to statistically evaluate safety, purity and potency, to evaluate the overall benefit-risk profile of the investigational product, and to provide an adequate basis for physician labeling.

Phase 4. In some cases, the FDA may condition approval of a BLA for a product candidate on the sponsor's agreement to conduct additional clinical trials after approval. In other cases, a sponsor may voluntarily conduct additional clinical trials after approval to gain more information about the biological product. Such post-approval studies are typically referred to as Phase 4 clinical trials.

Sponsors must also report to the FDA, within certain timeframes, serious and unexpected adverse reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator's brochure, or any findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the product candidate. The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. We may also suspend or terminate a clinical trial based on evolving business objectives or competitive climate.

A manufacturer of an investigational biological product for a serious disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational biological product. This requirement applies on the earlier of the first initiation of a Phase 2 or Phase 3 trial of the investigational biological product or, as applicable, 15 days after the biological product receives a designation as a breakthrough therapy or fast track product.

Submission of a BLA to the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational product information is submitted to the FDA in the form of a BLA requesting approval to market the product for one or more indications. Under federal law, the submission of most BLAs is subject to an application user fee. For fiscal year 2020, the application user fee is $ 2,942,965, and the sponsor of an approved BLA is also subject to an annual program fee of $325,424 for each approved biological product on the market. These fees are typically increased annually. Applications for orphan drug products are exempted from the BLA user fees and may be exempted from program fees, unless the application includes an indication for other than a rare disease or condition.

A BLA must include all relevant data available from pertinent nonclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including trials initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational product to the satisfaction of the FDA.

The FDA conducts a preliminary review of all BLAs within the first 60 days after submission before accepting them for filing to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an application for filing. Once a BLA has been submitted, the FDA's goal for novel biological products generally is to review the application within ten months after it accepts the application for filing, or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months after the FDA accepts the application for filing. The review process is often significantly extended by the FDA's requests for additional information or clarification.

Before approving a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

The FDA is required to refer an application for a novel biological product to an advisory committee or explain why such referral was not made. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA's Decision on a BLA

After the FDA evaluates the BLA and conducts relevant inspections, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the biological product with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter will identify the deficiencies that prevent the FDA from approving the application and may require additional clinical data or an additional Phase 3 clinical trial(s), or other significant, expensive and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval and issue a denial.

The FDA could also approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, program to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

New government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Expedited Review and Accelerated Approval Programs

A sponsor may seek approval of its product candidate under programs designed to accelerate FDA's review and approval of BLAs. For example, Fast Track Designation may be granted to a biological product intended for treatment of a serious or life-threatening disease or condition that has potential to address unmet medical needs. The key benefits of fast track designation are more frequent interactions with the FDA during development and testing, the eligibility for priority review, and rolling review, which is submission of portions of an application before the complete marketing application is submitted.

Based on results of the Phase 3 clinical trial(s) submitted in a BLA, the FDA may grant the BLA a priority review designation, which sets the target date for FDA action on the application for a novel product at six months after the FDA accepts the application for filing. Priority review is granted where there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. If criteria are not met for priority review, the application is subject to the standard FDA review period of ten months after FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the accelerated approval program, the FDA may approve a BLA on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Post-marketing trials or completion of ongoing trials after marketing approval are generally required to verify the biological product's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit.

In addition, a sponsor may seek FDA designation of its product candidate as a breakthrough therapy if the biological product is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the biological product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The benefits of breakthrough therapy designation include the same benefits as a Fast Track designation, in addition to intensive guidance from FDA to ensure an efficient development program.

Post-Approval Requirements

Biological products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. Biological product manufacturers are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We rely, and expect to continue to rely, on third parties for the production of clinical quantities of our product candidates, and expect to rely in the future on third parties for the production of commercial quantities. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production, or distribution, or may require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing.

The FDA may suspend or revoke product license approvals if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. FDA has authority to require post-market studies, in certain circumstances, on reduced effectiveness of a biological product and FDA may require labeling changes related to new reduced effectiveness information. Other potential consequences of a failure to maintain regulatory compliance include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, untitled or warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Biological products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Pediatric Trials and Exclusivity

A sponsor who is planning to submit a marketing application for a biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan, or PSP, within sixty days of an end of Phase 2 meeting or as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. Generally, development program candidates designated as orphan drugs are exempt from the above requirements. FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs.

Pediatric exclusivity is another type of non-patent exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the five-year and three-year non-patent and orphan exclusivity. This six-month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of FDA-requested pediatric trials are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection covering the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot accept or approve another application relying on the BLA sponsor's data.

Patent Term Restoration

Depending upon the timing, duration, and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA, plus the time between the submission date and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent and within 60 days of the product's approval. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

Biosimilars and Exclusivity

The Patient Protection and Affordable Care Act, or Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCI Act, which created an abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product. This amendment to the PHSA attempts to minimize duplicative testing. Biosimilarity, which requires that there be no clinically meaningful differences between the proposed biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

A reference biologic is granted twelve years of exclusivity from the time of first licensure of the reference product.

European Union/Rest of World Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. The cost of establishing a regulatory compliance system for numerous varying jurisdictions can be very significant. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union and in other jurisdictions, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a clinical trial authorization application, or CTA, must be submitted for each clinical protocol to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is accepted in accordance with a country's requirements, the clinical trial may proceed.

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

To obtain regulatory approval of an investigational medicinal product under European Union regulatory systems, we must submit a marketing authorization application. The content of the BLA filed in the United States is similar to that required in the European Union, with the exception of, among other things, country-specific document requirements.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing product licensing, pricing, and reimbursement vary from country to country.

Countries that are part of the European Union, as well as countries outside of the European Union, have their own governing bodies, requirements, and processes with respect to the approval of biological products. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Authorization Procedures in the European Union

Medicines can be authorized in the European Union by using either the centralized authorization procedure or national authorization procedures.

Centralized procedure. The European Medicines Agency, or EMA, implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the European Economic Area, or EEA, which is comprised of the 28 member states of the European Union plus Norway, Iceland, and Lichtenstein. This procedure results in a single marketing authorization issued by the EMA that is valid across the EEA. The centralized procedure is compulsory for human medicines that are: derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines.

For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the European Commission following a favorable opinion by the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

National authorization procedures. There are also two other possible routes to authorize medicinal products in several European Union countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure:

Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one European Union country of medicinal products that have not yet been authorized in any European Union country and that do not fall within the mandatory scope of the centralized procedure.

Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one European Union Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

In some cases, a Pediatric Investigation Plan, or PIP, or a request for waiver or deferral, is required for submission prior to submitting a marketing authorization application. A PIP describes, among other things, proposed pediatric trials and their timing relative to clinical trials in adults.

New Chemical Entity Exclusivity

In the European Union, new chemical entities, sometimes referred to as new active substances, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic (abbreviated) application for eight years, after which generic marketing authorization can be submitted, and the innovator's data may be referenced, but not approved for two years. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Accelerated Review

Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the EMA's Committee for Medicinal Products for Human Use, or CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. In this circumstance, EMA ensures that the opinion of the CHMP is given within 150 days, excluding clock stops.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we may receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement for our products from third-party payors, such as government healthcare programs (e.g.,, Medicare, Medicaid), managed care providers, private health insurers, health maintenance organizations, and other organizations. These third-party payors decide which medications they will pay for and will establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and other third-party payors is essential for most patients to be able to afford treatments such as antibody-based therapies.

In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent our products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved

No uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication.

Further, third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or comparable regulatory approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Our product candidates may nonetheless not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition.

In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, in the European Union Member States can restrict the range of medicinal products for which their national health insurance systems provide reimbursement and they can control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Approaches between Member States are diverging. For example, in France, effective market access will be supported by agreements with hospitals and products may be reimbursed by the Social Security Fund. The price of medicines is negotiated with the Economic Committee for Health Products, or CEPS. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Current and future healthcare reform legislation

In the United States and in some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Affordable Care Act, or ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, expands the types of entities eligible for the 340B drug discount program, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases rebates for drugs sold to Medicaid programs owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and created a mandatory discount program for certain Medicare Part D beneficiaries in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, or BBA, effective as of January 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing legal and constitutional challenges in the United States Supreme Court; the Trump Administration has issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. Specifically, the Joint Select Committee on Deficit Reduction was created to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2012 through 2021, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, and due to subsequent legislative amendments, will stay in effect through 2030 unless additional Congressional action is taken. However, the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, the 2% Medicare sequester reductions will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. The American Taxpayer Relief Act of 2012, or the ATRA. The ATRA, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, in December 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of a federal district court litigation regarding the method CMS uses to determine this risk adjustment. Since then, the ACA risk adjustment program payment parameters have been updated annually.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare and reform government program reimbursement methodologies for drug products. For example, at the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Although a number of these, and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Other Healthcare Laws and Compliance Requirements

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our business operations and any current or future arrangements with third-party payors, healthcare providers and physicians 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 develop, market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include, among others:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration (including any kickback, bribe, or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or for the purchase, lease, order or recommendation of, or arranging for, an item, good, facility or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid. The term remuneration has been interpreted broadly to include anything of value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. A person or entity need not have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Violations are subject to significant civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act, or FCA;

- federal civil and criminal false claims laws, including the FCA, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors, that are false, fictitious or fraudulent; knowingly making, using, or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring qui tam actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme, to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- the federal Physician Payment Sunshine Act, created under the ACA and its implementing regulations, which requires drug, device, medical supply, and biologics manufacturers to disclose payments under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to HHS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;

- HIPAA, as amended by the Health Information Technology and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which imposes, among other things, certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," those independent contractors or agents of covered entities that create, receive, maintain, transmit or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions; and

- analogous state and foreign law equivalents of each of the above U.S. federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state and local marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements; state laws that require the reporting of information related to drug pricing; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; state and local laws that require the licensure of sales representatives; state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require the registration of pharmaceutical sales representatives; data privacy and security laws and regulations in foreign jurisdictions that may be more stringent than those in the United States (such as the European Union, which adopted the General Data Protection Regulation, which became effective in May 2018); and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices do 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 the laws described above or any other governmental regulations that apply to us, we may be subject to administrative, civil, and criminal penalties, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, damages, fines, disgorgement, reputational harm, the curtailment or restructuring of our operations, and additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to similar actions, penalties and sanctions. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from its business.

We are also subject to the U.S. Foreign Corrupt Practices Act, or FCPA, which prohibits improper payments or offers of payments to foreign governments and their officials for the purpose of obtaining or retaining business and requires companies to maintain accurate books and records and a system of internal accounting controls. Safeguards we implement to discourage improper payments or offers of payments by our employees, consultants, and others may be ineffective, and violations of the FCPA and similar laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us, any of which would likely harm our reputation, business, financial condition and result of operations.

In the event we decide to conduct future clinical trials in the European Union, we may be subject to additional privacy restrictions. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the European Economic Area, or EEA, including personal health data, is subject to the EU General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. Further, the United Kingdom's decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated now that the United Kingdom has left the EU.

Employees

As of May 31, 2020, we had 28 employees, of which 27 were full-time employees, 17 were primarily engaged in research and development activities and 11 hold M.D. or Ph.D. degrees. None of our employees is represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Facilities

Our corporate headquarters are located in Cambridge, Massachusetts, and consist of 11,290 square feet of office space, 13,197 square feet of laboratory space and 4,339 square feet of storage space. We believe that these facilities are adequate for our current needs and that suitable additional or substitute space will be available in the future if needed.

Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings as part of our ordinary course of business. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business.

Corporate Information

We were incorporated as Olivia Ventures, Inc. in the State of Delaware on March 20, 2018. On June 17, 2020, a wholly-owned subsidiary of ours merged with and into Compass Therapeutics, a private limited liability company formed on January 29, 2014. Following the Merger, Compass Therapeutics was the surviving entity and became our wholly-owned subsidiary, and all of the outstanding common and preferred membership interests of Compass Therapeutics were converted into shares of our common stock. On June 17, 2020, we changed our name to Compass Therapeutics, Inc. As a result of the Merger, we acquired the business of Compass Therapeutics and we will continue the existing business operations of Compass Therapeutics as a public reporting company under the name Compass Therapeutics, Inc.

Our principal executive offices are located at 245 First Street, 3rd Floor, Cambridge, Massachusetts 02142, and our telephone number is (617) 500-8099.

Available Information

Our website address is www.compasstherapeutics.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to such reports are filed with the SEC. We are subject to the informational requirements of the Exchange Act and file or furnish reports, proxy statements, and other information with the SEC. Such reports and other information filed by us with the SEC will be available free of charge on our website at www.compasstherapeutics.com when such reports are available on the SEC's website. The SEC maintains a website that contains reports, proxy and information statements, and other information that issuers file electronically with the SEC at www.sec.gov.

The contents of the websites referred to above are not incorporated into this filing. Further, our references to the URLs for these websites are intended to be inactive textual references only.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below together with all of the other information in this Report, including our financial statements and the related notes and the information described in the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," and in our other filings with the SEC. If any of the events described below actually occurs, our business, results of operations, financial conditions, cash flows or prospects could be harmed. If that were to happen, you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and no products approved for commercial sale. We have a history of significant losses, expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We are a clinical-stage biopharmaceutical company with a limited operating history. Since our founding in 2014, we have incurred significant net losses. Our net losses were $34.7 million for the year ended December 31, 2019 and $6.4 million for the three months ended March 31, 2020. As of March 31, 2020, we had an accumulated deficit of $128.3 million. We have funded our operations to date primarily with proceeds from private placements of preferred and common equity and borrowings under the 2018 credit facility with Pacific Western Bank, Inc., or the 2018 Credit Facility. Since commencing operations, we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, identifying business development opportunities, raising capital, securing intellectual property rights related to our product candidates, conducting discovery, and research and development activities for our product candidates.

We expect that it will be several years, if ever, before we have a commercialized product. We expect to continue to incur significant expenses and operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if, and as, we:

- continue to advance the preclinical and clinical development of our existing product candidates and our research programs;
- leverage our research and development capabilities to advance additional product candidates into preclinical and clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- hire additional clinical, quality control, regulatory, scientific and administrative personnel;
- expand our operational, financial and management systems and increase personnel, including to support our clinical development and our operations as a public company;
- maintain, expand and protect our intellectual property portfolio;
- establish a marketing, sales, distribution and medical affairs infrastructure to commercialize any products for which we may obtain marketing approval and commercialize, whether on our own or jointly with a partner;
- acquire or in-license other technologies or engage in strategic partnerships; and
- incur additional legal, accounting or other expenses in operating our business, including the additional costs associated with operating as a public company.

To become and remain profitable, we must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval for product candidates, manufacturing, marketing and selling products and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We have never generated revenue from product sales and may never be profitable.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with our collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our product candidates. We do not anticipate generating revenue from product sales for the next several years, if ever. Our ability to generate future revenue from product sales depends heavily on our, or our existing or future collaborators', success in:

- completing preclinical studies and clinical trials of our product candidates, including our ongoing Phase 1 clinical trial of CTX-471 as a monotherapy and other clinical trials for CTX-471, CTX-8371 and CTX-8573;
- seeking and obtaining marketing approvals for any product candidates that we or our collaborators develop;
- identifying and developing new product candidates;
- launching and commercializing product candidates for which we obtain marketing approval by establishing a marketing, sales, distribution and medical affairs infrastructure or, alternatively, collaborating with a commercialization partner;
- achieving coverage and adequate reimbursement by hospitals and third-party payors, including governmental authorities, such as Medicare and Medicaid, private insurers and managed care organizations, for product candidates, if approved, that we or our collaborators develop;
- obtaining market acceptance of product candidates, if approved, that we develop as viable treatment options;
- addressing any competing technological and market developments;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations under such arrangements;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- defending against third-party interference or infringement claims, if any; and
- attracting, hiring and retaining qualified personnel.

We anticipate incurring significant costs associated with commercializing any product candidate that is approved for commercial sale. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies to perform clinical trials or studies in addition to those that we currently anticipate, or if there are any delays in establishing appropriate manufacturing arrangements for or in completing our clinical trials for the development of any of our product candidates, for example, as a result of any setbacks or delays due to the COVID-19 pandemic. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

We will require substantial additional financing to pursue our business objectives, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development, commercialization efforts or other operations.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of our current and future programs. If we receive marketing approval for any product candidates, including CTX-471, CTX-8371 and CTX-8573, we will require significant additional amounts of cash in order to launch and commercialize such product candidates. In addition, other unanticipated costs may arise. Because the designs and outcomes of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development of and commercialize any product candidate we develop. Additionally, any COVID-19 related program setbacks or delays due to changes in federal, state, or local laws and regulations or clinical site policies could impact our programs and increase our expenditures.

Our future capital requirements depend on many factors, including:

- the scope, progress, timing, results and costs of researching and developing CTX-471, CTX-8371, CTX-8573 and our other product candidates, including targets identified through our NKp30 innate cell engager platform, and of conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approval for CTX-471, CTX-8371, CTX-8573 and any future product candidates we develop, if clinical trials are successful;
- the costs of manufacturing CTX-471, CTX-8371, CTX-8573 and any future product candidates for preclinical studies and clinical trials and in preparation for marketing approval and commercialization;
- the impact of COVID-19 on the initiation or completion of preclinical studies or clinical trials, the third-parties on whom we rely, and the supply of our product candidates;
- the costs of commercialization activities, including marketing, sales and distribution costs, for CTX-471, CTX-8371, CTX-8573 and any future product candidates we develop, whether alone or with a collaborator, if any of these product candidates are approved for sale;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements on favorable terms, if at all;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of any such litigation;
- our current collaboration and license agreements remaining in effect and our achievement of milestones and the timing and amount of milestone payments we are required to make, or that we may be eligible to receive, under those agreements;
- the timing, receipt and amount of sales of, on our future products, if any; and
- the emergence of competing therapies and other adverse developments in the oncology and immunology market.

Until we can generate sufficient product revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity and debt financings, marketing and distribution arrangements, other collaborations, strategic alliances and licensing arrangements. As of March 31, 2020, we had $17.5 million in cash, cash equivalents and marketable securities. In June 2020, we raised an aggregate of $54.0 million in net proceeds from the Private Placement. Based on our research and development plans, we expect that these cash resources will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2021. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in, and progress of, our development activities, acquisitions of additional product candidates and changes in regulation.

If we raise additional capital through marketing, sales and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, future revenue streams or research programs, technologies or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through additional sales of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to obtain additional financing on favorable terms when needed, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials, or other research and development activities or one or more of our development programs.

Risks Related to the Discovery and Development of Our Product Candidates

Our business is dependent on our ability to advance our current and future product candidates through clinical trials, obtain marketing approval and ultimately commercialize them.

We are early in our development efforts. We initiated our first clinical trial for CTX-471, our lead product candidate, in July 2019. Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of CTX-471, CTX-8371, CTX-8573 and any other current or future product candidates we develop, which may never occur. Our current product candidates, including CTX-471, CTX-8371 and CTX-8573, and any future product candidates we develop will require additional preclinical or clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other jurisdictions, demonstration of effectiveness to pricing and reimbursement authorities, sufficient cGMP manufacturing supply for both preclinical and clinical development and commercial production, building of a commercial organization and substantial investment and significant marketing efforts before we generate any revenues from product sales.

The clinical and commercial success of our current and future product candidates will depend on several factors, including the following:

- timely and successful completion of preclinical studies and our clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- our plans to successfully submit IND applications with the FDA for CTX-471, CTX-8371, CTX-8573 and or other current and future product candidates;
- our ability to complete preclinical studies for current or future product candidates;
- successful enrollment in, including maintaining or reaching target enrollment levels during the COVID-19 pandemic, and completion of clinical trials;
- successful data from our clinical program that supports an acceptable risk-benefit profile of our product candidates in the intended patient populations;
- our ability to establish agreements with third-party manufacturers on a timely and cost efficient manner;
- whether we are required by the FDA or comparable foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned or anticipated to support approval of our product candidates;
- acceptance of our proposed indications and the primary endpoint assessments evaluated in the clinical trials of our product candidates by the FDA and comparable foreign regulatory authorities;
- receipt and maintenance of timely marketing approvals from applicable regulatory authorities;
- successfully launching commercial sales of our product candidates, if approved;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates, if approved;
- entry into collaborations to further the development of our product candidates;

- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- acceptance of the benefits and uses of our product candidates, if approved, by patients, the medical community and third-party payors;
- maintaining a continued acceptable safety, tolerability and efficacy profile of the product candidates following approval;
- our compliance with any post-approval requirements imposed on our products, such as post-marketing studies, a Risk Evaluation and Mitigation Strategy, or REMS, or additional requirements that might limit the promotion, advertising, distribution or sales of our products or make the products cost prohibitive;
- competing effectively with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors;
- our ability to identify bispecifics through our NKp30 platform or otherwise; and
- enforcing and defending intellectual property rights and claims.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our current or future product candidates, and could otherwise materially harm our business. Successful completion of preclinical studies and clinical trials does not mean that CTX-471, CTX-8371, CTX-8573 or any other current or future product candidates we develop will receive regulatory approval. Even if regulatory approvals are obtained, we could experience significant delays or an inability to successfully commercialize our current and any future product candidates we develop, which would materially harm our business. If we are not able to generate sufficient revenue through the sale of any current or future product candidate, we may not be able to continue our business operations or achieve profitability.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be materially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate. Neither we nor any future collaborator is permitted to market any biological product in the United States until we or the future collaborator receives regulatory approval of a biologics license application, or BLA, from the FDA. It is possible that none of our current or future product candidates will ever obtain regulatory approval from the FDA or comparable foreign regulatory authorities.

Our current and future 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 regulatory authorities that a product candidate has an acceptable risk-benefit profile in the proposed indication;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that the facility in which a product candidate is manufactured meets standards designed to assure that the product candidate continues to be safe, pure, and potent;
- 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 a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA to the FDA or regulatory submissions to comparable regulatory authorities to obtain regulatory approval in such jurisdiction; and
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve our manufacturing processes or facility or the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies.

This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market any product candidate we develop, which would significantly harm our business, results of operations and prospects. The FDA and other comparable foreign authorities have substantial discretion in the approval process and in determining when or whether regulatory approval will be granted for any product candidate that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority.

In addition, even if we were to obtain approval, the FDA may approve any of our product candidates for fewer or more limited indications, or a more limited patient population, than we request, may grant approval contingent on the performance of costly clinical trials or other post-marketing requirements, or may approve a product candidate with a label that does not include the labeling claims we believe are necessary or desirable for the successful commercialization of such product candidates.

In addition, the FDA or comparable foreign regulatory authorities may change their policies, promulgate additional regulations, revise existing regulations or take other actions that may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Clinical development involves a lengthy and expensive process with uncertain outcomes. We may incur additional costs and experience delays in developing and commercializing or be unable to develop or commercialize our current and future product candidates.

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe, pure and potent in humans. Clinical testing is expensive and can take many years to complete, and its outcome is highly uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful. We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials. Although we initiated a Phase 1 clinical trial of CTX-471 in July 2019, we may experience delays in completing this trial or in initiating any planned clinical trials and development efforts. Additionally, we cannot be certain the ongoing and planned preclinical studies or clinical trials for CTX-471, CTX-8371, CTX-8573 or any other current or future product candidates will begin on time, not require redesign, enroll an adequate number of subjects on time or be completed on schedule, if at all. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- results from preclinical studies or clinical trials may not be predictive of results from later clinical trials of any product candidate;
- the FDA or other regulatory authorities, Institutional Review Boards, or IRBs, or independent ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- the FDA or other regulatory authorities may require us to submit additional data such as long-term toxicology studies, or impose other requirements on us, before permitting us to initiate a clinical trial;

- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, as the terms of these agreements can be subject to extensive negotiation and vary significantly among different CROs and trial sites;

- clinical trials of any product candidate may fail to show safety, purity or potency, or may produce negative or inconclusive results, which may cause us to decide, or regulators to require us, to conduct additional nonclinical studies or clinical trials or which may cause us to decide to abandon product candidate development programs;

- the number of patients required for clinical trials may be larger than we anticipate, or we may have difficulty in recruiting and enrolling patients to participate in clinical trials, including as a result of the size and nature of the patient population, the proximity of patients to clinical trial sites, eligibility criteria for the clinical trial, the nature of the clinical trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications and clinical trial subjects;

- even though, as of June 1, 2020, we have not experienced challenges in enrolling patients into our ongoing Phase 1 clinical trial of CTX-471, there can be no assurance that we will not encounter such challenges in the future for this trial or other trials. It may be difficult to enroll a sufficient number of patients, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or may fail to return for post-treatment follow-up at a higher rate than we anticipate;

- our CROs and other third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;

- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that participants are being exposed to unacceptable health risks;

- any of our product candidates could cause undesirable side effects that could result in significant negative consequences, including the inability to enter clinical development or receive regulatory approval;

- the cost of preclinical or nonclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate;

- we may face hurdles in addressing subject safety concerns that arise during the course of a trial, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate trials, or reports may arise from nonclinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our product candidates;

- the supply, quality or timeliness of delivery of materials for product candidates we develop or other materials necessary to conduct clinical trials may be insufficient or inadequate; and

- we may need to change the manufacturing site and potentially the CMO for our product candidates from those that are able to produce clinical supply for our Phase 1 clinical trials to those with the capacity and ability to perform commercial manufacturing and/or the production of clinical material for our later stage clinical trials.

We could encounter delays if a clinical trial is suspended or terminated by us, or by the IRBs of the institutions in which such trials are being conducted, ethics committees or the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, 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. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval of our product candidates. The FDA or other regulatory authorities may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials. Further, the FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials. For example, we are conducting and may in the future conduct "open-label" clinical trials. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Moreover, patients selected for early clinical studies often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge.

Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or a regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of the marketing application we submit. Any such delay or rejection could prevent or delay us from commercializing our current or future product candidates.

If we experience delays in the completion, or termination, of any clinical trial of our product candidates, including as a result of the COVID-19 pandemic, the commercial prospects of our product candidates will be harmed and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down the development and approval process for our product candidates and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates.

Any such events would impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates or result in the development of our product candidates stopping early.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for biological products or modifications to approved biological products to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns prevents the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. For example, on April 16, 2020, the FDA announced that it was continuing to meet key review program user fee performance goals, approve applications and communicate with applicants. However, the FDA noted that it may not be able to sustain its current level of performance indefinitely during the COVID-19 pandemic. If the FDA becomes unable to continue its current level of performance, we could experience delays and setbacks for our product candidates and for any approvals we may seek which could adversely affect our business.

Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all.

With the exception of CTX-471, all of our product candidates are still in the preclinical stage, and the risk of failure for such product candidates is high. In order to obtain FDA approval to market a new biologic we must demonstrate proof of safety, purity and potency, including efficacy, in humans. To meet these requirements we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned clinical trials in humans. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our current or future product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time of such testing may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are conducting preclinical testing and studies may cause us to incur additional operating expenses. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including but not limited to:

- an inability to generate sufficient preclinical or other *in vivo* or *in vitro* data to support the initiation of clinical studies;
- delays in reaching a consensus with regulatory agencies on study design;
- any setbacks or delays on account of the COVID-19 pandemic; and
- the FDA or foreign regulatory authorities not permitting the reliance on preclinical or other data from published scientific literature.

Positive results from preclinical studies and early-stage clinical trials may not be predictive of future results. Initial positive results in any of our clinical trials may not be indicative of results obtained when the trial is completed or in later stage trials.

The results of preclinical studies may not be predictive of the results of clinical trials. Preclinical studies and early-stage clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules, and the results of any early-stage clinical trials may not be predictive of the results of later-stage, large-scale efficacy clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs and biological products proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and any such setbacks in our clinical development could have a material adverse effect on our business and operating results.

Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, the results of our preclinical studies may not be predictive of the results of outcomes in human clinical trials. For example, our current or future product candidates may demonstrate different chemical, biological and pharmacological properties in patients than they do in laboratory studies or may interact with human biological systems in unforeseen or harmful ways. Product candidates in later stages of clinical trials may fail to show desired pharmacological properties or produce the necessary safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Even if we are able to initiate and complete clinical trials, the results may not be sufficient to obtain regulatory approval for our product candidates. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

Interim and preliminary results from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit, validation and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim data, including interim top-line results or preliminary results from our clinical trials. Interim data and results from our clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line results also remain subject to audit, validation and verification procedures that may result in the final data being materially different from the interim and preliminary data we previously published. As a result, interim and preliminary data may not be predictive of final results and should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

Our approach to the discovery and development of product candidates using our NKp30 platform is unproven and may not result in marketable products.

The success of our business depends in part upon our ability to identify product candidates based on our proprietary NKp30 platform and to develop and commercialize therapeutic antibodies. Our approach to the discovery of targets using the NKp30 platform is novel. We have not yet completed a clinical trial of any product candidate developed for a target identified from the NKp30 platform. Even if we are able to identify targets from the NKp30 platform and to develop corresponding product candidates, we cannot assure that such product candidates will achieve marketing approval to safely and effectively treat the indications we target.

NKp30 is a novel target for drug development. No therapeutic targeting NKp30 has ever been approved, and to our knowledge no drug targeting NKp30 has ever been tested in humans.

If we uncover any previously unknown risks related to our NKp30 platform, or if we experience unanticipated problems or delays in developing our NKp30 product candidates, we may be unable to achieve our strategy of building a platform of NKp30 innate cell engagers for oncology and autoimmune disease.

Our agonist monoclonal antibody product candidates are a new potential class of therapeutics, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval, if at all.

Our agonist monoclonal antibody technology is relatively new and no agonist monoclonal antibodies to any target have been approved to date. As such it is difficult to accurately predict the developmental challenges we may incur for our product candidates as they proceed through product discovery or identification, preclinical studies and clinical trials. In addition, because we have not completed clinical trials, we have not yet been able to meaningfully assess safety in humans, and there may be short-term or long-term effects from treatment with any product candidates that we develop that we cannot predict at this time. Also, animal models may not exist for some of the diseases we choose to pursue in our programs. Furthermore, agonist antibodies have demonstrated substantial toxicity in humans and there is no assurance that our product candidates will not have the same adverse side effects. As a result of these factors, it is more difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the application of our antibody therapeutics and our bispecifics, or any similar or competitive technologies, will result in the identification, development, and regulatory approval of any products. There can be no assurance that any development problems we experience in the future related to our agonist antibodies or any of our research programs will not cause significant delays or unanticipated costs, or that such development problems can be solved. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate or commercializing any product candidates we may develop on a timely or profitable basis, if at all.

The clinical trial requirements of the FDA, the EMA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the product candidate. No products based on agonist antibodies have been approved to date by regulators. As a result, the regulatory approval process for product candidates such as ours is uncertain and may be more expensive and take longer than the approval process for product candidates based on other, better known or more extensively studied technologies. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in either the United States or the European Union or other regions of the world or how long it will take to commercialize our product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product candidate to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects may be harmed.

Our current or future product candidates may cause undesirable side effects or have other properties when used alone or in combination with other approved products or investigational new drugs that could halt their clinical development, delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe, pure and potent for use in each target indication, and failures can occur at any stage of testing. As with most biological products, use of our current or future product candidates could be associated with side effects or adverse events which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. There have been serious adverse side effects reported in response to antibody therapeutics and bispecifics in oncology.

Immuno-oncology drugs have been observed to cause side effects, generally related to over activation of the immune system. These include colitis, diabetes, pituitary inflammation, thyroiditis, myocarditis, liver inflammation, thrombocytopenia, among others. Our immune-oncology product candidates, including our lead candidate, CTX-471, may have similar or additional side effects. As of May 24, 2020, 19 patients have been enrolled in our ongoing Phase 1 clinical trial of CTX-471 and received at least one dose of CTX-471. There have been six serious adverse events reported, two of which in two patients were considered treatment-related. The two treatment-related serious adverse events are hypoxia, which resolved, and thrombocytopenia purpura that also resolved. Two dose-limiting toxicities of immune-related thrombocytopenia have been reported. In addition to any potential side effects caused by the product or product candidate, the administration process or related procedures also can cause adverse side effects. If unacceptable adverse events occur, our clinical trials or any future marketing authorization could be suspended or terminated.

We are developing CTX-8371 as potential a bispecific antibody that simultaneously targets both PD-1 and PD-L1, the targets of well-known and widely used checkpoint inhibitor antibodies. While we have observed so far in preclinical testing that simultaneous targeting of both PD-1 and PD-L1 has been associated with less toxicity than targeting either PD-1 alone or PD-L1 alone, there can be no assurance that CTX-8371 will not demonstrate unacceptable toxicities in later testing that may render it unsafe or intolerable.

If unacceptable side effects arise in the development of our product candidates, we, the FDA, the IRBs at the institutions in which our studies are conducted or the DSMB could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Although our current and future product candidates have undergone and will undergo safety testing to the extent possible and, where applicable, under such conditions discussed with regulatory authorities, not all adverse effects of drugs can be predicted or anticipated. Antibody therapeutics and bispecifics and their method of action of harnessing the body's immune system are powerful and could lead to serious side effects that we only discover in clinical trials or during commercial marketing. Unforeseen side effects could arise either during clinical development or after our product candidates have been approved by regulatory authorities and the approved product has been marketed, resulting in the exposure of additional patients. So far, we have not demonstrated that CTX-471, CTX-8371, CTX-8573 or any other product candidate is safe in humans, and we cannot predict if ongoing or future clinical trials will do so. If any of our current or future product candidates fail to demonstrate safety and efficacy in clinical trials or do not gain marketing approval, we will not be able to generate revenue and our business will be harmed.

In addition, we intend to pursue CTX-471 in part in combination with other therapies and may develop CTX-8371, CTX-8573 and future product candidates in combination with other therapies, which exposes us to additional risks relating to undesirable side effects or other properties. For example, the other therapies may lead to toxicities that are improperly attributed to our product candidates or the combination of our product candidates with other therapies may result in toxicities that the product candidate or other therapy does not produce when used alone. The other therapies we are using in combination may be removed from the market, or we may not be able to secure adequate quantities of such materials for which we have no guaranteed supply contract, and thus be unavailable for testing or commercial use with any of our approved products. The other therapies we may use in combination with our product candidates may also be supplanted in the market by newer, safer or more efficacious products or combinations of products.

Even if we successfully advance one of our product candidates through clinical trials, such trials will likely only include a limited number of subjects and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be uncovered when a significantly larger number of patients are exposed to the product candidate. Further, any clinical trial may not be sufficient to determine the effect and safety consequences of taking our product candidates over a multi-year period.

If any of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- we may be required to implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and result in the loss of significant revenues, which would materially harm our business. In addition, if one or more of our product candidates or our antibody therapeutic development approach generally prove to be unsafe, our entire technology platform and pipeline could be affected, which would also materially harm our business.

As an organization, we have limited experience designing and implementing clinical trials and we have never conducted pivotal clinical trials. Failure to adequately design a trial, or incorrect assumptions about the design of the trial, could adversely affect the ability to initiate the trial, enroll patients, complete the trial, or obtain regulatory approval on the basis of the trial results, as well as lead to increased or unexpected costs and in delayed timelines.

The design and implementation of clinical trials is a complex process. We have limited experience designing and implementing clinical trials, and we may not successfully or cost-effectively design and implement clinical trials that achieve our desired clinical endpoints efficiently, or at all. A clinical trial that is not well designed may delay or even prevent initiation of the trial, can lead to increased difficulty in enrolling patients, may make it more difficult to obtain regulatory approval for the product candidate on the basis of the study results, or, even if a product candidate is approved, could make it more difficult to commercialize the product successfully or obtain reimbursement from third-party payors. Additionally, a trial that is not well-designed could be inefficient or more expensive than it otherwise would have been, or we may incorrectly estimate the costs to implement the clinical trial, which could lead to a shortfall in funding. We also expect to continue to rely on third parties to conduct our clinical trials. See "*—Risks Related to Reliance on Third Parties—We rely or will rely on third parties to help conduct our ongoing and planned preclinical studies and clinical trials for CTX-471, CTX-8371, CTX-8573 and any future product candidates we develop. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize CTX-471, CTX-8371, CTX-8573 and any current or future product candidates we develop and our business could be materially harmed*." Consequently, we may be unable to successfully and efficiently execute and complete clinical trials that are required for BLA submission and FDA approval of CTX-471, CTX-8371, CTX-8573 or current or future product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop.

If we or our collaborators encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise be adversely affected.

The successful and timely completion of clinical trials in accordance with their protocols depends on, among other things, our ability to enroll a sufficient number of patients who remain in the trial until the trial's conclusion, including any follow-up period. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the nature and size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients;
- the number and location of participating clinical sites or patients;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- the availability of competing commercially available therapies and other competing drug candidates' clinical trials;
- our ability to obtain and maintain patient informed consents for participation in our clinical trials;
- the impact of the COVID-19 pandemic or future pandemics or similar events on patients' willingness and ability to participate in clinical trials or on study site policies; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may be late-stage cancer patients, will not survive the full terms of the clinical trials.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our current and potential future product candidates. This competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such sites. Moreover, because our current and potential future product candidates may represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, rather than enroll patients in our ongoing or any future clinical trial. Additionally, the recent COVID-19 pandemic may have an impact on our ability to recruit and follow-up with patients either due to continued or renewed restrictions on travel or shelter-in-place orders or policies, or due to changes in patient willingness to participate in trials or travel to study sites in the wake of the pandemic. Additionally, COVID-19 related study site policies may create delays or setbacks in our ability to continue to enroll or to dose patients.

Delays of difficulties in patient enrollment may result in increased costs or may affect the timing, outcome or completion of clinical trials, which would adversely affect our ability to advance the development of the product candidates we develop.

Because the number of subjects in our Phase 1 clinical trial of CTX-471 is small, the results from this trial, once completed, may be less reliable than results achieved in larger clinical trials.

A study design that is considered appropriate includes a sufficiently large sample size with appropriate statistical power, as well as proper control of bias, to allow a meaningful interpretation of the results. The preliminary results of studies with smaller sample sizes and heterogeneous patient populations, such as our ongoing Phase 1 clinical trial of CTX-471, can be disproportionately influenced by the impact the treatment had on a few individuals, which limits the ability to generalize the results across a broader community, thus making the study results less reliable than studies with a larger number of subjects and with more homogeneous patient populations. As a result, there may be less certainty that CTX-471 would achieve a statistically significant effect in any future clinical trials. If we conduct any future clinical trials of CTX-471, we may not achieve a statistically significant result or the same level of statistical significance seen, if any, in our Phase 1 clinical trial. Similarly, if we conduct a clinical trial of any other product candidate we develop, including CTX-471, with a smaller sample size, the results of any such trial may be less reliable than results achieved in larger clinical trials and may provide less certainty of achieving statistically significant effects in any future clinical trials.

We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.

Clinical trials must be conducted in accordance with the FDA's current good clinical practices requirements, or cGCP, or analogous requirements of applicable foreign regulatory authorities. Clinical trials are subject to oversight by the FDA, other foreign governmental agencies and IRBs or ethical committees at the study sites where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates manufactured in accordance with applicable cGMP. Clinical trials may be suspended by the FDA, other foreign regulatory authorities, us, or by an IRB or ethics committee with respect to a particular clinical trial site, for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or study protocols;
- deficiencies in the clinical trial operations or trial sites;
- unforeseen adverse side effects or the emergence of undue risks to study subjects;
- deficiencies in the trial design necessary to demonstrate efficacy;
- the product candidate may not appear to offer benefits over current therapies; or
- the quality or stability of the product candidate may fall below acceptable standards.

We have chosen to prioritize development of CTX-471, CTX-8371 and CTX-8573. We may expend our limited resources on product candidates or indications that do not yield a successful product and fail to capitalize on other candidates or indications for which there may be a greater likelihood of success or may be more profitable.

Because we have limited resources, we have strategically determined to prioritize development of CTX-471, CTX-8371 and CTX-8573 rather than other product candidates based, in part, on the significant resources required for developing and manufacturing antibody therapeutics and bispecifics. To date, no regulatory authority has granted approval for an antibody therapeutic targeting CD137, also known as 4-1BB, as well as the target of CTX-471. Of note, several drugs targeting CD137 have been tested in early stage clinical trials. At least one of these drugs had severe side effects. It is possible that CTX-471 may have similar adverse effects, including toxicity, in humans. In addition, no drug targeting NKp30 has ever been tested in humans, so the effects and safety profile of CTX-8573 is unpredictable. As a result, we may be foregoing other potentially more profitable antibody therapies or drugs with a greater likelihood of success. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties with respect to certain programs may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our current or future product candidates or misread trends in the oncology, autoimmunology or biopharmaceutical industry, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain development and commercialization rights.

We intend to develop CTX-471 in part in combination with other therapies and may develop CTX-8371, CTX-8573 and future product candidates in combination with other therapies, which exposes us to additional regulatory risks.

We intend to develop CTX-471 in part in combination with other therapies, such as trastuzumab, and may develop CTX-8371, CTX-8573 and future product candidates in combination with one or more currently approved cancer therapies. These combinations have not been previously tested in the clinic and may, among other things, fail to demonstrate synergistic activity, may fail to achieve superior outcomes relative to the use of single agents or other combination therapies, or may fail to demonstrate sufficient safety or efficacy traits in clinical trials to enable us to complete those clinical trials or obtain marketing approval for the combination therapy.

In addition, we did not develop or obtain regulatory approval for, and we do not manufacture or sell, any of these approved therapeutics. Therefore, even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risk that the FDA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially. Combination therapies are commonly used for the treatment of cancer diseases, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer.

We may also evaluate CTX-471, CTX-8371, CTX-8573 or any future product candidate in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell CTX-471, CTX-8371, CTX-8573 or any product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA or comparable foreign regulatory authorities do not approve these other biological products or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the biological products we choose to evaluate in combination with CTX-471, CTX-8371, CTX-8573 or any product candidate we develop, we may be unable to obtain approval of or market any such product candidate.

Risks Related to the Regulatory Approval and Commercialization of Product Candidates and Other Legal Compliance Matters

We may be unable to obtain FDA approval any of our product candidates under applicable regulatory requirements. The denial or delay of any such approval would prevent or delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations.

To gain approval to market our product candidates in the United States, we must provide the FDA with clinical data that adequately demonstrate the safety, purity and potency, including efficacy, of the product candidate for the proposed indication or indications in a BLA submission. Product development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical development programs. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after promising results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of clinical trials by other parties may not be indicative of the results in trials we may conduct.

We have not previously submitted a BLA or any other marketing application to the FDA or similar filings to comparable foreign regulatory authorities. A BLA or other similar regulatory filing requesting approval to market a product candidate must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, pure and potent for each desired indication. The BLA or other similar regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product.

The research, testing, manufacturing, labeling, approval, marketing, sale and distribution of biological products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market our product candidates in the United States or in any foreign countries until they receive the requisite approval from the applicable regulatory authorities of such jurisdictions.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of our product candidates for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or a comparable foreign regulatory authority that our product candidates are safe and effective for the requested indication;
- the FDA or a comparable foreign regulatory authority’s disagreement with our trial protocol or the interpretation of data from preclinical studies or clinical trials;
- our inability to demonstrate that the clinical and other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA or a comparable foreign regulatory authority’s requirement for additional preclinical studies or clinical trials;
- the FDA or a comparable foreign regulatory authority’s non-approval of the formulation, labeling, or specifications of our product candidates;
- the FDA or a comparable regulatory authority’s failure to approve our manufacturing processes and facilities or the manufacturing processes and facilities of third-party manufacturers upon which we rely; or
- potential for approval policies or regulations of the FDA or a comparable foreign regulatory authority to significantly change in a manner rendering our clinical data insufficient for approval.

Even if we eventually complete clinical testing and receive approval from the FDA or comparable foreign regulatory authorities for any of our product candidates, the FDA or comparable foreign regulatory authorities may grant approval contingent on the performance of costly additional clinical trials which may be required after approval. The FDA or comparable foreign regulatory authorities also may approve any of our product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA or comparable foreign regulatory authorities may not approve any of our product candidates with the labeling that we believe is necessary or desirable for the successful commercialization of any such product candidates.

Of the large number of biopharmaceutical products in development, only a small percentage successfully complete the FDA or other regulatory bodies' approval processes and are commercialized. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of our product candidates and would materially harm our business.

Even if a current or future product candidate receives marketing approval, it 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 current or future product candidate we develop receives marketing approval, whether as a single agent or in combination with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. For example, current approved antibody therapeutics, and other cancer treatments like chemotherapy and radiation therapy, are well established in the medical community, and doctors may continue to rely on these therapies. Our approach to targeting different components of the tumor microenvironment is novel and unproven. For example, NKp30 is a novel target for drug development, and no therapeutic targeting NKp30 has ever been approved nor, to our knowledge, has any drug targeting NKp30 ever been tested in humans. In addition, adverse events in clinical trials testing our product candidates or in clinical trials of others developing similar product candidates and the resulting publicity, as well as any other adverse events in the field of immuno-oncology that may occur in the future, could result in a decrease in demand for our current or future product candidates. Furthermore, to date, only a few bispecific products have received marketing approval and only a few have advanced to late-stage clinical development. Future adverse events in immuno-oncology or the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Similarly, the use of agonist antibodies for the treatment of autoimmune diseases is novel and there can be no assurance that our product candidates for the treatment of autoimmune diseases, if approved, would gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community.

If our current and any future product candidates we develop 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 current and any future product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments, including those that are not yet approved;
- the ability to offer our products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing, sales and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement, including with respect to the use of the approved product as a combination therapy; and
- the prevalence and severity of any side effects.

The market opportunities for any current or future product candidate we develop, if approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.

Any revenue we are able to generate in the future from product sales will be dependent, in part, upon the size of the market in the United States and any other jurisdiction for which we gain regulatory approval and have commercial rights. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, even if approved.

Cancer therapies are sometimes characterized as first-line, second-line or third-line, and the FDA often approves new therapies initially only for third-line use. When cancer is detected early enough, first-line therapy, usually chemotherapy, hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. The number of patients who receive second- and third-line treatment is significantly smaller than the number of patients who receive first-line treatment, and the prognosis of patients who receive second- or third-line treatment is often poorer than that of patients who receive first-line treatment.

We may initially seek approval for CTX-471, CTX-8371, CTX-8573 and any other product candidates we develop as second- or third-line therapies. If we do so, for those products that prove to be sufficiently beneficial, if any, we would expect potentially to seek approval as a first-line therapy, but there is no guarantee that any product candidate we develop, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

The number of patients who have the types of cancer or autoimmune diseases we are targeting may turn out to be lower than expected. Additionally, the potentially addressable patient population for our current or future product candidates may be limited, if and when approved. Even if we obtain significant market share for any product candidate, if and when approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications, including to be used as first- or second-line therapy.

Even if we receive marketing approval of a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. If we fail to comply or experience unanticipated problems with our products, we may be subject to administrative and judicial enforcement, including monetary penalties, for non-compliance and our approved products, if any, could be deemed misbranded or adulterated and prohibited from continued distribution.

Any marketing approvals that we receive for any current or future product candidate may be subject to limitations on the approved indicated uses for which the product may be marketed or the conditions of approval, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require implementation of a REMS as a condition of approval of any product candidate, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event and deviation reporting, storage, advertising, promotion, import and export and record keeping for the product candidate will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and cGCP, for any clinical trials that we may conduct post-approval. Later discovery of previously unknown problems with any approved candidate, including adverse events of unanticipated severity or frequency, or with our or our third-party manufacturers' manufacturing processes or facilities, or failure to comply with regulatory requirements, may result in, among other things:

- suspension of, or imposition of restrictions on, the marketing or manufacturing of the product, withdrawal of the product from the market, or product recalls;
- Warning Letters or Untitled Letters, or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications we file, or suspension or revocation of approved biologics licenses;
- product seizure or detention, monetary penalties, refusal to permit the import or export of the product, or placement on Import Alert; and
- permanent injunctions and consent decrees including the imposition of civil or criminal penalties.

Given the nature of biological products manufacturing, there is a risk of contamination. Any contamination could materially adversely affect our ability to produce product candidates on schedule and could, therefore, harm our results of operations and cause reputational damage. Some of the raw materials and other components required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product or product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially and adversely affect our development and commercialization timelines and our business, financial condition, results of operations and prospects and could adversely affect our ability to meet our supply obligations.

Moreover, the FDA strictly regulates the promotional claims that may be made about drug and biological products. In particular, an approved product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling, or off-label uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. The FDA has issued guidance on the factors that it will consider in determining whether a firm's product communication is consistent with the FDA-required labeling for that product, and those factors contain complexity and potential for overlap and misinterpretation. A company that is found to have improperly promoted off-label uses of their products may be subject to significant civil, criminal and administrative penalties.

The FDA and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval of a product. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

Certain policies of the Trump Administration may impact our business and industry. President Trump has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Obtaining and maintaining marketing approval of our current and future product candidates in one jurisdiction does not mean that we will be successful in obtaining and maintaining marketing approval of our current and future product candidates in other jurisdictions.

Obtaining and maintaining marketing approval of our current and future product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction, while a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the marketing approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign marketing approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

We depend on our information technology systems, and any failure of these systems could harm our business. Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital form that is necessary to conduct our business, and we are dependent on our information technology systems and those of third parties to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information, and data to comply with cGMP and data integrity requirements. It is critical that we do so in a secure manner to maintain data security and data integrity of such information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent a data compromise. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions, phishing, persons inside our organization or persons with access to systems inside our organization.

The risk of a security breach or disruption or data loss, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. We would also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

The successful commercialization of our product candidates will depend in part on the extent to which third-party payors, including governmental authorities and private health insurers, provide coverage and adequate reimbursement levels, as well as implement pricing policies favorable for our product candidates. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. The availability of coverage and adequacy of reimbursement by third-party payors, including government healthcare programs (e.g., Medicare, Medicaid), managed care providers, private health insurers, health maintenance organizations, and other organizations is essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates. Third-party payors decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and other third-party payors is essential for most patients to be able to afford treatments such as antibody-based therapies. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent our products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Our ability to successfully commercialize our product candidates, whether as a single agent or combination therapy, will depend in part on the extent to which coverage and adequate reimbursement for our products and related treatments will be available from third-party payors, including government healthcare programs (e.g., Medicare, Medicaid), managed care providers, private health insurers, health maintenance organizations, and other organizations. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. If coverage and adequate 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. Further, due to the COVID-19 pandemic, millions of individuals have lost/will be losing employer-based insurance coverage, which may adversely affect our ability to commercialize our products.

No uniform policy for coverage and reimbursement for products exist among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication.

A decision by a third-party payor not to cover or not to separately reimburse for our products or procedures using our products could reduce physician utilization of our products once approved. Assuming there is coverage for our product candidates, or procedures using our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, will be available for our current or future product candidates, or for any procedures using such product candidates, and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future. Further, if we or our collaborators develop companion diagnostic tests for use with our product candidates, we, or our collaborators, will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved.

Further, increasing efforts by third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or comparable regulatory approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Our product candidates may nonetheless not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition. We expect to experience pricing pressures from third-party payors in connection with the potential sale of any of our product candidates.

Lastly, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, in the European Union Member States can restrict the range of medicinal products for which their national health insurance systems provide reimbursement and they can control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Approaches between Member States are diverging. For example, in France, effective market access will be supported by agreements with hospitals and products may be reimbursed by the Social Security Fund. The price of medicines is negotiated with the Economic Committee for Health Products, or CEPS. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Therefore, coverage and reimbursement for products can differ significantly from payor to payor.

Enacted healthcare legislation, changes in healthcare law and implementation of regulations, as well as changes in healthcare policy, may increase the difficulty and cost for us to commercialize our product candidates, may impact our business in ways that we cannot currently predict, could affect the prices we may set, and could have a material adverse effect on our business and financial condition.

In the United States and in some foreign jurisdictions, there have been and likely will continue to be a number of legislative and regulatory changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare.. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the ACA, was passed, which substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, expands the types of entities eligible for the 340B drug discount program, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program in which, as a condition of coverage of its products under Medicare Part D, manufacturers must now agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, or BBA, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing legal and constitutional challenges in the United States Supreme Court; the Trump Administration has issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. Also, in December 2018, the Centers for Medicare and Medicaid Services, or CMS, issued a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional congressional action is taken. However, the Medicare sequester reductions under the BCA will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, the BBA, among other things, amended the ACA, effective January 1, 2019, to increase the point-of-sale discount (from 50% under the ACA to 70%) that is owed by pharmaceutical manufacturers who participate in Medicare Part D and, closed the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole".

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare and reform government program reimbursement methodologies for drug products. For example, at the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, he Trump Administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has started soliciting feedback on some of these measures and, at the same, is implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Although a number of these and other proposed measures may require additional authorization to become effective, Congress and the Trump Administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions on coverage or access could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates that we successfully commercialize or put pressure on our product pricing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the extent to which state and federal governments cover particular healthcare products and services and could limit the amounts that the federal and state governments will pay for healthcare products and services. This could result in reduced demand for any product candidate or complementary or companion diagnostics we develop or could result in additional pricing pressures.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our relationships with customers, third-party payors and others may 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, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market and distribute any products for which we obtain marketing approval.

The applicable federal and state healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under the Medicare and Medicaid programs or other federal healthcare programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The term remuneration has been interpreted broadly to include anything of value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers, among others, on the other. A person or entity need not have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Violations are subject to significant civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act, or FCA;

- The federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent, or knowingly making, or using or causing to be made or used, a false record or statement material to a false, fictitious, or fraudulent claim or obligation to pay or transmit money or property to the federal government, or to knowingly avoid, decrease, or conceal an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. Private individuals, commonly known as “whistleblowers”, can bring FCA qui tam actions, on behalf of the federal government and such individuals and may share in amounts paid by the entity to the government in recovery or settlement.;

- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits knowingly and willfully executing a scheme, or attempting to execute a scheme, to defraud any healthcare benefit program, including private third-party payors by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor, and further prohibits knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating the HIPAA fraud provisions without actual knowledge of the statutes or specific intent to violate them;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, imposes, among other things, certain requirements relating to the privacy, security and transmission of individually identifiable health information on covered entities and their business associates, those independent contractors or agents of covered entities that create, receive, maintain, transmit or obtain protected health information in connection with providing a service on behalf of a covered entity. . HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;

- The federal Physician Payments Sunshine Act, being implemented as the Open Payments Program, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held in a company by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners; and

- Analogous U.S. state and local laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payors, including private insurers; state and local marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; state laws that require drug manufacturers to report information related to clinical trials, or information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require drug manufacturers to report information on the pricing of certain drugs; state laws and local ordinances that require identification or licensing of sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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 the laws described above or any other government regulations that apply to us, we may be subject to significant sanctions, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, reputational harm, exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, if the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to similar penalties. In addition, the approval and commercialization of any product candidate we develop outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. All of these could harm our ability to operate our business and our financial results.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

European data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.

In the event we decide to conduct clinical trials or enroll subjects in our future clinical trials, we may be subject to additional privacy restrictions. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the European Economic Area, or EEA, including personal health data, is subject to the EU General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. Further, the United Kingdom's decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated now that the United Kingdom has left the EU.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations, or, collectively, Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Our business is heavily regulated and therefore involves significant interaction with public officials. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase in time. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. In particular, our operations will be subject to FCPA, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government-owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof. Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could also result in prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

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 have a material adverse effect on the success of 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. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of 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.

Although 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, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

Risks Related to Manufacturing

The loss of our third-party manufacturing partners or our, or our partners', failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.

We have contracted with qualified third-party contract manufacturing organizations, or CMOs, to manufacture our product candidates for preclinical and clinical trials. If approved, commercial supply of CTX-471, CTX-8371, CTX-8573 and any future product candidates may also be manufactured at one or more CMOs.

The facilities used by our CMOs to manufacture our product candidates are subject to various regulatory requirements and may be subject to the inspection of the FDA or other regulatory authorities. We do not control the manufacturing process at our CMOs, and are completely dependent on them for compliance with current regulatory requirements. If we or our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable regulatory authorities in foreign jurisdictions, we may not be able to rely on their manufacturing facilities for the manufacture of elements of our product candidates. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds our facilities or those of our CMOs inadequate for the manufacture of our product candidates or if such facilities are subject to enforcement action in the future or are otherwise inadequate, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates.

Additionally, our CMOs may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments or on account of global pandemics or similar events, including the COVID-19 pandemic. If our CMOs were to encounter any of these difficulties, our ability to provide our product candidate to patients in clinical trials, or to provide product for the treatment of patients once approved, would be jeopardized.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. In addition, we will likely need to change our CMO for CTX-471 manufacturing to one that can support commercial-scale manufacturing. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

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

The process of manufacturing antibody therapeutics and bispecifics, including our product candidates, is complex, time-consuming, highly regulated and subject to several risks, including:

- product loss during the manufacturing process, including loss caused by contamination, equipment failure or improper installation or operation of equipment, or operator error. 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, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination;

- we will likely need to change our CMO for CTX-471 manufacturing to one that can support large-scale manufacturing for later stage clinical trials as well as commercial supply needs;

- the manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor and raw material shortages, natural disasters, power failures and numerous other factors; and

- any adverse developments affecting 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 products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

We may also make changes to our manufacturing processes at various points during development, for a number of reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our ongoing or future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform ex vivo comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial.

Risks Related to Intellectual Property

If we are unable to obtain and maintain patent protection for our product candidates, or if the scope of the patent protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidates may be adversely affected.

Our success depends, in large part, on our and in a few cases, our licensors' ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and platform. We and our licensors have sought, and intend to seek, to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates and technology that are important to our business. No patent has yet issued from our patent applications.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation.

As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our technology or product candidates or that effectively prevent others from commercializing competitive technologies and product candidates. In particular, during prosecution of any patent application, the issuance of any patents based on the application may depend upon our ability to generate additional preclinical or clinical data that support the patentability of our proposed claims. We may not be able to generate sufficient additional data on a timely basis, or at all. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may not be aware of all third-party intellectual property rights potentially relating to our product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, only upon issuance or not at all. Therefore, we cannot be certain that we, or a licensor, were the first to make the inventions claimed in any owned or any licensed patents or pending patent applications, respectively, or which entity was the first to file for patent protection until such patent application publishes or issues as a patent. Databases for patents and publications, and methods for searching them, are inherently limited, so it is not practical to review and know the full scope of all issued and pending patent applications. As a result, the issuance, scope, validity, enforceability, and commercial value of our and our licensed patent rights are uncertain. Furthermore, if third parties have filed such patent applications, we may challenge their ownership, for example in a derivation proceeding before the U.S. Patent and Trademark Office, or USPTO, to determine who has the right to the claimed subject matter in the applications. Similarly, if our patent applications are challenged in a derivation proceeding, the USPTO may hold that a third-party is entitled to certain patent ownership rights instead of us. We may then be forced to seek a license from the third party that may not be available on commercially favorable terms, or at all.

The patent prosecution process is expensive, time consuming and complex, and we may not have and may not in the future be able to file, prosecute, maintain, enforce, defend or license all necessary or desirable patent applications in some or all relevant jurisdictions at a reasonable cost or in a timely manner. For example, in some cases, the work of certain academic researchers in the field has entered the public domain, which may compromise our ability to obtain patent protection for certain inventions related to or building upon such prior work. Consequently, we may not be able to obtain any such patents to prevent others from using our technology for, and developing and marketing competing products to treat, these indications. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. In some cases, we may be able to obtain patent protection, but such protections may expire before we commercialize the product protected by those rights, leaving us no meaningful protection for our products. In other cases, where our intellectual property is being managed by a third-party collaborator, licensee or partner, that third party may fail to act diligently in prosecuting, maintaining, defending or enforcing our patents. Such conduct may result in the failure to maintain or obtain protections, loss of rights, loss of patent term or, in cases where a third party has acted negligently or inequitably, patents being found unenforceable.

Even if the patent applications we license or own do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner..

In spite of a legal presumption of validity, the issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity, or enforceability which may be challenged in the courts and patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology, resulting in termination of our access to such intellectual property or increase our financial or other obligations to our licensors.

The agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our licensed patents and/or applications and any patent rights we own or may own in the future. We rely, in part, on our outside counsel or our licensing partners to pay these fees due to the USPTO and to non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction and may compromise the strength of other intellectual property in our portfolio. In such an event, potential competitors might be able to enter the market and this circumstance could have a material adverse effect on our business.

On February 1, 2019 the government of Venezuela, in response to certain U.S. sanctions, began to require that foreign entities pay all official fees, including patent fees (either for pending matters or new petitions), in PETRO, a “cryptocurrency” created by the Nicolás Maduro administration in February 2018 as a way to collect U.S. dollars while avoiding American financial sanctions issued under an Executive Order of President Trump on March 19, 2018. The Executive Order banned transactions involving “any digital currency, digital coin, or digital token, that was issued by, for, or on behalf of the Government of Venezuela on or after January 9, 2018.” The prohibition is applicable to any U.S. entity unless exempted by license. We do not hold such a license and therefore may not be able to secure patents in Venezuela. A presidential decree dated January 14, 2020 formally established the PETRO as a mandatory means of payment. In response, the Venezuelan Patent Office established an alternative payment method allowing the receipt of deposits with the value of corresponding Official fees in U.S. Dollars and Euros in cash at a non-sanctioned governmental bank. While this has been an adequate course of action to proceed in compliance, there is no guarantee it will remain so.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and enforcing 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 are and could remain less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may be less likely to be able to prevent third parties from infringing our patents in all countries outside the United States, or from selling or importing products that infringe our patents in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products or methods of treatment, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. For example, with "Brexit", there is uncertainty associated with obtaining, defending, and enforcing intellectual property rights in the United Kingdom. International treaties and regulations promulgated as a result of this transition could impede or eliminate our ability to obtain or maintain meaningful intellectual property rights in the United Kingdom. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business, financial condition, results of operations and prospects may be adversely affected.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In most countries, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest national filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, it is possible that patents protecting our product candidates might expire before or shortly after we commercialize those candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension and data exclusivity for our product candidates, our business may be harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch Waxman Act. The Hatch Waxman Act permits a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended per FDA-approved product, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Further, certain of our licenses currently or in the future may not provide us with the right to control decisions the licensor or its other licensees on Orange Book listings or patent term extension decisions under the Hatch-Waxman Act. Thus, if one of our important licensed patents is eligible for a patent term extension under the Hatch-Waxman Act, and it covers a product of another licensee in addition to our own product candidate, we may not be able to obtain that extension if the other licensee seeks and obtains that extension first. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements.

The Biologics Price Competition and Innovation Act of 2009 provides up to 12 years of market exclusivity for a reference biological product. We may not be able to obtain such exclusivity for our products. Moreover, the applicable time-period or the scope of patent protection afforded during any such extension could be less than we request. If we are unable to obtain patent term extension or the scope of term of any such extension is less than we request, the period during which we will have the right to exclusively market our product may be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be materially reduced.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, enacted in September 2011, or the America Invents Act, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention.

The America Invents Act also includes several significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity or ownership of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to such third-party pre-issuance submission of prior art to the USPTO or become involved in other contested proceedings such as opposition, derivation, reexamination, *inter partes* review, or post-grant review proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products.

In addition, the patent positions of companies in the development and commercialization of biological products and pharmaceuticals are particularly uncertain. Recent rulings from the U.S. Court of Appeals for the Federal Circuit and the U.S. Supreme Court have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

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

Competitors may infringe our patents or the patents of our licensors, or we may be required to defend against claims of infringement. Countering infringement or unauthorized use claims or defending against claims of infringement can be expensive and time-consuming. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. 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 marketing, sales or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. 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 and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

In addition, many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own, develop or license.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court. We may not be able to protect our trade secrets in court.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce any patent that is issued covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-enablement. In addition, patent validity challenges may, under certain circumstances, be based upon non-statutory obviousness-type double patenting, which, if successful, could result in a finding that the claims are invalid for obviousness-type double patenting or the loss of patent term, including a patent term adjustment granted by the USPTO, if a terminal disclaimer is filed to obviate a finding of obviousness-type double patenting. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, *inter partes* review and equivalent proceedings in foreign jurisdictions. Such proceedings could result in the revocation or cancellation of or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art of which the patent examiner and we or our licensing partners were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we could lose part, and perhaps all, of the patent protection on one or more of our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

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, processes for which patents are difficult to enforce and any 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, and some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In most countries, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest national filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, it is possible that patents protecting our product candidates might expire before or shortly after we commercialize those candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more U.S. patents that we license or may own in the future may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent per product may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, even if we were to seek a patent term extension, it may not be granted because of, for example, the failure to exercise due diligence during the testing phase or regulatory review process, the failure to apply within applicable deadlines, the failure to apply prior to expiration of relevant patents, or the failure to otherwise satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded under an extension request could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. If we are unable to obtain patent term extension or if the term of any requested extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, be able to enter the market sooner, and our revenue could be reduced, and our business, financial condition, prospects and results of operations could be materially harmed.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business and financial condition.

Our commercial success depends upon our ability and the ability of any collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current manufacturing methods, product candidates or future methods or products, resulting in either an injunction prohibiting our manufacture or sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including post grant review and *inter partes* review before the USPTO. The risks of being involved in such litigation and proceedings may also increase as our product candidates approach commercialization and as we gain greater visibility as a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any of our product candidates or technologies covered by the asserted third-party patents.

If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidates and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidates. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

Others may claim an ownership interest in our intellectual property and our product candidates, which could expose us to litigation and have a significant adverse effect on our prospects.

While we are presently unaware of any claims or assertions by third parties with respect to our patents or other intellectual property, we cannot guarantee that a third party will not assert a claim or an interest in any of such patents or intellectual property. For example, a third party may claim an ownership interest in one or more of our, or our licensors', patents or other proprietary or intellectual property rights. A third party could bring legal actions against us to seek monetary damages or enjoin clinical testing, manufacturing or marketing of the affected product candidate or product. If we become involved in any litigation, it could consume a substantial portion of our resources and cause a significant diversion of effort by our technical and management personnel. If any such action is successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product candidate or product, in which case we could be required to pay substantial royalties or grant cross-licenses to patents. We cannot, however, assure you that any such license would be available on acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product, or forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases, which may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or prospects.

If we are unable to protect the confidentiality of our proprietary information, the value of our technology and products could be adversely affected.

Trade secrets and know-how can be difficult to protect. To maintain the confidentiality of trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, collaborators and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes, and individuals with whom we have these agreements may not comply with their terms. Thus, despite such agreement, there can be no assurance that such inventions will not be assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all. We also seek to preserve the integrity and confidentiality of our trade secrets by other means, including maintaining physical security of our premises and physical and electronic security of our information technology systems. However, these security measures may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, others may independently discover or develop our trade secrets and proprietary information, and the existence of our own trade secrets affords no protection against such independent discovery. For example, a public presentation in the scientific or popular press on the properties of our product candidates could motivate a third party, despite any perceived difficulty, to assemble a team of scientists having backgrounds similar to those of our employees to attempt to independently reverse engineer or otherwise duplicate our antibody technologies to replicate our success.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our directors, employees, consultants, and advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals, or we, have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our product candidates, are rightfully owned by their former or current employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our employees, consultants, advisors and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Any registered trademarks or trade names may be challenged, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

Collaborations with third parties, including academic collaborations, may limit our ability to obtain, maintain, enforce or defend intellectual property necessary to conduct our business.

We may sometimes collaborate with non-profit and academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to develop our program.

In some circumstances, particularly in-licenses with academic institutions, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain, enforce or defend the patents, covering technology that we license from third parties. Therefore, we cannot be certain that these patents and applications will be prosecuted, maintained and enforced in a manner consistent with the best interests of our business. If our licensors fail to maintain such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize any of our products that are the subject of such licensed rights could be adversely affected. In certain circumstances, we have or may license technology from third parties on a non-exclusive basis. In such instances, other licensees may have the right to enforce our licensed patents in their respective fields, without our oversight or control. Those other licensees may choose to enforce our licensed patents in a way that harms our interest, for example, by advocating for claim interpretations or agreeing on invalidity positions that conflict with our positions or our interest. In addition to the foregoing, the risks associated with patent rights that we license from third parties will also apply to patent rights we own or may own in the future.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of the patents that we own or license or may own in the future;
- we, or any partners or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or any partners or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects.

Changes to national patent laws and diminished or limited access to U.S. and/or foreign patent counsel and the courts in response to the ongoing SARS-CoV-2 coronavirus pandemic may compromise our ability to pursue, obtain, enforce or defend our intellectual property patent protections throughout the world.

Following the discovery of a novel strain of coronavirus in Wuhan, China in December 2019, and the subsequent spread of the virus around the world, including the declaration of a public health emergency in January 2020 by the World Health Organization, many national patent offices promulgated emergency measures and alternative procedures for filing, prosecuting and adjudicating disputes regarding intellectual property. While some of these new rules involve the provision of extensions for certain filing deadlines, none of these emergency-situation rules have been tested in a litigation setting or for their harmonization with the laws of other countries.

Access to the USPTO and other patent offices has been restricted by government mandated shelter-in-place or stay-home orders thereby limiting our ability to appear before any tribunal in support of our intellectual property. Should the remaining electronic access to these tribunals be interrupted or non-existent, we may not be able to secure, defend or enforce patent protections in all jurisdictions.

We also rely on U.S. and foreign patent counsel in the management of our intellectual property. Should our access to counsel be diminished or lost due to effects of COVID-19 on these service providers and their organizations, we may not be able to manage, maintain or secure our intellectual property position.

Risks Related to Reliance on Third Parties

We rely or will rely on third parties to help conduct our ongoing and planned preclinical studies and clinical trials for CTX-471, CTX-8371, CTX-8573 and any future product candidates we develop. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize CTX-471, CTX-8371, CTX-8573 and any current or future product candidates we develop and our business could be materially harmed.

We currently do not have the ability to independently conduct preclinical studies that comply with the regulatory requirements known as current good laboratory practice, or GLP, requirements. We also do not currently have the ability to independently conduct any clinical trials. The FDA and regulatory authorities in other jurisdictions require us to comply with regulations and standards, including cGCP, or requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GLP-compliant preclinical studies and cGCP-compliant clinical trials on our product candidates properly and on time. While we have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. The third parties with whom we contract for execution of our GLP-compliant preclinical studies and our cGCP-compliant clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our current or future product candidates. Although we rely on these third parties to conduct our GLP-compliant preclinical studies and cGCP-compliant clinical trials, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

Many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. Further, under certain circumstances, these third parties may unilaterally terminate their agreements with us. If the third parties conducting our preclinical studies or our clinical trials do not adequately perform their contractual duties or obligations, experience significant business challenges, disruptions or failures, do not meet expected deadlines, including on account of the COVID-19 pandemic, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or to GLP and cGCP, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated. As a result, we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

We may depend on other third-party collaborators for the discovery, development and commercialization of certain of our current and future product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

In the future, we may form or seek other strategic alliances, joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to product candidates we develop. Such potential future collaborations involving our product candidates may pose various risks to us, including:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;

- collaborators may not properly enforce, maintain or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation or that could jeopardize or invalidate our intellectual property or proprietary information, exposing us to potential litigation or other intellectual property proceedings;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;

- disputes may arise between a collaborator and us that cause the delay or termination of the research, development or commercialization of the product candidate, or that result in costly litigation or arbitration that diverts management attention and resources;

- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;

- if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; and

- collaboration agreements may restrict our right to independently pursue new product candidates.

If we enter into collaboration agreements and strategic partnerships or license our intellectual property, products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or net income that justifies such transaction. Any of the factors set forth above, among others, could delay the development and commercialization of our product candidates, which would harm our business prospects, financial condition and results of operations.

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

The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our current or future product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies with respect to development and potential commercialization. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for other collaborations 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 collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the progress of our clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

Further, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Such exclusivity could limit our ability to enter into strategic collaborations with future collaborators. 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 its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any marketing or sales activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Risks Related to Our Business

We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

We are highly dependent on members of our executive team. The loss of the services of any of them may adversely impact the achievement of our objectives. Any of our executive officers—Thomas J. Schuetz, our co-founder and Chief Executive Officer, and Vered Bisker-Leib, our Chief Operating Officer—could leave our employment at any time, as all of our employees are "at-will" employees. The loss of the services of Mr. Schuetz or Dr. Bisker-Leib could impede the achievement of our research, development and commercialization objectives.

Historically, we have experienced significant turnover in our research and development workforce and have operated with a limited team of scientific and technical personnel. We have had difficulty attracting and retaining qualified personnel for certain positions in our research and development groups and we may not be able to attract and retain such personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for skilled individuals. Recruiting and retaining qualified employees for our business, including scientific and technical personnel, will also be critical to our success. In addition, failure to succeed in preclinical studies, clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified scientific and technical personnel. The inability to recruit, or the loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. Our current or future product candidates may face competition from major pharmaceutical companies, specialty pharmaceutical companies, universities and other research institutions and from products and therapies that currently exist or are being developed, some of which products and therapies we may not currently know about. Many of our competitors have significantly greater financial, manufacturing, marketing, product development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining marketing approvals, recruiting patients and manufacturing pharmaceutical products, and they may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA or other regulatory approval or discovering, developing and commercializing products in our field before we do, which could result in our competitors establishing a strong market position before we are able to enter the market.

Our competitors may obtain FDA or other regulatory approval of their product candidates more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates or platform technologies. Our competitors may also develop drugs or discovery platforms that are more effective, more convenient, more widely used or less costly than our product candidates or our NKp30 platform or, in the case of drugs, have a better safety profile than our product candidates. These competitors may also be more successful than us in manufacturing and marketing their products, and have significantly greater financial resources and expertise in research and development.

There are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. Currently marketed oncology drugs and therapeutics range from traditional cancer therapies, including chemotherapy, to antibody-drug conjugates, such as Genentech's Kadcyla, to immune checkpoint inhibitors targeting CTLA-4, such as BMS' Yervoy, and PD-1/PD-L1, such as BMS' Opdivo, Merck & Co.'s Keytruda and Genentech's Tecentriq, to T cell-engager antibody therapeutics, such as Amgen's Blincyto. In addition, numerous compounds are in clinical development for cancer treatment. Many of these companies are well-capitalized and have significant clinical experience. In addition, we are exploring CTX-8573 for the treatment of severe autoimmune indications, for which there are several approved and marketed products that CTX-8573 may compete with, if approved, including Alexion's Soliris and Roche's Rituxan. See "*Business—Competition*".

Smaller and other early stage companies may also prove to be significant competitors. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our current and future product candidates. In addition, the biopharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our product candidates obsolete, less competitive or not economical.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, have a broader label, are marketed more effectively, are reimbursed or are less expensive than any products that we may develop. Our competitors may also obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates or platform technologies. Even if our product candidates achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. If we do not compete successfully, we may not generate or derive sufficient revenue from any product candidate for which we obtain marketing approval and may not become or remain profitable.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As our development plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, marketing, sales, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for CTX-471, CTX-8371, CTX-8573 and any other current or future product candidates we develop, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to advance development of and, if approved, commercialize CTX-471, CTX-8371, CTX-8573 and any current or future product candidates we develop will depend, in part, on our ability to effectively manage any future growth, and our management may have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of any current or future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize CTX-471, CTX-8371, CTX-8573 and any current or future product candidates we develop and, accordingly, may not achieve our research, development and commercialization goals.

If we are unable to establish marketing, sales and distribution capabilities for CTX-471, CTX-8371, CTX-8573 or any other product candidate that may receive regulatory approval, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have sales or marketing infrastructure. To achieve commercial success for CTX-471, CTX-8371, CTX-8573 and any other product candidate for which we may obtain marketing approval, we will need to establish a sales and marketing organization. In the future, we expect to build a focused sales and marketing infrastructure to market some of our product candidates in the United States, if and when they are approved. There are risks involved with establishing our own marketing, sales 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.

Factors that may inhibit our efforts to market our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, once approved;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own marketing, sales and distribution capabilities and are forced to enter into arrangements with, and rely on, third parties to perform these services, our revenue and our profitability, if any, are likely to be lower than if we had developed such capabilities ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish marketing, sales and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of our product candidates.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human trials and may face greater risk if we commercialize any products that we develop. Product liability claims may be brought against us by subjects enrolled in our trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against such claims, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate we may develop;
- withdrawal of trial participants;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;

- initiation of investigations by regulators;
- significant time and costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any product candidates that we may develop.

While we currently hold trial liability insurance coverage consistent with industry standards, the amount of coverage may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates, but we may be unable to obtain commercially reasonable product liability insurance. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business and financial condition.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Risks Related to Ownership of Our Common Stock

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earliest of (i) December 31, 2024, (ii) the last day of the first fiscal year in which we have total annual gross revenues of at least $1.07 billion, (iii) the last day of the first fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700.0 million on June 30th and (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may rely on 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.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of this extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

There is currently no market for our common stock and there can be no assurance that any market will ever develop. You may therefore be unable to re-sell shares of our common stock at times and prices that you believe are appropriate.

Our common stock is not listed on a national securities exchange or any other exchange, or quoted on an over-the-counter market. Therefore, there is no trading market, active or otherwise, for our common stock and our common stock may never be included for trading on any stock exchange, automated quotation system or any over-the-counter market. Accordingly, our common stock is highly illiquid and you will likely experience difficulty in re-selling such shares at times and prices that you may desire.

Our common stock may not be eligible for listing or quotation on any securities exchange.

We do not currently meet the initial quantitative listing standards of any national securities exchange or over-the-counter trading system. We cannot assure you that we will be able to meet the initial listing standards of any national securities exchange, or, if we do meet such initial listing standards, that we will be able to maintain any such listing. Further, the national securities exchanges are adopting so-called "seasoning" rules that will require that we meet certain requirements, including prescribed periods of time trading over-the-counter and minimum filings of periodic reports with the SEC, before we are eligible to apply for listing on such national securities exchanges. We intend to contact an authorized market maker for an over-the-counter quotation system for sponsorship of our common stock, but we cannot guarantee that such sponsorship will be approved and our common stock listed and quoted for sale. Even if our common stock is quoted for sale on an over-the-counter quotation system, buyers may be insufficient in numbers to allow for a robust market and it may prove impossible to sell your shares. In addition, an investor may find it difficult to obtain accurate quotations as to the market value of our common stock. In addition, if we fail to meet the criteria set forth in SEC regulations, various requirements would be imposed by law on broker-dealers who sell our securities to persons other than established customers and accredited investors. Consequently, such regulations may deter broker-dealers from recommending or selling our common stock, which may further affect its liquidity. This would also make it more difficult for us to raise additional capital.

The designation of our common stock as "penny stock" would limit the liquidity of our common stock.

Our common stock may be deemed a "penny stock" (as that term is defined under Rule 3a51-1 of the Exchange Act) in any market that may develop in the future. Generally, a "penny stock" is a common stock that is not listed on a securities exchange and trades for less than $5.00 a share. Prices often are not available to buyers and sellers and the market may be very limited. Penny stock in start-up companies is among the riskiest equity investments. Broker-dealers who sell penny stock must provide purchasers with a standardized risk-disclosure document prepared by the SEC. The document provides information about penny stock and the nature and level of risks involved in investing in the penny stock market. A broker must also provide purchasers with bid and offer quotations and information regarding broker and salesperson compensation and make a written determination that the penny stock is a suitable investment for the purchaser and obtain the purchaser's written agreement to the purchase. Many brokers choose not to participate in penny stock transactions. If our common stock is deemed "penny stock", because of penny stock rules, there may be less trading activity in any market that develops for our common stock in the future and stockholders are likely to have difficulty selling their shares.

FINRA sales practice requirements may limit a stockholder's ability to buy and sell our common stock.

The Financial Industry Regulatory Authority, or FINRA, has adopted rules requiring that, in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative or low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA has indicated its belief that there is a high probability that speculative or low-priced securities will not be suitable for at least some customers. If these FINRA requirements are applicable to us or our securities, they may make it more difficult for broker-dealers to recommend that at least some of their customers buy our common stock, which may limit the ability of our stockholders to buy and sell our common stock and could have an adverse effect on the market for and price of our common stock.

The market price of our common stock may be highly volatile, and may be influenced by numerous factors, some of which are beyond our control.

If a market for our common stock develops, its market price could fluctuate substantially due to a variety of factors, including market perception of our ability to meet our growth projections and expectations, quarterly operating results of other companies in the same industry, trading volume in our common stock, changes in general conditions in the economy and the financial markets or other developments affecting our business and the business of others in our industry. In addition, the stock market itself is subject to extreme price and volume fluctuations. This volatility has had a significant effect on the market price of securities issued by many companies for reasons related and unrelated to their operating performance and could have the same effect on our common stock. The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- results of clinical trials of our product candidates;
- the timing of the release of results of our clinical trials;
- results of clinical trials of our competitors' products;
- safety issues with respect to our products or our competitors' products;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated fluctuations in our financial condition and operating results;
- publication of research reports by securities analysts about us or our competitors or our industry;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- the passage of legislation or other regulatory developments affecting us or our industry;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- sales of our common stock by us, our insiders or our other stockholders;
- speculation in the press or investment community;
- announcement or expectation of additional financing efforts;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities;
- changes in market conditions for biopharmaceutical stocks; and
- changes in general market and economic conditions.

In addition, the stock market has recently experienced significant volatility, including as a result of the COVID-19 pandemic and particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. As we operate in a single industry, we are especially vulnerable to these factors to the extent that they affect our industry or our products, or to a lesser extent our markets. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

As of June 23, 2020, after giving effect to the Merger and the initial closing of the Offering, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 82.6% of our common stock, including shares subject to outstanding options that are exercisable within 60 days after such date. Accordingly, these stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our board of directors and approval of significant corporate transactions. This concentration of ownership could have the effect of entrenching our management and/or the board of directors, delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock.

The shares of common stock issued in the Merger and the Offering are "restricted securities" and, as such, may not be sold except in limited circumstances.

None of the shares of common stock issued in the Merger and the Offering have been registered under the Securities Act of 1933, as amended, or the Securities Act, or registered or qualified under any state securities laws. The shares of common stock issued in the Merger and the Offering were sold and/or issued pursuant to exemptions contained in and under those laws. Accordingly, such shares of common stock are "restricted securities" as defined in Rule 144 under the Securities Act and must, therefore, be held indefinitely unless registered under applicable federal and state securities laws, or an exemption is available from the registration requirements of those laws. The certificates representing the shares of common stock issued in the Merger and the Offering reflect their restricted status.

We have agreed to register the shares of common stock issued in the Merger and the Offering. There can be no assurance, however, that the SEC will declare the registration statement effective, thereby enabling the shares of common stock issued in the Merger or the Offering to be freely tradable. In addition, Rule 144 under the Securities Act, which permits the resale, subject to various terms and conditions, of limited amounts of restricted securities after they have been held for six months will not immediately apply to our common stock because we were at one time designated as a "shell company" under SEC regulations. Pursuant to Rule 144(i), securities issued by a current or former shell company that otherwise meet the holding period and other requirements of Rule 144 nevertheless cannot be sold in reliance on Rule 144 until one year after the date on which the issuer filed current "Form 10 information" (as defined in Rule 144(i)) with the SEC reflecting that it ceased being a shell company, and provided that at the time of a proposed sale pursuant to Rule 144, the issuer has satisfied certain reporting requirements under the Exchange Act. We believe this requirement to file Form 10 information has been satisfied by the filing of this Report. Because, as a former shell company, the reporting requirements of Rule 144(i) will apply regardless of holding period, the restrictive legends on certificates for the shares of common stock issued in the Merger and the Offering cannot be removed except in connection with an actual sale that is subject to an effective registration statement under, or an applicable exemption from the registration requirements of, the Securities Act.

If we are unable to register in a timely manner the shares of common stock issued to stockholders in the Merger or the Offering, then the ability to re-sell shares of our common stock so issued will be delayed.

We have agreed, at our expense, to prepare a registration statement, and to cause our Company to file a registration statement with the SEC registering the resale of an aggregate of 52,151,798 shares of our common stock issued in connection with the Merger and the Offering. There are many reasons, including some over which we have little or no control, which could keep the registration statement from being declared effective by the SEC, including delays resulting from the SEC review process and comments raised by the SEC during that process. The shares of common stock covered by such registration statement will not be eligible for resale until the registration statement is effective or an exemption from registration, such as Rule 144, becomes available. If the registration statement is not filed within 60 days of the closing of the Offering, then we may be subject to certain liquidated damages pursuant to the registration rights agreement we entered into with the holders of 52,151,798 shares of our common stock issued in connection with the Merger and the Offering. See "The Merger and Related Transactions—Registration Rights Agreement" for more information.

Because we became a reporting company under the Exchange Act by means other than a traditional underwritten initial public offering, we may not be able to attract the attention of research analysts at major brokerage firms.

Because we did not become a reporting company by conducting an underwritten initial public offering of our common stock, and because we will not be listed on a national securities exchange, security analysts of brokerage firms may not provide coverage of our company. In addition, investment banks may be less likely to agree to underwrite secondary offerings on our behalf than they might if we became a public reporting company by means of an underwritten initial public offering, because they may be less familiar with our company as a result of more limited coverage by analysts and the media, and because we became public at an early stage in our development. The failure to receive research coverage or support in the market for our shares will have an adverse effect on our ability to develop a liquid market for our common stock.

Because the Merger was a reverse merger, the registration statement we file with respect to the shares of common stock received by investors in the Merger might be subject to heightened scrutiny by the SEC, and we may not be able to attract the attention of major brokerage firms.

Additional risks may exist as a result of our becoming a public reporting company through a "reverse merger". Certain SEC rules are more restrictive when applied to reverse merger companies, such as the ability of stockholders to re-sell their shares of common stock pursuant to Rule 144, and the SEC may subject the registration statement we file with respect to the shares of common stock received by investors in the Merger and the Offering to heightened scrutiny. In addition, securities analysts of major brokerage firms may not provide coverage of our capital stock or business. Because we became a public reporting operating company through a reverse merger, there is no incentive to brokerage firms to recommend the purchase of our common stock. We cannot assure you that brokerage firms will want to provide analyst coverage of our capital stock or business in the future.

The resale of shares covered by a registration statement could adversely affect the market price of our common stock in the public market, should one develop, which result would in turn negatively affect our ability to raise additional equity capital.

The sale, or availability for sale, of our common stock in the public market may adversely affect the prevailing market price of our common stock and may impair our ability to raise additional capital by selling equity or equity-linked securities. We have agreed, at our expense, to prepare a registration statement, and to cause us to file a registration statement with the SEC registering the resale of 52,151,798 shares of our common stock issued in connection with the Merger and the Offering. Once effective, the registration statement will permit the resale of these shares at any time. The resale of a substantial number of shares of our common stock in the public market could adversely affect the market price for our common stock and make it more difficult for you to sell shares of our common stock at times and prices that you feel are appropriate. Furthermore, we expect that, because there will be a large number of shares registered pursuant to a registration statement, selling stockholders will continue to offer shares covered by such registration statement for a significant period of time, the precise duration of which cannot be predicted. Accordingly, the adverse market and price pressures resulting from an offering pursuant to a registration statement may continue for an extended period of time and continued negative pressure on the market price of our common stock could have a material adverse effect on our ability to raise additional equity capital.

Future issuances of common or preferred stock to fund our operations may substantially dilute your investment and reduce your equity interest in our company.

We may need to raise capital in the future through issuances of common or preferred stock to fund the development of our drug candidates or for other purposes. At its sole discretion, our board of directors may issue additional securities without seeking stockholder approval. Any future issuances of common or preferred stock to fund our operations may substantially dilute your investment and reduce your equity interest in our company.

We will incur increased costs as a result of being a public company and our management expects to devote substantial time to public company compliance efforts.

As a public company, we will incur significant legal, insurance, accounting and other expenses that we did not incur as a private company. In addition, our administrative staff will be required to perform additional tasks. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from product development activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. In connection with the Merger, we are increasing our directors' and officers' insurance coverage, which will increase our insurance cost. In the future, it will be more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

In addition, in order to comply with the requirements of being a public company, we may need to undertake various actions, including implementing new internal controls and procedures and hiring new accounting or internal audit staff. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that information required to be disclosed in reports under the Securities Exchange Act of 1934 as amended, or the Exchange Act, is accumulated and communicated to our principal executive and financial officers. Any failure to develop or maintain effective controls could adversely affect the results of periodic management evaluations. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate, or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our ordinary shares could decline. In addition, if we are unable to continue to meet these requirements, we may not be able to obtain listing on a national securities exchange.

Our management team and board of directors will need to devote significant efforts to maintaining adequate and effective disclosure controls and procedures and internal control over financial reporting in order to comply with applicable regulations, which may include hiring additional legal, financial reporting and other finance and accounting staff and engaging consultants to assist in designing and implementing such procedures. Additionally, any of our efforts to improve our internal controls and design, implement and maintain an adequate system of disclosure controls may not be successful and will require that we expend significant cash and other resources. In addition, our management will be required to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting. This assessment will need to include the disclosure of any material weaknesses in our internal control over financial reporting identified by our management or our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statement.

We have broad discretion in the use of our cash resources, including the net proceeds from the Offering, and may not use them effectively.

We currently intend to use our cash resources, including the net proceeds from the Offering, for continuing clinical development of CTX-471, including the continuation of our ongoing Phase 1 clinical trial and the preparation for and initiation of the Phase 2 trials, the advancement of our second product candidate, CTX-8371, into IND-enabling studies in the third quarter of 2020, the advancement of our third product candidate, CTX-8573, into IND-enabling studies in the first half of 2021 and for working capital and other general corporate purposes. Although we currently intend to use the net proceeds from the Offering in such a manner, we will have broad discretion in the application of the net proceeds. Our failure to apply these funds effectively could affect our ability to continue to develop and commercialize our product candidates. Pending their use, we may invest the net proceeds from the Offering in a manner that does not produce income or loses value.

Provisions in our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws that we have adopted in connection with the Merger contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, or DGCL, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These antitakeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Any provision of our amended and restated certificate of incorporation, our amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated bylaws designate certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favourable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our bylaws (in each case, as they may be amended form time to time) or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein; provided, however, that this exclusive forum provision will not apply to any causes of action arising under the Securities Act of 1933, as amended, or the Securities Act, or the Exchange Act. Our bylaws further provide that, unless we consent in writing to an alternative forum, the United States District Court for the District of Massachusetts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. We have chosen the United States District Court for the District of Massachusetts as the exclusive forum for such Securities Act causes of action because our principal executive offices are located in Cambridge, Massachusetts. In addition, our amended and restated bylaws will provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions. We recognize that the forum selection clause in our bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts, as applicable. Additionally, the forum selection clause in our bylaws may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. The Court of Chancery of the State of Delaware or the United States District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Our business, results of operations and future growth prospects could be materially and adversely affected by the COVID-19 pandemic.

Due to the evolving and uncertain global impacts of the COVID-19 pandemic, we cannot precisely determine or quantify the impact this pandemic will have on our business operations for the remainder of our fiscal year ending December 31, 2020 or beyond. The extent to which COVID-19 may impact our business, results of operations and future growth prospects will depend on a variety of factors and future developments, which are highly uncertain and cannot be predicted with confidence, including the ultimate geographic spread of the disease, the duration, scope and severity of the pandemic, the duration and extent of travel restrictions and social distancing in the U.S. and other countries, business closures or business disruptions and the effectiveness of actions taken in the U.S. and other countries to contain and treat COVID-19.

For example, public health actions being undertaken globally in response to the COVID-19 pandemic, including quarantines, stay-at-home, executive and similar government orders and the prioritization of healthcare resources, could adversely impact our business, results of operations and future growth prospects. For ongoing and planned clinical trials, we anticipate and have experienced some temporary delays or disruptions due to the COVID-19 pandemic, including limited or reduced patient access to trial investigators, hospitals and trial sites, delayed initiation of new clinical trial sites and limited on-site personnel support at various trial sites, which could adversely impact our development plans, including the initiation of planned clinical trials and our ability to conduct ongoing clinical trials. There may also be local orders affecting one or more trial sites, which may trigger mandated changes to our clinical trial protocols or temporary suspensions in the affected trial sites. In addition, quarantines, stay-at-home, executive and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations have occurred and could continue to occur or be expanded in scope or duration, which could adversely impact ongoing and planned clinical trials, our employees and business operations, personnel at our third-party suppliers and other vendors in the U.S. and other countries, the availability, cost or supply of materials, which may cause delays or disruptions to development plans for our product candidates, and sales and marketing activities for any product candidates for which we may receive marketing approval in the U.S. or other geographies in the future.

To the extent the COVID-19 pandemic adversely affects our business, results of operations and future growth prospects, it may also have the effect of heightening many of the other risks described in this "*Risk Factors*" section.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our operations. In addition, our 2018 Credit Facility contains, and any future debt financing arrangement we enter into may contain, terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included in this Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties as described under the heading "Forward-Looking Statements" elsewhere in this Report. You should review the disclosure under the heading "Risk Factors" in this Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company developing proprietary antibody therapeutics intended to engage the immune system to treat both solid tumors and hematological malignancies. Our immuno-oncology product candidates include a clinical-stage monoclonal antibody and a portfolio of bispecific antibodies. These product candidates are designed to address three critical components required for an effective immune response to cancer: induction of a potent innate immune response; activation of the adaptive immune system; and alleviation of immunosuppressive mechanisms used by tumors to evade immune surveillance and activation. We plan to advance our product candidates through clinical development, either as standalone therapies or in combination with existing therapies as supported by clinical and nonclinical data.

Since our inception, we have devoted substantially all of our efforts to organizing and staffing our company, business planning, raising capital, research and development activities, building our intellectual property portfolio and providing general and administrative support for these operations. To date, we have funded our operations primarily with proceeds from the sale of convertible preferred equity and borrowings under the 2018 Credit Facility. Through March 31, 2020, we had received gross proceeds of $132.0 million from sales of convertible preferred equity and borrowed $15.0 million under the 2018 Credit Facility.

We have incurred significant operating losses since inception. We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products in the near future, if at all. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of our therapies and any future product candidates. Our net losses were $34.7 million and $38.3 million for the years ended December 31, 2019 and 2018, respectively, and $6.4 million and $10.8 million for the three months ended March 31, 2020 and 2019, respectively. We expect to continue to incur significant expenses for at least the next several years as we advance through clinical development, develop additional product candidates and seek regulatory approval of any product candidates that complete clinical development. In addition, if we obtain marketing approval for any product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. We may also incur expenses in connection with the in-licensing or acquisition of additional product candidates. Furthermore, upon the completion of the Merger, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations, compliance and other expenses that we did not incur as a private company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through equity and debt financings, or other capital sources, which may include collaborations with other companies or other strategic transactions. As of March 31, 2020, we had $17.5 million in cash, cash equivalents and marketable securities. In June 2020, we raised an aggregate of $54.0 million in net proceeds from the Private Placement. Based on our research and development plans, we expect that such cash resources will enable us to fund our operating expenses and capital expenditures requirements into the fourth quarter of 2021. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, reduce or eliminate the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Recent Developments

Reverse Merger

On June 17, 2020, Olivia Ventures, Inc., Acquisition Sub, Compass Therapeutics, Blockers, Blockers Merger Subs and Blocker Holders entered into the Merger Agreement, pursuant to which Acquisition Sub merged with and into Compass Therapeutics, with Compass Therapeutics continuing as the surviving entity and our wholly-owned subsidiary, and each Blocker Merger Sub merged with and into the applicable Blocker, with each Blocker continuing as the surviving entity and our wholly-owned subsidiary. As a result of the Merger, we acquired the business of Compass Therapeutics.

At the Effective Time, an aggregate of 31,627,139 shares of our common stock were issued to holders of common membership interests of Compass Therapeutics (including common membership interests issued upon the conversion of preferred membership interests) and 7,428,217 shares of our common stock were issued to the holders of equity interests of the Blockers, after adjustments due to rounding for fractional shares. With respect to 15 holders of an aggregate of 131,472 Compass Therapeutics common membership interests who were not accredited investors, we paid an aggregate of approximately $68 thousand in cash in consideration for cancelling such membership interests in connection with the Merger. In addition, 2,930,836 shares of our common stock were reserved for issuance under our 2020 Stock Option and Incentive Plan. Immediately prior to the Effective Time, an aggregate of 4,000,000 of the 5,000,000 shares of our common stock held by pre-Merger stockholders of Olivia Ventures, Inc. were forfeited and surrendered for cancellation.

The Merger and the Blocker Mergers were treated as a recapitalization and reverse acquisition by us for financial reporting purposes. Compass Therapeutics is considered the acquirer for accounting purposes, and our historical financial statements before the Merger will be replaced with the historical financial statements of Compass Therapeutics before the Merger in future filings with the SEC. The Merger is intended to be treated as a tax-free reorganization under Section 368(a) of the Code.

Private Placement Offering

On June 19, 2020, we sold 12,096,442 shares of our common stock pursuant to the initial closing of a private placement offering for up to 14,000,000 shares of our common stock, at a purchase price of $5.00 per share for approximately $54.0 million in net proceeds. The Offering closed on June 19, 2020. We may hold one or more subsequent closings at any time prior to July 19, 2020, unless otherwise extended, to sell any remaining shares in the Offering. We may also sell up to an additional 2,000,000 shares of our common stock at the Offering Price to cover over-subscriptions in the event the Offering is oversubscribed.

COVID-19 Update

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. As of June 2020, COVID-19 has spread to Europe, the United States and many other countries, and has been declared a pandemic by the World Health Organization. In an effort to contain the spread of COVID-19, the United States, Europe and Asia have implemented severe travel restrictions, social distancing requirements, stay-at-home or shelter-in-place orders and have delayed the commencement of non-COVID-19-related clinical trials, among other restrictions. As a result, the COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, communities and business operations, as well as contributing to significant volatility and negative pressure on the U.S. economy and in 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 mitigate its impact, and the economic impact on local, regional, national and international markets.

We have been carefully monitoring the COVID-19 pandemic and its potential impact on our business, and have taken important steps to help ensure the safety of our employees and their families and to reduce the spread of COVID-19 community-wide. We have established a work-from-home policy for all employees since mid-March 2020, while ensuring essential staffing levels at our operations remain in place, including maintaining key personnel in our laboratory facilities. For those employees, we have implemented stringent safety measures designed to comply with applicable federal, state and local guidelines instituted in response to the COVID-19 pandemic.

To date, we have been able to continue to pursue our Phase 1 clinical trial without delays or major difficulties despite the COVID-19 pandemic. Nevertheless, we expect that COVID-19 precautions may directly or indirectly impact the timeline for our ongoing clinical trial and potential future trials. We are continuing to assess the potential impact of the COVID-19 pandemic on our current and future business and operations, including our expenses and clinical trials, as well as on our industry and the healthcare system.

Components of Results of Operations

Research and development

Research and development expenses consist primarily of costs incurred in connection with the development of our product candidates, CTX-471, CTX-8371 and CTX-8573, and our NKp30 innate cell engager platform, as well as unrelated discovery program expenses. We expense research and development costs as incurred. These expenses include:

- employee-related expenses, including salaries, related benefits and equity-based compensation expense, for employees engaged in research and development functions;
- expenses incurred under agreements with organizations that support our platform program development;
- CMOs that are primarily engaged to provide drug substance and product for our clinical trials, research and development programs, as well as investigative sites and consultants that conduct our clinical trials, nonclinical studies and other scientific development services;
- the cost of acquiring and manufacturing nonclinical and clinical trial materials, including manufacturing registration and validation batches;
- costs related to compliance with quality and regulatory requirements; and
- payments made under third-party licensing agreements.

Advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will increase substantially in connection with our planned clinical development activities in the future. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the clinical development of any future product candidates.

Our clinical development costs may vary significantly based on factors such as:

- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the location where the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;

- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates; and
- the efficacy and safety profile of our product candidates.

The successful development and commercialization of product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the following:

- the timing and progress of nonclinical and clinical development activities;
- the number and scope of nonclinical and clinical programs we decide to pursue;
- raising necessary additional funds;
- the progress of the development efforts of parties with whom we may enter into collaboration arrangements;
- our ability to maintain our current development program and to establish new ones;
- our ability to establish new licensing or collaboration arrangements;
- the successful initiation and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt and related terms of regulatory approvals from applicable regulatory authorities;
- the availability of drug substance and drug product for use in production of our product candidate;
- establishing and maintaining agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidates are approved;
- our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- our ability to protect our rights in our intellectual property portfolio;
- the commercialization of our product candidate, if and when approved;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- the acceptance of our product candidate, if approved, by patients, the medical community and third-party payors;
- competition with other products;
- the impact of any business interruptions to our operations, including the timing and enrollment of patients in our planned clinical trials, or to those of our manufacturers, suppliers, or other vendors resulting from the COVID-19 pandemic or similar public health crisis; and
- a continued acceptable safety profile of our therapies following approval.

A change in the outcome of any of these variables with respect to the development of our product candidates could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any of our product candidates.

General and administrative expenses

General and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, corporate and business development, and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and administrative consulting services; insurance costs; administrative travel expenses; marketing expenses and other operating costs.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our business operations. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs, as well as investor and public relations expenses associated with being a public company.

Interest income

Interest income consists primarily of interest income received on our cash and cash equivalents.

Interest expense

Interest expense consists primarily of cash interest under our 2018 Credit Facility that we entered into in March 2018 and the related non-cash interest attributable to the amortization of deferred financing costs incurred in connection with this facility.

Change in fair value of call right liability

Our Series A-1 convertible preferred membership interests issued in 2015 included future tranche participation rights permitting investors to purchase Series A-2 through A-5 convertible preferred membership interests at fixed purchase prices. The call right liability is a freestanding financial instrument that was recorded at its fair value and re-measured at each reporting period until the liability was settled in June 2018.

Change in fair value of derivative liability

Our 2018 Credit Facility includes contingent interest rate reset features and a contingent feature to pay a success fee upon the occurrence of certain liquidity events as defined in the credit agreement. These features have been bifurcated from the 2018 Credit Facility, recorded at their estimated fair values and are re-measured at each reporting period until they are exercised, expire, or otherwise settled.

Realized foreign exchange loss

We recognized foreign exchange losses for payment arrangements that are denominated in currencies other than the U.S. dollar.

Income taxes

Compass Therapeutics LLC, the business that we acquired in the Merger, is treated as a partnership for income tax reporting purposes and therefore, federal and state income taxes are the responsibility of its individual members. As such, no federal or state income taxes related to Compass Therapeutics LLC are recorded in our consolidated financial statements. The wholly-owned subsidiary of Compass Therapeutics LLC, Compass Therapeutics Advisors Inc., is organized as a C corporation and is subject to federal and state income taxes. All such taxes have been recorded in our consolidated financial statements.

Results of Operations

Comparison of the Three Months Ended March 31, 2020 and 2019

The following table summarizes the results of operations of Compass Therapeutics for the three months ended March 31, 2020 and 2019, respectively:

	Three Months Ended March 31,		
	2020	2019	Change
(in thousands)			
Operating expenses:			
Research and development	$ 3,571	$ 7,243	$ (3,672)
General and administrative	2,260	3,351	(1,091)
Total operating expenses	5,831	10,594	(4,763)
Loss from operations	(5,831)	(10,594)	4,763
Other Income (expense):			
Interest income	41	234	(193)
Interest expense	(276)	(318)	42
Change in fair value of derivative liability	(320)	(57)	(263)
Realized foreign exchange loss	—	(7)	7
Total other income (expense), net	(555)	(148)	(407)
Loss before income tax expense	(6,386)	(10,742)	4,356
Income tax expense	(16)	(29)	13
Net loss	$ (6,402)	$ (10,771)	$ 4,369

Research and development expenses

Research and development expenses decreased by $3.6 million from $7.2 million for the three months ended March 31, 2019 to $3.6 million for the three months ended March 31, 2020. The decrease was primarily attributable to the completion of our preclinical efforts for our product candidate CTX-471 and the related filing of our IND in February 2019. As a result, research and development expenses decreased by $2.2 million, of which $0.6 million was due to a milestone payment we made under the Adimab Agreement. In addition, we initiated efforts to reduce our workforce in April 2019, which resulted in a decrease in salaries and related benefits of $1.4 million. We anticipate our research and development expenses to increase in future periods as we begin our IND-enabling studies for CTX-8371 and continue to further develop our other preclinical product candidates.

General and administrative expenses

General and administrative expenses decreased by $1.1 million from $3.4 million for the three months ended March 31, 2019 to $2.3 million for the three months ended March 31, 2020. The decrease was primarily attributable to our efforts to reduce our workforce in April 2019, which resulted in a decrease in salaries and related benefits of $0.6 million. Our cost reduction efforts also resulted in lower professional fees and facility-related costs of $0.3 million and $0.1 million, respectively. We anticipate our general and administrative expenses to increase in future periods as we expand our operations to support our research and development efforts and operate as a publicly traded company.

Interest income

We recognized interest income of $41,000 and $0.2 million during the three months ended March 31, 2020 and 2019, respectively. The decrease in interest income is primarily attributable to the lower average balance of our cash and cash equivalents.

Interest expense

We recognized interest expense of $0.3 million during each of the three months ended March 31, 2020 and 2019, respectively, as average balance of our debt arrangements was consistent during each period.

Change in fair value of derivative liability

We recognized a change in our derivative liability of $0.3 million and $57,000 during the three months ended March 31, 2020 and 2019, respectively. The increase in fair value of the derivative liability is primarily attributable to the increased likelihood of a liquidity event occurring whereby a success fee payment would be payable to Pacific Western Bank under the 2018 Credit Facility. Upon completion of the Merger in June 2020, which qualified as a liquidity event under the 2018 Credit Facility, we paid a success fee of $1.1 million to Pacific Western Bank.

Realized foreign exchange loss

Our realized foreign exchange losses were immaterial and unchanged during the three months ended March 31, 2020 and 2019, respectively, as we have a limited number of payment arrangements denominated in a currency other that the U.S. dollar.

Income tax expense

During the three months ended March 31, 2020 and 2019, we recognized income tax expenses of $16,000 and $29,000, respectively. Our income tax expense is primarily attributable to the services that our wholly-owned subsidiary, a C corporation, provides at cost plus a profit margin.

Comparison of the Years Ended December 31, 2019 and 2018

The following table summarizes the results of operations of Compass Therapeutics for the years ended December 31, 2019 and 2018, respectively:

	Year Ended December 31,		
	2019	**2018**	**Change**
(in thousands)			
Operating expenses:			
Research and development	$ 22,449	$ 27,095	$ (4,646)
General and administrative	11,603	11,217	386
Total operating expenses	34,052	38,312	(4,260)
Loss from operations	(34,052)	(38,312)	4,260
Other Income (expense):			
Interest income	743	663	80
Interest expense	(1,228)	(767)	(461)
Change in fair value of call right liability	—	313	(313)
Change in fair value of derivative liability	(104)	(67)	(171)
Realized foreign exchange loss	(12)	(13)	1
Total other income (expense), net	(601)	129	(730)
Loss before income tax expense	(34,653)	(38,183)	3,530
Income tax expense	(91)	(103)	12
Net loss	$ (34,744)	$ (38,286)	$ 3,542

Research and development expenses

Research and development expenses decreased by $4.6 million from $27.1 million for the year ended December 31, 2018 to $22.4 million for the year ended December 31, 2019. The decrease was primarily attributable to the completion of our preclinical efforts for our product candidate CTX-471 and the related filing of our IND in February 2019. As a result, research and development expenses decreased by $5.9 million. In addition, we initiated efforts to reduce our workforce in April 2019 which resulted in a decrease in salaries and related benefits of $0.7 million for the year ended December 31, 2019. These decreases were offset by $1.7 million in milestone payments we made under the Adimab Agreement and $0.3 million in increased facility and related costs during 2019.

We track outsourced development, outsourced personnel costs and other external research and development costs of specific programs. We do not track our internal research and development costs on a program-by-program basis. Research and development expenses are summarized by program in the table below:

	Year Ended December 31,		Three Months Ended March 31,	
	2018	2019	2019	2020
	(in thousands)			
CTX-471	$ 7,120	$ 5,573	$ 1,694	$ 858
NKP30 cell engagement platform	72	824	122	42
CTX-7371	—	29	—	53
Unallocated research and development expenses	19,903	16,023	5,427	2,618
Total research and development expenses	**$ 27,095**	**$ 22,449**	**$ 7,243**	**$ 3,571**

General and administrative expenses

General and administrative expenses increased by $0.4 million from $11.2 million for the year ended December 31, 2018 to $11.6 million for the year ended December 31, 2019. The increase was primarily attributable to $0.5 million in compensation and related benefits, including stock-based compensation, that was offset by a $0.1 million decrease in facility and related expenses.

Interest income

Interest income increased by $80,000 during the year ended December 31, 2019 compared to 2018 and was primarily attributable to the increase in cash and cash equivalents following the sale of Series A-5 preferred membership interests in June 2018, and the transfer of our cash and cash equivalents into highly liquid investments with higher interest rates compared to the interest earned on operating cash accounts.

Interest expense

Interest expense was $1.2 million during the year ended December 31, 2019, compared to $0.8 million during the year ended December 31, 2018. The increase of $0.4 million was primarily due to interest paid under the 2018 Credit Facility, which we entered into in March 2018.

Change in fair value of call right liability

The call right liability was settled in June 2018 and was no longer subject to remeasurement. As a result, we had no change in fair value of this liability during the year ended December 31, 2019. The change in fair value of liability during the year ended December 31, 2018 was attributable to the final remeasurement of the liability immediately prior to its settlement.

Change in fair value of derivative liability

We recognized a $0.1 million expense associated with the change in the fair value of our derivative liability during the year ended December 31, 2019, compared to a gain of $67,000 during the year ended December 31, 2018. The increase in fair value of the derivative liability is primarily attributable to the increased likelihood of a liquidity event occurring whereby a success fee payment would be payable to Pacific Western Bank under the 2018 Credit Facility. Upon completion of the Merger in June 2020, which qualified as a liquidity event under the 2018 Credit Facility, we paid a success fee of $1.1 million to Pacific Western Bank.

Realized foreign exchange loss

Our realized foreign exchange losses were relatively small and unchanged during the years ended December 31, 2019 and 2018, respectively, as we have a limited number of payment arrangements denominated in a currency other that the U.S. dollar.

Income tax expense

During the years ended December 31, 2019 and 2018, we recognized income tax expenses of $91,000 and $0.1 million, respectively. Our income tax expense is primarily attributable to the services that our wholly-owned subsidiary, a C corporation, provides at cost plus a profit margin.

Liquidity and Capital Resources

Since our inception, we have not yet generated any revenue from any product sales or any other sources, and we have incurred significant operating losses. We have not yet commercialized any products and we do not expect to generate revenue from sales of products for several years, if at all. To date, we have funded our operations primarily with proceeds from the sale of convertible preferred equity and borrowings under the 2018 Credit Facility. Through March 31, 2020, we had received gross proceeds of $132.0 million from sales of convertible preferred equity and borrowed $15.0 million under the 2018 Credit Facility. As of March 31, 2020, we had cash and cash equivalents of $17.5 million.

Funding Requirements

Our primary use of cash is to fund operating expenses, primarily research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, timing, progress and results of discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the costs of manufacturing our product candidates for clinical trials and in preparation for marketing approval and commercialization;
- the extent to which we enter into collaborations or other arrangements with additional third parties in order to further develop our product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the costs and fees associated with the discovery, acquisition or in-license of additional product candidates or technologies;
- our ability to establish additional collaborations on favorable terms, if at all;
- the costs required to scale up our clinical, regulatory and manufacturing capabilities;
- the costs of future commercialization activities, if any, including establishing sales, marketing, manufacturing and distribution capabilities, for any of our product candidates for which we receive marketing approval; and
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval.

We will need additional funds to meet operational needs and capital requirements for clinical trials, other research and development expenditures, and business development activities. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical studies.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table shows a summary of our cash flows for the periods indicated:

	Year ended December 31,		Three months ended March 31,	
(in thousands)	**2019**	**2018**	**2020**	**2019**
Cash used in operating activities	$ (31,741)	$ (33,679)	$ (7,761)	$ (10,477)
Cash used in investing activities	(466)	(2,020)	(12)	(319)
Cash provided by financing activities	—	64,031	—	—
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (32,207)	$ 28,332	$ (7,773)	$ (10,796)

Operating Activities

During the three months ended March 31, 2020, we used $7.8 million of cash in operating activities, resulting from net loss of $6.4 million and the change in operating assets and liabilities of $2.4 million, offset by non-cash charges of $1.1 million. Our non-cash charges were comprised of depreciation and amortization of $0.5 million, unit-based compensation expense of $0.2 million, a change in fair value of our derivative liability of $0.3 million and non-cash interest expense of $26,000. The change in our operating assets was primarily related to the decrease in our accounts payable and accrued expenses and due to the timing in which we pay our vendors.

During the three months ended March 31, 2019, we used $10.5 million of cash in operating activities, resulting from net loss of $10.8 million and the change in operating assets and liabilities of $0.6 million, offset by non-cash charges of $0.9 million. Our non-cash charges were comprised of depreciation and amortization of $0.5 million, unit-based compensation expense of $0.3 million, a change in fair value of our derivative liability of $57,000 and non-cash interest expense of $33,000. The change in our operating assets was primarily related to the decrease in our accounts payable and accrued expenses.

During the year ended December 31, 2019, we used $31.7 million of cash in operating activities, resulting from net loss of $34.7 million and the change in operating assets and liabilities of $0.3 million, offset by non-cash charges of $3.3 million. Our non-cash charges were comprised of depreciation and amortization of $2.1 million, unit-based compensation expense of $0.9 million, a change in fair value of our derivative liability of $0.1 million and non-cash interest expense of $0.1 million. The change in our operating assets was primarily related to the decrease in our accounts payable offset by the decrease in prepaid expenses and the increase in accrued expenses.

During the year ended December 31, 2018, we used $33.7 million of cash in operating activities, resulting from net loss of $38.3 million, offset by non-cash charges of $2.4 million and the change in operating assets and liabilities of $2.2 million. Our non-cash charges were comprised of depreciation and amortization of $1.9 million, unit-based compensation expense of $0.7 million and non-cash interest expense of $0.1 million, which was offset by a net gain in the change in fair value of our derivative and call right liabilities of $0.2 million. The change in our operating assets was primarily related to the increase in our accounts payable and accrued expenses.

Investing Activities

During the three months ended March 31, 2020 and 2019 and during the years ended December 31, 2019 and 2018, cash used in investing activities was $12,000, $0.3 million, $0.5 million and $2.0 million, respectively, and attributable to the purchases of property and equipment.

Financing Activities

We had no financing activities during the three months ended March 31, 2020 and 2019 and during the year ended December 31, 2019. During the year ended December 31, 2018, cash provided by financing activities was $64.0 million, consisting of $49.0 million in net proceeds received from the sale of our Series A-5 preferred units and $15.0 million in net proceeds from the 2018 Credit Facility.

Indebtedness

In March 2018, we entered into the 2018 Credit Facility with Pacific Western Bank, which consists of $15.0 million in term loans: a $10.0 million Tranche 1 term loan, and a $5.0 million Tranche 2 term loan. We borrowed the $10.0 million Tranche 1 term loan in March 2018 and the $5.0 million Tranche 2 term loan in September 2018.

Pursuant to the 2018 Credit Facility, we provided a first priority security interest in all existing and future acquired assets, excluding intellectual property and certain other assets, owned by us. The 2018 Credit Facility contains a negative pledge on intellectual property owned by us and also contains customary indemnification obligations and customary events of default, including, among other things, (i) non-payment, (ii) breach of warranty, (iii) non-performance of covenants and obligations, (iv) default on other indebtedness, (v) judgments, (iv) change of control, (vii) bankruptcy and insolvency, (viii) impairment of security, (ix) key permit events, (x) key person event, (xi) regulatory matters, (xii) and key contracts. In addition, we must maintain a minimum cash balance of $6.0 million beginning in April 2020. In the event of default under the 2018 Credit Facility, we would be required to pay interest on principal and all other due and unpaid obligations at the current rate in effect plus 5%.

The 2018 Credit Facility matures on March 1, 2022 and bears interest at a rate equal to the greater of 6.25% and 1.5%, plus the prime rate as published by the Wall Street Journal. We are required to make monthly interest and principal payments beginning March 2020 through March 1, 2022 when the 2018 Credit Facility matures. Upon completion of the Merger, which qualified as a liquidity event under the 2018 Credit Facility, we paid a success fee of $1.1 million to the lender.

Future Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance our lead product candidate into the expansion stage of our Phase I trial and our second product candidate to IND enabling studies. In addition, we expect to incur additional costs associated with operating as a public company. The timing and amount of our operating expenditures will depend largely on:

- the initiation, progress, timing, costs and results of clinical trials for our product candidate or any future product candidates we may develop;
- the initiation, progress, timing, costs and results of nonclinical studies for our product candidates or any future product candidates we may develop;
- our ability to maintain our relationships with key collaborators;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more nonclinical studies or clinical trials than those that we currently expect or change their requirements on studies that had previously been agreed to;
- the cost to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;
- the effect of competing technological and market developments;
- the costs of continuing to grow our business, including hiring key personnel and maintain or acquiring operating space;
- market acceptance of any approved product candidates, including product pricing, as well as product coverage and the adequacy of reimbursement by third-party payors;

- the cost of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the cost and timing of selecting, auditing and potentially validating a manufacturing site for commercial-scale manufacturing;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval and that we determine to commercialize; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

We believe that our existing cash and cash equivalents as of March 31, 2020, plus the net proceeds from the Offering, will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2021, which we expect to enable us to complete Part 2 of our ongoing Phase 1 clinical trial of CTX-471, commence the planned Phase 1 development of CTX-8371, subject to satisfactory completion of IND-enabling activities for that product candidate, and to complete IND-enabling activities with respect to our NKp30 bispecific program. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We expect that we will require additional funding to complete the clinical development of CTX-471, initiate clinical development of CTX-8371, begin IND-enabling studies with CTX-8573, commercialize our product candidates, if we receive regulatory approval, and pursue in-licenses or acquisitions of other product candidates. If we receive regulatory approval for CTX-471, CTX-8371, CTX-8573 or other product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize ourselves.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity and debt financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2019 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments due by Period				
(in thousands)	**Total**	**Less than 1 year**	**1 to 3 years**	**3 to 5 years**	**More than 5 years**
Principal and interest payments on long-term debt[(1)]	$ 16,329	$ 6,526	$ 9,803	$ —	$ —
Operating lease commitments[(2)]	2,079	1,919	160	—	—
Total[(3)]	$ 18,407	$ 8,444	$ 9,963	$ —	$ —

(1) Interest payable reflects the rate in effect as of December 31, 2019. The interest rate on borrowings under the 2018 Credit Facility is variable and resets monthly.

(2) Reflects payments due for our lease of office and laboratory space in Cambridge, Massachusetts under an operating lease agreement that expires in January 2021.

(3) This table does not include (i) any milestone payments that are not deemed probable under license agreements as the timing and likelihood of such payments are not known with certainty, (ii) any royalty payments to third parties as the amounts, timing and likelihood of such payments are not known, and (iii) contracts that are entered into in the ordinary course of business that are not material in the aggregate in any period presented above.

Quantitative and Qualitative Disclosures about Market Risk

Our cash is held on deposit in demand accounts at a large financial institution in amounts in excess of the Federal Deposit Insurance Corporation, or FDIC, insurance coverage limit of $250,000 per depositor, per FDIC-insured bank, per ownership category. We have reviewed the consolidated financial statements of this institution and believe it has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us. Financial instruments that potentially subject us to concentrations of credit risk principally consist of cash equivalents. We limit our credit risk associated with cash equivalents by placing investments in highly-rated money market funds.

As discussed above under "*—Liquidity and Capital Resources — Indebtedness*", the 2018 Credit Facility bears interest at a floating interest rate, which resets monthly and is equal to the greater of 6.25% and 1.5%, plus the prime rate as published by the Wall Street Journal. As a result, we are exposed to risks from changes in interest rates. A 1.0% increase in interest rates would have resulted in a $0.1 million increase to our interest expense for the year ended December 31, 2019.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amount of revenue and expenses during the reporting period. We base our estimates on historical experience, known trends and events, and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 3 to our consolidated financial statements, which are filed as Exhibit 99.1 to this Report, we believe that the following accounting policies are the most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the development of our product candidates. We expense research and development costs as incurred.

At the end of each reporting period, we compare payments made to third-party service providers to the estimated progress toward completion of the applicable research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that we estimate has been made as a result of the service provided, we may record net prepaid or accrued expenses relating to these costs. As of March 31, 2020, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Valuation of Derivative Liability

Our derivative liability is comprised of the contingent interest rate reset features and a contingent feature to pay a success fee upon the occurrence of certain liquidity events under the 2018 Credit Facility. At issuance and at each reporting period, we are required to estimate the fair value of the derivative liability using a probability-weighted expected return method. This method requires judgment when estimating the timing and probability of future events, such as a change in control event, future liquidity events, and repayment of our debt obligation under the 2018 Credit Facility. We then apply a risk-adjusted discount rate reflecting the expected risk profile for each of the potential settlement scenarios and relating timing. Due to the nature of and inputs in the model used to assess the fair value of the future tranche rights, it is not abnormal to experience significant fluctuations during each remeasurement period.

Unit-Based Compensation

The following table summarizes unit-based compensation expense resulting from profits interests:

	Year ended December 31,		Three months ended March 31,	
(in thousands)	**2019**	**2018**	**2020**	**2019**
Research and development	$ 383	$ 284	$ 81	$ 114
General and administrative	532	372	166	111
Total unit-based compensation	$ 915	$ 656	$ 247	$ 255

We measure profits interests and other unit-based awards based on their estimated fair value on the date of the grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award, while awards containing a performance condition are recognized when the achievement of the performance criteria is considered probable. We apply the straight-line method of expense recognition to all awards with service-based vesting conditions.

We estimate the fair value of profits interests using the Black-Scholes option-pricing model, which requires subjective assumptions, including the fair value of membership interests, volatility, the expected term of profits interests, the risk-free interest rate for a period that approximates the expected term of profits interests, and expected dividend yield. Certain assumptions used in our Black-Scholes option-pricing model represent management's best estimates and involve a number of variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective. If any assumptions change, our unit-based compensation expense could be materially different in the future.

These assumptions are estimated as follows:

- *Risk-free interest rate.* The risk-free interest rate was based on the yields of U.S. Treasury securities with maturities commensurate with the expected term of the stock option.

- *Expected dividend yield.* We have not paid dividends on our member units nor do we expect to pay dividends in the foreseeable future.

- *Expected term.* The expected term represents the period that our profits interests are expected to be outstanding. We calculated the expected term using the simplified method based on the average of each profits interest's vesting term and the contractual period during which the award can be exercised, which is typically 10 years following the date of grant.

- *Expected volatility.* The expected volatility was based on the historical stock volatility of several of our comparable publicly traded companies over a period of time equal to the expected term of the profits interests, as we do not have any trading history to use the volatility of our own member units.

- *Fair value of member units.* As our member units have not historically been publicly traded, we have periodically estimated the fair value of our units. See "*— Estimating the Fair Value of Member Units*".

Estimating the Fair Value of Member Units

As there has been no public market for our membership interests to date, their estimated fair value has been determined by our board of directors as of the date of each profits interest grant, with input from management, considering our most recently available third-party valuation of member units, and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. In addition to considering the results of these third-party valuations, our board of directors considered various objective and subjective factors to determine the fair value of our membership interests as of each grant date, including:

- the prices at which we sold preferred membership interests and the superior rights and preferences of the preferred membership interests relative to our membership interests at the time of each grant;
- the progress of our commercialization efforts;
- the progress of our research and development programs, including the status and results of preclinical studies for our product candidates;
- our stage of development and our business strategy;
- external market conditions affecting the medical device industry and trends within the medical device industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common and preferred membership interests;
- the likelihood of achieving a liquidity event, such as an initial public offering, or IPO, reverse merger, or sale of our company in light of prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry.

In determining the estimated fair value of membership interests, our board of directors considered the subjective factors discussed above in conjunction with the most recent valuations of our membership interests that were prepared by an independent third-party. The foregoing valuation methodologies are not the only methodologies available and they will not be used to value our common stock after the closing of the Merger. We cannot make assurances as to any particular valuation for our common stock. Accordingly, we caution you not to place undue reliance on the foregoing valuation methodologies as an indicator of future stock prices.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 3 to our consolidated financial statements, which are filed as Exhibit 99.1 to this Report.

Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements in accordance with GAAP. As a result of becoming a public company, we will be required, under Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting beginning with our Annual Report on Form 10-K for the year ending December 31, 2020. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. The SEC defines a material weakness as a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company's annual or interim consolidated financial statements will not be detected or prevented on a timely basis.

In accordance with the provisions of the Sarbanes-Oxley Act, neither we nor our independent registered public accounting firm has performed an evaluation of our internal control over financial reporting during any period included in this Report.

JOBS Act Accounting Election

Under Section 107(b) of the JOBS Act, an "emerging growth company" can delay the adoption of new or revised accounting standards until such time as those standards would apply to private companies. We have made the election to delay the adoption of such accounting standards as provided in the JOBS Act. There are other exemptions and reduced reporting requirements provided by the JOBS Act that we are currently evaluating. For example, as an "emerging growth company", we are exempt from Sections 14A(a) and (b) of the Exchange Act that would otherwise require us to (i) submit certain executive compensation matters to stockholder advisory votes, such as "say-on-pay", "say-on-frequency", and "golden parachutes"; and (ii) disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of our Chief Executive Officer's compensation to our median employee compensation. We also intend to rely on an exemption from the rule requiring us to provide an auditor's attestation report on our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. We will continue to remain an "emerging growth company" until the earliest of the following: (i) the last day of the fiscal year following the fifth anniversary of the date of the first sale of our equity securities pursuant to a registration statement under the Securities Act; (ii) the last day of the fiscal year in which our total annual gross revenue is equal to or more than $1.07 billion; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information relating to the beneficial ownership of our common stock, as of June 23, 2020, immediately following the closing of the Merger and the Offering, by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of outstanding shares of common stock;
- each of our directors;
- each of our named executive officers; and
- all of our directors and executive officers as a group.

The number of shares beneficially owned by each entity, person, director or executive officer is determined in accordance with SEC rules, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days of June 23, 2020 through the exercise of any stock option, warrants or other rights. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock held by such person.

The percentage of shares beneficially owned is computed on the basis of 52,151,798 shares of common stock outstanding as of June 23, 2020, after giving effect to the Merger and the Offering. Shares of common stock that a person has the right to acquire within 60 days of June 23, 2020 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group. Unless otherwise indicated below, the address for each beneficial owner is c/o Compass Therapeutics, Inc., 245 First Street, 3rd Floor, Cambridge, Massachusetts 02142.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares beneficially Owned
Greater than 5% Stockholders:		
OrbiMed Private Investments V-KA, LP[(1)]	12,714,404	24.9%
Anderson Entities[(2)]	5,290,270	10.3%
F-Prime Entities[(3)]	4,122,414	8.1%
Cowen Healthcare Investments Entities[(4)]	3,181,683	6.2%
Consonance Entities[(5)]	3,000,000	5.9%
Borealis Ventures Entities[(6)]	2,749,256	5.3%
Named Executive Officers and Directors:		
Thomas Schuetz, MD, Ph.D.[(7)]	4,525,467	8.8%
Vered Bisker-Leib, Ph.D., MBA[(8)]	513,401	1.0%
Phil Ferneau, MBA, J.D.[(6)]	169,914	*
Carl L. Gordon, Ph.D., CFA[(1)]	12,714,404	24.9%
Steven Squinto, Ph.D.[(1)(9)]	34,540	*
Julie Sunderland, MBA[(10)]	2,502,025	4.9%
All current directors and executive officers as a group (6 persons)	20,459,751	40.0%

* Indicates beneficial ownership of less than 1% of the total outstanding common stock.

(1) Consists of 12,714,404 shares of common stock owned directly by OrbiMed Private Investments V-KA, LP, or OPI V. OrbiMed Capital GP V LLC, or GP V, is the general partner of OPI V. OrbiMed Advisors LLC, or OrbiMed, is the managing member of GP V. By virtue of such relationships, GP V and OrbiMed may be deemed to have voting and investment power over the shares held by OPI V and as a result may be deemed to have beneficial ownership of such shares. OrbiMed exercises voting and investment power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and Jonathan T. Silverstein, each of whom disclaims beneficial ownership of the shares held by OPI V. Each of Carl L. Gordon, a member of OrbiMed, and Stephen Squinto, an executive partner of OrbiMed, is a member of our Board. Each of GP V, OrbiMed, Dr. Gordon and Dr. Squinto disclaims beneficial ownership of the shares held by OPI V, except to the extent of its or his pecuniary interest therein, if any. The address for the OrbiMed entities is c/o OrbiMed Advisors LLC, 601 Lexington Avenue, 54th Floor, New York, New York 10022.

(2) Consists of (i) 2,054,398 shares of common stock held of record by Errik Anderson, (ii) 1,190,331 shares of common stock held of record by Ulysses Consolidated, LLC, (iii) 1,661,899 shares of common stock held of record by GTP AW Fund I, LLC, and (iv) 383,642 shares of common stock held of record by GTP AW Fund II, LLC. Mr. Anderson exercises sole voting and investment power of the securities held by the entities described above in clauses (i), (ii) and shared voting and investment power of the securities held by the entities described above in clauses (iii) and (iv). Mr. Anderson disclaims beneficial ownership of the shares held by such entities, except to the extent of any actual pecuniary interest. The address for Mr. Anderson and his affiliated entities is 44 South Main Street, 3rd Fl, Hanover, NH 03755.

(3) Consists of (i) 2,299,440 shares of common stock held of record by F-Prime Capital Partners HC Cambridge Fund IV LP, or F-Prime Cambridge IV, (ii) 1,351,050 shares of common stock held of record by F-Prime Capital Partners HC International Fund IV LP, or F-Prime International IV, and (iii) 471,924 shares of common stock held of record by F-Prime Capital Partners Healthcare Fund IV LP, or F-Prime Healthcare Fund. F-Prime Capital Partners Healthcare Advisors Fund IV LP, or F-Prime Advisors IV, is the general partner of each of F-Prime Cambridge IV, F-Prime International IV and F-Prime Healthcare Fund. F-Prime Advisors IV is solely managed by Impresa Management LLC, the managing member of its general partner and its investment manager. Impresa Management LLC is owned, directly or indirectly, by various shareholders and employees of FMR LLC. Each of the entities listed above expressly disclaims beneficial ownership of the shares listed above except to the extent of any pecuniary interest therein. The address of these entities is 245 Summer Street, Boston, MA 02210.

(4) Consists of (i) 667,264 shares of common stock held of record by Cowen Private Investments LP, or CPI, and (ii) 2,514,419 shares of common stock held of record by CHO II Holdco LP, or CHI II. CHI Advisors LLC, the investment adviser of CPI and CHI II has voting and investment power with respect to the shares held by each of CPI and CHI II. The address for CPI and CHI II is c/o CHI Advisors LLC, 599 Lexington Avenue, 19th Floor, New York, New York 10022.

(5) Consists of (i) 1,000,000 shares of common stock owned directly by Consonance Capital Master Account L.P., or Consonance Master, (ii) 626,211 shares of common stock owned directly by P Consonance Opportunities Ltd., or P Consonance, and (iii) 1,373,789 shares of common stock owned directly by Consonance Capital Opportunity Master Fund, LP, or Consonance Opportunity Master. Consonance Capital Management LP, or the Capital Management Adviser, is the investment adviser of Consonance Master and Consonance Opportunity Master, and pursuant to investment advisory agreements, the Capital Management Adviser exercises voting and investment power over the common stock held by Consonance Master and Consonance Opportunity Master. Consonance Capital Opportunity Fund Management LP, or the Capital Opportunity Adviser, is the investment adviser of P Consonance, and pursuant to an investment advisory agreement, the Capital Opportunity Adviser exercises voting and investment power over the common stock held by P Consonance. Consonance Capman GP LLC, or Capman, is the general partner of the Capital Management Adviser and the Capital Opportunity Advisor and Mitchell Blutt, as the Manager & Member of Capman and Chief Executive Officer of the Capital Management Adviser and the Capital Opportunity Advisor, may be deemed to control Capman, the Capital Management Adviser and the Capital Opportunity Advisor. Mr. Blutt, as the Manager & Member of Capman, may be deemed to control Capman. Each of Capman and Mr. Blutt may be deemed to beneficially own these common stock. The address for Consonance Master, P Consonance, Consonance Opportunity Master, the Capital Management Adviser, the Capital Opportunity Advisor, Capman and Mr. Blutt is 1370 Avenue of the America, Floor 33, New York, New York 10019.

(6) Consists of (i) 2,348,976 shares of common stock owned directly by Borealis Granite Fund, L.P. and (ii) 400,280 shares of common stock owned directly by Vox Health Fund, L.P. Borealis Capital Partners III, LLC is the general partner of Borealis Granite Fund, L.P. Borealis Capital Partners IV, LLC is the general partner of Vox Health Fund, L.P. Phil Ferneau, a member of our board of directors, is a managing partner of Borealis Ventures. Voting and investment decisions with respect to the securities held by Borealis Granite Fund, L.P. are made by a committee of three or more individuals, none of whom individually has the power to direct such decisions. Mr. Ferneau holds a majority ownership interest in Borealis Capital Partners IV, LLC and is the designated manager with voting and investment power over the shares held by Vox Health Fund, L.P. Mr. Ferneau disclaims beneficial ownership of the shares held by Borealis Granite Fund, L.P., except to the extent of any actual pecuniary interest. The address for Borealis Granite Fund, L.P. and Vox Health Fund, L.P. is 10 Allen Street, Hanover, NH 03755.

(7) Includes 586,546 shares of restricted stock over which Mr. Schuetz has voting power.

(8) Includes 410,530 shares of restricted stock over which Ms. Bisker-Leib has voting power.

(9) Includes 916 shares of restricted stock over which Mr. Squinto has voting power.

(10) Consists of 2,502,025 shares of common stock owned directly by Biomatics – Compass, Inc. Julie Sunderland, a member of our board of directors, is the co-founder of and a managing partner at Biomatics Capital Partners, and exercises sole voting and investment power of the securities held by Biomatics – Compass, Inc. The address for Biomatics – Compass, Inc. is 245 Main St., Cambridge, MA 02142.

SIGNATURE

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this Amended Report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: July 31, 2020

COMPASS THERAPEUTICS, INC.

By: /s/ Thomas J. Schuetz
Name: Thomas J. Schuetz
Title: Chief Executive Officer